COMPETITION TRIBUNAL
TRIBUNAL DE LA CONCURRENCE

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CT- 2020-003

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REGISTRAR / REGISTRAIRE

OTTAWA, ONT. | # 1

CT- 2020-003

THE COMPETITION TRIBUNAL

IN THE MATTER OF the *Competition Act*, R.S.C. 1985, c. C-34,

AND IN THE MATTER OF an application by the Commissioner of Competition for an order pursuant to section 74.11 of the *Competition Act* regarding conduct reviewable pursuant to paragraph 74.01(1)(b) of the *Competition Act*;

BETWEEN:

COMMISSIONER OF COMPETITION

Applicant

– and –

NUVOCARE HEALTH SCIENCES INC. and RYAN FOLEY

Respondents

APPLICATION RECORD

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CT-

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TAB 1

CT-

THE COMPETITION TRIBUNAL

IN THE MATTER OF the *Competition Act*, R.S.C. 1985, c. C-34;

AND IN THE MATTER OF an application by the Commissioner of Competition for an order pursuant to section 74.11 of the *Competition Act* regarding conduct reviewable pursuant to paragraph 74.01(1)(b) of the *Competition Act*;

B E T W E E N:

COMMISSIONER OF COMPETITION

Applicant

- and-

NUVOCARE HEALTH SCIENCES INC. and RYAN FOLEY

Respondents

NOTICE OF APPLICATION

TAKE NOTICE that the Commissioner of Competition (the "**Commissioner**") will make an application (the "**Application**") to the Competition Tribunal (the "**Tribunal**") for an order pursuant to section 74.11 of the *Competition Act*, R.S.C. 1985, c. C-34 (the "**Act**"), in respect of conduct reviewable pursuant to paragraph 74.01(1)(b) of the Act.

AND TAKE NOTICE that the Commissioner relies on the following Notice of Application, the affidavits filed in support of this Application, and on such further or other material as counsel may advise and the Tribunal may permit.

AND TAKE NOTICE that if you do not appear at the hearing of this Application, which date shall be determined by the Tribunal, the Tribunal may, upon application by

the Commissioner and without further notice, make such order or orders as it may consider just, including the order sought in this Application.

THE ADDRESSES FOR SERVICE ARE:

For the Respondents:

Nuvocare Health Sciences Inc.
2004-59 E. Liberty Street
Toronto, ON M6K 3R1

Ryan Foley
President & CEO
Nuvocare Health Sciences Inc.
4968 Yonge Street, suite 2005
Toronto, ON M2N 3P9

For the Commissioner of Competition:

Department of Justice Canada
Competition Bureau Legal Services
Place du Portage, Phase I
50 Victoria Street, 22nd Floor
Gatineau, Quebec

Attention: Talitha Nabbali
Ellé Nekiar

APPLICATION

1. The Commissioner makes this Application pursuant to section 74.11 of the Act for an order prohibiting the Respondents from:

   a) making, by any means whatsoever, any representation to the public in the form of a statement, warranty or guarantee of performance or efficacy that is not based on adequate and proper testing;

   b) making by any means whatsoever, any representation to the public in the form of a statement, warranty or guarantee of performance or efficacy that is not based on adequate and proper testing about the products WeightOFF Max! under the NutraCentials and SlimCentials brands, the product Forskolin+ under the SlimCentials brand, and the product Forskolin Nx under the NutraCentials brand, as well as any other variation of these products (collectively, the "**Products**");

      a. Without limiting the generality of the foregoing, making, by any means whatsoever, any representation to the public in the form of a statement, warranty or guarantee of performance or efficacy that is not based on adequate and proper testing about the Products' capacity to:

         i. cause weight loss;
         ii. burn fat;
         iii. increase fat release;
         iv. block fat storage;
         v. block carbohydrates;
         vi. cut appetite;
         vii. decrease emotional eating;
         viii. target belly fat; or
         ix. increase metabolism.

2. The Respondents shall, within 20 days of the issuance of this Order, provide a report to the Commissioner's authorized representative setting out all actions it has taken to comply with this order.

3. The Commissioner's costs of this application as against the Respondents ordered payable forthwith.

STATEMENT OF GROUNDS AND MATERIAL FACTS

I. OVERVIEW

4. Nuvocare Health Sciences Inc. and Mr. Ryan Foley (collectively, the "**Respondents**") market and sell certain natural health products to the public. The products at issue in this application are: WeightOFF Max! marketed under Nuvocare's SlimCentials and NutraCentials brands, Forskolin+ marketed under Nuvocare's SlimCentials brand, and Forskolin Nx marketed under Nuvocare's NutraCentials brand.

5. The Respondents represent and claim that the Products, alone or when used together, will cause weight loss or burn fat, along with seven other related claims. Although the Respondents have made and continue to make these claims systematically, across a wide range of platforms, the Respondents have provided no evidence that they relied on adequate and proper testing of the Products to make all of these claims, and there is no reason to believe that testing exists that is adequate and proper.

6. By making performance and efficacy claims about the Products that are not supported by adequate and proper testing, the Respondents are violating Part VII.1 of the Act.

7. The Respondents' conduct is systematic, widespread, and ongoing, and serious harm to consumers and competition is likely to ensue unless the temporary order sought by the Commissioner is issued. In particular: consumers are suffering

economic harm commensurate with the price paid for the Products; the Products can pose risks to consumers who use the Products for serious conditions and/or delay proper treatment by relying on the Products; and the misrepresentations made by the Respondents affect the proper functioning of the market.

8. In contrast, should the temporary order sought be issued, there is little if any inconvenience to the Respondents. Even if complying with the Tribunal's order did cause inconvenience to the Respondents, the public interest in having the Act obeyed outweighs any hardship that compliance with the Act may cause to the Respondents.

II. THE PARTIES

9. The Commissioner is an officer appointed by the Governor in Council under section 7 of the Act and is responsible for the administration and enforcement of the Act.

10. Nuvocare Health Sciences Inc. ("**Nuvocare**") is a private corporation federally incorporated under the *Canada Business Corporations Act*. Nuvocare markets and sells a variety of natural health products, including the Products.

11. Mr. Ryan Foley ("**Mr. Foley**") is the President and the CEO of Nuvocare, and holds himself out as the founder, creator and formulator of Nuvocare products. In fact, he is the prime mover of the business, and is effectively responsible for the representations made to the public about the Products by both himself and Nuvocare. Moreover, Mr. Foley personally markets, sells, and makes representations to the public relating to Nuvocare products, including the Products.

III. COMPETITION BUREAU ENFORCEMENT EFFORTS

12. On February 8, 2019, the Competition Bureau ("**Bureau**") issued a warning to sellers and marketers of natural health products in Canada to ensure weight loss claims are not false, misleading, or unsubstantiated.

13. On March 20, 2019, the Bureau sent a letter by registered mail to the Respondents requesting that testing be provided to the Bureau to substantiate performance claims made about the Products.

14. On April 6, 2019, Mr. Foley responded to the Bureau by email, requesting clarification of the Bureau's request and offering to "provide claim substantiation back up if claims are supported".

15. On April 25, 2019, the Bureau responded to Mr. Foley by email and provided clarification of the Bureau's request. The Bureau requested that testing to substantiate the performance claims made about the Products be provided by May 3, 2019.

16. The Respondents never provided any testing to the Bureau to substantiate any of the performance claims the Respondents have been making about the Products.

17. On February 13, 2020, the Commissioner commenced an inquiry, under subparagraph 10(1)(b)(ii) of the Act on the basis that he has reason to believe that grounds exist for the making of an order under Part VII.1 of the Act, specifically pursuant to paragraphs 74.01(1)(a), 74.01(1)(b) and subsection 74.011(2) of the Act.

IV. HEALTH CANADA'S REGULATION OF NATURAL HEALTH PRODUCTS

18. All natural health products ("**NHPs**") sold in Canada are subject to the *Natural Health Products Regulations* ("**NHPR**"). Pursuant to the *Natural Health Products Regulations*, all NHPs are reviewed by Health Canada, more

specifically its Natural and Non-Prescription Health Products Directorate ("**NNHPD**"), through a product licence application.

19. Pursuant to the NHPR, all NHPs are reviewed by Health Canada, more specifically by NNHPD through a product licence application. Once Health Canada has reviewed the information submitted by the applicant and decided it meets the safety, efficacy and quality requirements under the recommended conditions of use, it will issue a product licence for the NHP, along with an eight-digit product number (often called Natural Product Number ("NPN")). Only NHPs that have obtained product licences from Health Canada can be legally sold in Canada.

20. Once a product licence is granted for an NHP, the health claim(s) an NHP can make are explicitly outlined in the NHP's produce licence. In general, health claims permitted by an NHP's licence should be made verbatim, or convey the exact same meaning as the health claims authorized. An NHP licence holder cannot make health claims about an NHP other than the claim(s) that are authorized, including claims that are false, misleading, convey a stronger claim or make a claim that exceeds the scope of the health claims authorized by Health Canada for the NHP.

21. The Products are NHPs and have obtained product licences. None of the Products have been authorized by Health Canada to make health claims that they cause weight loss, burn fat, release fat, block fat, target belly fat, cut appetite, block carbohydrates, decrease emotional eating or increase metabolism.

V. THE RESPONDENTS ARE ENGAGING IN REVIEWABLE CONDUCT

22. The Respondents have made and continue to make representations to the public about the performance or efficacy of the Products for the purpose of promoting the Products and their business interests. These representations are made on their

websites, on social media sites, at consumer expos, in promotional emails, in online or print magazines, and on product labels or packaging.

23. The Respondents' representations fall within the scope of paragraph 74.01(1)(b) of the Act, which expressly provides that any statement relating to the performance or efficacy of a product must be based on an adequate and proper test.

24. The onus is on the Respondents to prove that adequate and proper testing of the Products supports the performance or efficacy claims made by the Respondents. Yet, the Respondents have failed to provide any evidence to the Commissioner that they rely on adequate and proper testing to substantiate the performance or efficacy representations they have made and continue to make relating to the Products.

A. Representations relating to WeightOFF Max!

25. The Respondents have made and continue to make representations to the public about the performance or efficacy of WeightOFF Max! sold under the SlimCentials (NPN 80057549) and NutraCentials (NPN 80053895) brands (the "**WeightOFF Max! Products**") on their websites, on social media sites, at consumer expos, in promotional emails, in online and print magazines, and on product labels or packaging. These include representations that the WeightOFF Max! Products:

a. cause weight loss;

b. burn fat, increase fat release, or block fat storage;

c. cut appetite;

d. block carbohydrates; and

e. decrease emotional eating.

i. Weight Loss Representations

26. The Respondents make numerous representations that create the general impression that NutraCentials WeightOFF Max! will cause weight loss. For example, the Respondents' representations include:

a. "Our most powerful weight loss formula ever!"; and

b. "The nutrients in WeightOFF MAX! naturally work together to make it one of the most powerful weight loss formulas on the market!".

27. Similarly, the Respondents make numerous representations that create the general impression that SlimCentials WeightOFF Max! will cause weight loss. For example, the Respondents' representations include:

a. "The world's best premium weight loss ingredients in dosages clinically proven to work";

b. "The nutrients in WeightOFF MAX! naturally combine to deliver 6 key benefits that make weight-loss faster and easier!"; and

c. "Clinical studies PROVE that WeightOFF MAX! can CUT 200% MORE WEIGHT THAN DIETING ALONE".

ii. Fat Burning, Fat Release and Fat Blocking Representations

28. The Respondents make numerous representations that create the general impression that NutraCentials WeightOFF Max! will burn fat, increase fat release, and block fat storage. For example, the Respondents' representations include:

a. "Increases fat release and burning while also blocking fat storage";

b. "Our most powerful fat burner"; and

c. "Speeds up your metabolism helping you burn fat easier".

29. Similarly, the Respondents make numerous representations that create the general impression that SlimCentials WeightOFF Max! will burn fat. For example, the Respondents' representations include:

    a. "THE ULTIMATE ALL-IN-ONE NATURAL FAT-BURNING SOLUTION"; and

    b. "Burns fat as energy".

iii. Cut Appetite Representations

30. The Respondents make numerous representations that create the general impression that the WeightOFF Max! Products will cut appetite. For example, representations pertaining to NutraCentials WeightOFFMax! include "Cut appetite and ignite metabolism". The Respondents make similar claims regarding SlimCentials WeightOFF Max! such as "Cuts appetite and curbs emotional eating".

iv. Blocks Carbohydrates Representations

31. The Respondents make numerous representations that create the general impression that SlimCentials WeightOFF Max! will block carbohydrates, such as:

    a. "BLOCKS CARBOHYDRATES"; and

    b. "Blocks carbohydrate usage making it easier for the body to burn fat as energy".

v. Decrease Emotional Eating Representations

32. Finally, the Respondents also make numerous representations claiming that the WeightOFF Max! Products will decrease emotional eating. For example, representations pertaining to NutraCentials WeightOFFMax! include "Decreases emotional eating and your natural desire to crave sweets". The Respondents make similar claims regarding SlimCentials WeightOFF Max! such as "Cuts appetite and curbs emotional eating".

B. Representations relating to Forskolin+ and Forskolin Nx

33. The Respondents make representations to the public about the performance or efficacy of Forskolin+ sold under the SlimCentials (NPN 80058127) brand and Forskolin Nx sold under the NutraCentials (NPN 80058127) brand (the "**Forskolin Products**") on their websites, on social media sites, in promotional emails, at consumer expos, in online and print magazines, and on product labels or packaging. These include representations that the Forskolin Products will:

a. burn fat;

b. target belly fat; and

c. increase metabolism.

i. Fat Burning Representations

34. The Respondents make numerous representations that create the general impression that the Forskolin Products will burn fat, such as:

a. "When it comes to burning body fat and preserving muscle, Forskolin should be your solution";

b. "Stimulates an enzyme responsible in the body for fat burning"; and

c. "Speeds up your metabolism helping you burn fat easier".

35. The Respondents make numerous other representations specifically regarding SlimCentials Forskolin+ , such as:

    a. "Clinically proven fat burning solution";

    b. "This powerful formula delivers potent fat burning effects"; and

    c. "Increases KEY Fat-Burning enzyme".

36. Similar claims are made by the Respondents specifically regarding NutraCentials Forskolin Nx, such as:

    a. "Stimulates enzyme to Help Burn More Fat";

    b. "Lose an average 9.9 lbs of body fat in 12 weeks*";

    c. "Forskolin is lightning in a bottle and a miracle flower to help you fight fat"; and

    d. "This potent fat melting nutrient ignites metabolism and fat burning and promotes leaner, tighter muscle tone".

ii. Belly Fat Representations

37. The Respondents' claims go further, and state that the Forskolin Products target belly fat, with representations such as "DUAL BELLY-FAT MELTING REMEDY".

iii. Increase Metabolism Representations

38. Finally, the Respondents make representations that create the general impression that the Forskolin Products will increase metabolism, such as claims like "Speeds up your metabolism helping you burn fat easier".

C. Representations relating to the Combination of the WeightOFF Max! Products and the Forskolin Products

39. Not only have the Respondents made the aforementioned claims about each of the Products, the Respondents have also made and continue to make representations to the public about the performance or efficacy of the WeightOFF Max! Products when combined with the Forskolin Products on their websites, on social media sites, in promotional emails, in online and print magazines, and on product labels or packaging. These representations create the general impression that consumers will achieve greater weight loss results if they purchase and use both products.

40. The following are examples of the representations made by the Respondents as to the performance or efficacy of combining the WeightOFF Max! Products with the Forskolin Products:

    a. "For even more powerful weight loss results, try combining WeightOFF Max! with SlimCentials Forskolin+";

    b. "Combining Forskolin Nx with WeightOFF! MAX will ignite your metabolism while promoting leaner tighter muscle tone while reducing body fat & curbing your appetite";

    c. "Combine Multi-Award Winning WeighOFF MAX! + Forskolin Nx and Achieve Even More Dramatic LEAN BODY RESULTS!"; and

    d. "This potent combination tackles weight-loss from 7 angles".

VI. SERIOUS HARM

41. Unless the order sought is issued, serious harm to consumers and competition in Canada is likely to continue.

42. Serious harm ensues from the continuation of conduct that Parliament has made reviewable pursuant to the Act. By making it reviewable conduct to make representations to the public relating to the efficacy or performance of a product

that are not based on adequate and proper testing, and subjecting such conduct to remedies such as administrative monetary penalties, Parliament has indicated that the conduct of the Respondents, as described above, is likely to lead to serious harm.

43. Moreover, the facts show that the reviewable conduct in this case is ongoing, systemic and widespread. The representations made by the Respondents are on their websites, on social media sites, in promotional emails, in online and print magazines, and on product labels or packaging. The Products are available to Canadian consumers nationally through a wide array of retailers and channels. This includes major retail stores and health food retailers, as well as online through the Nuvocare.ca website and other online retailers. Through Nuvocare's websites alone, the representations are available to all Canadians with an Internet-connected device. Meaning that, an untold number of consumers are being exposed to the Respondents' representations at all times.

44. The Respondents' representations indicate that the target market of the Products is anyone looking for a natural health product that will cause weight loss or burn fat. The Respondents also identify four (4) specific categories of consumers that the Products are intended to benefit. These categories include: "obese"; "overweight"; "spare tire"; and "want to lose those last few lbs".

45. The Respondents further identify the types of consumers who should use NutraCentials brand products as follows:

    a. Males and females over the age of 18 who want to lose body fat and maintain muscle;

    b. Individuals taking diabetic, heart, thyroid and other medications;

    c. Individuals taking vitamins and other medications; and

    d. Anyone who wants to use the purest, cleanest, highest quality, most potent nutrients clinically proven to have powerful fat loss benefits while also improving overall health.

46. The Respondents target vulnerable consumers seeking to lose weight or burn fat and other similar benefits. The reviewable conduct is causing direct harm to these consumers as:

    a. These consumers purchase the Products to obtain the weight loss, fat burn and other benefits of the Products touted by the Respondents, and therefore suffer an economic loss commensurate with the price they paid for the Products; and

    b. These consumers may use the Products for serious conditions and/or may delay proper treatment of a condition based on the representations made by the Respondents.

47. The reviewable conduct also causes harm to competitors and competition, as unsubstantiated representations that a product will perform in a specific way harm the proper functioning of the market.

VII. BALANCE OF CONVENIENCE

48. The balance of convenience favours the issuing of the order sought by the Commissioner. There is compelling evidence that reviewable conduct is taking place, and that this conduct is causing and will continue to cause serious harm to consumers. In a situation such as this, particularly where the relief is being sought by a public law enforcement official with a mandate to protect the public interest, the balance of convenience should strongly favour issuing the temporary order sought.

49. By contrast, any inconvenience caused to the Respondents by the issuance of the order is minimal. If the order is issued, the Respondents will simply have to refrain from making representations that violate the Act in promotional emails, online or print magazines and at consumer expos, and make whatever changes are required to their websites, social media sites, and product labels or packaging to bring them into compliance with the Act.

50. Any hardship imposed on the Respondents by the temporary order sought is far outweighed by the public interest in having the reviewable conduct stop. More specifically, any harm suffered by the Respondents is a direct result of their decision not to comply with the Act, the public interest in having the Act obeyed outweighs any hardship the temporary order would cause the Respondents.

VIII. TRIBUNAL'S AUTHORITY TO ISSUE THE TEMPORARY ORDER SOUGHT

51. The Tribunal may issue a temporary order pursuant to section 74.11 of the Act if it appears to the Tribunal that:

    a. the Respondents are engaging in conduct that is reviewable under Part VII.1 of the Act;

    b. serious harm is likely to ensue unless the order is issued; and

    c. the balance of convenience favours issuing the order.

52. The Commissioner submits that the requirements of section 74.11 of the Act are met, in that:

    a. the Respondents are making representations that are not based on adequate and proper testing on their websites, on social media sites, in promotional emails, in online and print magazines, at consumer expos, and on product labels or packaging;

    b. serious harm to consumers and competition is occurring and will continue unless the temporary order is issued; and

    c. the balance of convenience favours requiring the Respondents to refrain from making representations that violate the Act pending the completion of the Commissioner's inquiry.

IX. RELIEF SOUGHT

53. The Commissioner claims the relief set out in paragraph 1, above.

X. DOCUMENTARY EVIDENCE TO BE RELIED UPON

54. The following documentary evidence will be relied upon during the proceeding:

    a. the Affidavit of Danielle McKenzie, affirmed February 28, 2020;

    b. the Affidavit of Virginie Treyvaud-Amiguet, affirmed February 27, 2020; and

    c. such further and other materials as counsel may advise and this Tribunal may permit.

XI. PROCEDURAL MATTERS

55. The Commissioner relies on sections 74.01 and 74.11 of the Act, section 8 of the *Competition Tribunal Act* R.S.C., 1985, c. 19, and Rules 2, 95 and 96 of the *Competition Tribunal Rules*, SOR/ 2008-141.

56. The Commissioner requests that this proceeding be conducted in English.

57. The Commissioner requests that this application be heard in Ottawa.

DATED AT Gatineau, Quebec, this 2nd day of March 2020.

Talitha Nabbali / Ellé Nekiar
Counsel for the Applicant,
Commissioner of Competition

TAB 2

Court File No.

THE COMPETITION TRIBUNAL

IN THE MATTER OF the *Competition Act*, R.S.C. 1985, c. C-34;

AND IN THE MATTER OF an application by the Commissioner of Competition for an order pursuant to section 74.11 of the *Competition Act* regarding conduct reviewable pursuant to paragraph 74.01(1)(b) of the *Competition Act*;

BETWEEN:

COMMISSIONER OF COMPETITION

Applicant

-and-

NUVOCARE HEALTH SCIENCES INC. and RYAN FOLEY

Respondents

AFFIDAVIT OF DANIELLE MCKENZIE

I, Danielle McKenzie, of the City of Ottawa in the Province of Ontario, MAKE OATH AND SAY AS FOLLOWS:

1. I make this Affidavit in support of the Commissioner of Competition's Application under section 74.11 of the *Competition Act*, R.S.C., 1985, c. C-34 (the "**Act**").

2. I am an authorized representative of the Commissioner of Competition (the "**Commissioner**") for the purpose of this application, appointed and designated to administer and enforce the Act.

3. I have been employed as a Competition Law Officer with the Cartels and Deceptive Marketing Practices Branch of the Competition Bureau (the "**Bureau**") since October 2016, during which time I have participated in

inquiries into marketing practices alleged to contravene the deceptive marketing practices provisions of the Act.

4. I hold a Bachelor of Arts in Criminology and Criminal Justice with a concentration in Law and a Master of Arts in Law and Legal Studies from Carleton University.

5. I have received training in digital surveillance and evidence collection from the Canadian Police College. I have attended other training courses and seminars relating to notetaking, evidence collection and handling, and investigative techniques offered by the Bureau and by external training providers.

6. I am the primary officer responsible for an ongoing inquiry (the "**Inquiry**"), made pursuant to paragraph 10(1)(b) of the Act, into certain marketing practices of Nuvocare Health Sciences Inc. ("**Nuvocare**") and Ryan Foley ("**Mr. Foley**"), President and CEO of Nuvocare. As such, I have personal knowledge of the matters hereinafter set out, except where I specifically state that such knowledge is based on information and belief.

7. Where my knowledge is based on information and belief, I have carefully considered the reliability of all my sources of information and I am satisfied that they are trustworthy.

8. I have relied upon information provided to me by the following Bureau representatives: Michael Selvadurai, Kegan Chang, Mélanie Larouche, Jana Baldwin, Amani Syed, Jessica Melo, Kevin McCollum, François Goulet, Michael Knight, Brian Uliana, and Edward King. Each one of the aforementioned are authorized representatives of the Commissioner and as such, are duty bound to be truthful.

I. THE PARTIES

9. The Commissioner is appointed under section 7 of the Act as an Officer responsible for the administration and enforcement of the Act.

10. Nuvocare and Mr. Foley (the "**Respondents**") are directly involved in the making of representations that are the subject matter of this Application.

(a) Nuvocare

11. The Respondent, Nuvocare, is a private corporation federally incorporated under the *Canada Business Corporations Act*[1] on November 12, 2006.[2] The directors listed on the federal corporate records as of December 31, 2019, are Ryan J Foley, Howard Youhanan and Gary John Foley. The registered corporate address is 2004-59 E. Liberty St, Toronto, ON M6K 3R1. A copy of the Federal Corporation records obtained on December 31, 2019, is attached as **Exhibit 1** to this Affidavit.

12. Notwithstanding the registered corporate address, the Nuvocare.ca website indicates that the company address is 10 Four Seasons Place, Suite 1000, Toronto, ON M9B 6H7. A copy of a capture of the website's "Contact Us" page taken on February 21, 2020, is attached as **Exhibit 2** to this Affidavit.

13. On October 27, 2018, Bureau representative Michael Selvadurai and I visited the address at 10 Four Seasons Place, Toronto, ON M9B 6H7 and found that Regus, a multinational provider of serviced offices, co-working spaces, business lounges, virtual offices, meeting rooms and video teleconferencing services, was listed in the building directory at Suite 1000.

(b) Ryan Foley

14. The Respondent, Mr. Foley, is President and CEO of Nuvocare. A copy of a business card obtained from Mr. Foley on September 17, 2017, is attached as **Exhibit 3** to this Affidavit.

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[1] R.S.C., 1985, c. C-44.

[2] The corporate records indicate the registered corporate name was "Nuvocare Health Care Sciences Inc." from November 12, 2006 to December 11, 2006 and subsequently changed to "Nuvocare Health Sciences Inc." on December 11, 2006.

15. Mr. Foley's address, as indicated on the federal corporate records, is 4968 Yonge Street, Suite 2005, Toronto, ON, M2N 7G9. See **Exhibit 1** to this Affidavit.

16. Mr. Foley claims to be the founder, creator and formulator of Nuvocare products. Mr. Foley makes these claims in various fora, including videos on social media:

a. "My name is Ryan Foley. I am the founder and CEO of Nuvocare Health Sciences". A copy of a capture of the Facebook video "The truth behind Ryan Foley & Nuvocare | Corporate Video" taken on February 24, 2020, is attached as **Exhibit 4** to this Affidavit;

b. "Nuvocare Health Sciences is a company I proudly created back in 2006[...]" A copy of a capture of the YouTube video "Best proven weight loss supplement | How to lose weight faster with WeightOFF MAX!" taken on January 24, 2020, is attached as **Exhibit 5** to this Affidavit;

c. "[...] I formulate the ingredients based on human clinical research". A copy of a capture taken on February 21, 2020 of an episode of Dragon's Den[3] is attached as **Exhibit 6** to this Affidavit; and,

d. "I am the formulator – we own all of the intellectual property for these products including formula patents and trademarks [...] we design all of our products [...]" A copy of a capture taken on February 21, 2020 of an interview article from the Canadian Business Executive magazine featuring Mr. Foley, is attached as **Exhibit 7** to this Affidavit.

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[3] On or about November 17, 2010, an episode of *Dragon's Den* aired on CBC Television, featuring Ryan Foley of Nuvocare Health Sciences Inc., *Dragon's Den* is a reality television program in which entrepreneurs pitch their business ideas to a panel of venture capitalists in the hope of securing investment finance from them.

II. THE RESPONDENTS' BUSINESS

17. The Respondents market and sell a variety of natural health products, making various health-related claims. These products include supplements in capsule form that the Respondents claim will cause weight loss or burn fat, among other related representations about the performance or efficacy of the products. A copy of a capture of the Homepage from the Nuvocare.com website taken on January 29, 2020, is attached as **Exhibit 8** to this Affidavit.

18. Certain products that the Respondents claim will cause weight loss or burn fat are marketed under the NutraCentials Slimming Essentials ("**NutraCentials**") and SlimCentials ("**SlimCentials**") brands. A copy of a capture of the "Brands" page from the Nuvocare.com website taken on January 22, 2020, is attached as **Exhibit 9** to this Affidavit.

19. The SlimCentials design was registered as a trademark on October 31, 2014. The design includes a logo and the description reads: "SlimCentials includes a silhouette that reinforce the weight loss properties of the brand". A copy of a capture of the Canadian Trademarks Database record for the SlimCentials design taken on January 27, 2020, is attached as **Exhibit 10** to this Affidavit.

20. For the purpose of this Application, the Commissioner's Inquiry focuses on the products WeightOFF Max! under the NutraCentials and SlimCentials brands ("**WeightOFF Max!**"), the product Forskolin+ under the SlimCentials brand, and the product Forskolin Nx under the NutraCentials brand ("**Forskolin**"), as well as any other variation of these products (collectively, the "**Products**").

21. The Respondents use various websites to market and sell the Products including Nuvocare.ca, Nuvocare.com, NutraCentials.com, and SlimCentials.com (the "**Relevant Websites**"). The Respondents also market and sell the Products at various Canadian retailers, health food stores, and online retailers.

22. The Respondents are registrants of the Nuvocare.com, NutraCentials.com, and SlimCentials.com websites where the Products are marketed. Registrant information for the Nuvocare.ca website has been made private. Copies of captures of WHOIS search results taken from DomainBigData.com[4], for Nuvocare.com, NutraCentials.com, and SlimCentials.com on January 24, 2020 and for Nuvocare.ca on February 16, 2020, are attached as **Exhibit 11** to this Affidavit.

23. The Respondents also market the Products on Youtube, Facebook, and Instagram ("**social media sites**"), in promotional emails, at consumer expos, in online or print magazines, and on product labels or packaging[5].

III. THE RESPONDENTS' REPRESENTATIONS

24. The Respondents have made and continue to make representations to the public about the performance or efficacy of the Products for the purpose of promoting the Products and their business interests. These include representations that the use of the Products will cause weight loss or burn fat, as well as other related representations about the performance or efficacy of the Products (the "**Impugned Representations**").

(a) WeightOFF Max! Representations under the SlimCentials and NutraCentials Brands

25. SlimCentials WeightOFF Max! (NPN[6] 80057549) is a supplement in capsule form. A copy of a capture of the product label's list of ingredients from the

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[4] DomainBigData.com is a free online investigative tool that allows users to query "WHOIS" data (the owner of a domain name or IP address) to find a registrant. A reverse WHOIS search allows users to query other domains owned by the same registrant.

[5] Product labels could include photos of physical product labels and captures of digital images of product labels found on the Relevant Websites. Product packaging could include peripheral promotional material available upon purchase of the product, attached to the product or included in the product packaging.

[6] Natural health products are assigned an eight-digit Natural Product Number ("NPN") when they are issued a product licence by Health Canada.

Nuvocare.ca website taken on February 16, 2020, is attached as **Exhibit 12** to this Affidavit.

26. NutraCentials WeightOFF Max! (NPN 80053895) is a supplement in capsule form. A copy of a capture of the product label's list of ingredients from the Nuvocare.ca website taken on February 16, 2020, is attached as **Exhibit 13** to this Affidavit.

27. The Respondents have made and continue to make a number of representations to the public about the performance or efficacy of the WeightOFF Max! Products on the Relevant Websites, on social media sites, in promotional emails, at consumer expos, in online or print magazines, and on product labels or packaging.

WeightOFF Max! – WEIGHT LOSS Representations

28. The Respondents have made and continue to make representations on certain Relevant Websites, on certain social media sites, at consumer expos, and on product labels or packaging that the use of the WeightOFF Max! Products will cause weight loss. These representations include, but are not limited to:

a. "EXTRA STRENGTH WEIGHT LOSS"

SlimCentials WeightOFF Max!

- Nuvocare.ca website video featuring Mr. Foley: A copy of a capture of the website video "Best proven weight loss supplement | How to lose weight faster with WeightOFF MAX!" from the SlimCentials WeightOFF Max! product page taken on January 29, 2020, is attached as **Exhibit 14** to this Affidavit.

- YouTube video featuring Mr. Foley: See **Exhibit 5** to this Affidavit.

- Facebook video featuring Mr. Foley: A copy of a capture of the video "WeightOFF MAX!" from the Nuvocare Facebook page taken on February 24, 2020, is attached as **Exhibit 15** to this Affidavit.

- SlimCentials.com website video: A copy of a capture of the website video "Best proven weight loss supplement | How to lose weight faster with WeightOFF MAX!" from the SlimCentials WeightOFF Max! product page taken on January 29, 2020, is attached as **Exhibit 16** to this Affidavit.

- SlimCentials.com website: A copy of a capture of the Homepage taken on February 21, 2020, is attached as **Exhibit 17** to this Affidavit.

- SlimCentials.com website: A copy of a capture of the SlimCentials WeightOFF Max! "WeightOFF Presentation" taken on January 24, 2020, is attached as **Exhibit 18** to this Affidavit.

NutraCentials WeightOFF Max!

- Nuvocare.ca website video: A copy of a capture of the website video "The all NEW WeightOFF Max! – natural weight loss" from the NutraCentials WeightOFF Max! product page taken on February 16, 2020, is attached as **Exhibit 19** to this Affidavit.

- YouTube video: A copy of a capture the video "The all NEW WeightOFF Max! – natural weight loss" from the Nuvocare YouTube Channel taken on January 8, 2020, is attached **Exhibit 20** to this Affidavit.

- Facebook video: A copy of a capture of the video "NutraCentials WeightOFF Max" from the Nuvocare Facebook page taken on February 24, 2020, is attached as **Exhibit 21** to this Affidavit.

- NutraCentials.com website: A copy of a capture of the NutraCentials WeightOFF Max! product page taken on February 16, 2020, is attached as **Exhibit 22** to this Affidavit.

b. ***"EXTRA STRENGTH WEIGHT CONTROL"***.

SlimCentials WeightOFF Max!

- Nuvocare.com website: A copy of a capture of the product package taken on February 16, 2020, is attached as **Exhibit 23** to this Affidavit.

- Facebook page: A copy of a capture of a SlimCentials WeightOFF Max! post from the Nuvocare Facebook page taken on February 24, 2020, is attached as **Exhibit 24** to this Affidavit.

- Product Label: A copy of a photo of SlimCentials WeightOFF Max! from a February 2020 product purchase is attached as **Exhibit 25** to this Affidavit.

NutraCentials WeightOFF Max!

- Facebook page: A copy of a capture of a NutraCentials WeightOFF Max! post from the Nuvocare Facebook page taken on February 24, 2020, is attached as **Exhibit 26** to this Affidavit.

- Product Label: A copy of a photo of NutraCentials WeightOFF Max! from a February 2020 product purchase is attached as **Exhibit 27** to this Affidavit.

c. ***"The world's best premium weight loss ingredients at the dosages proven to work together in one formulation"***

SlimCentials WeightOFF Max!

- SlimCentials.com: A copy of a capture of the SlimCentials WeightOFF Max! product page taken on January 24, 2020, is attached as **Exhibit 28** to this Affidavit.

NutraCentials WeightOFF Max!

- Nuvocare.com website: A copy of a capture of the "Weight Loss Brands" page taken on January 24, 2020, is attached as **Exhibit 29** to this Affidavit.

- NutraCentials.com website: A copy of a capture of the "Slimming Essentials Products" page taken on January 24, 2020, is attached as **Exhibit 30** to this Affidavit.

- Product label: A copy of a photo of NutraCentials WeightOFF Max! from a February 2020 retail store visit is attached as **Exhibit 31** to this Affidavit.

d. ***"The world's best premium weight loss nutrients all in dosages clinically proven to work"***

SlimCentials WeightOFF Max!

- Nuvocare.ca website video featuring Mr. Foley: See **Exhibit 14** to this Affidavit.

- YouTube video featuring Mr. Foley: See **Exhibit 5** to this Affidavit.

- Facebook video featuring Mr. Foley: See **Exhibit 15** to this Affidavit.

- SlimCentials.com video featuring Mr. Foley: See **Exhibit 16** to this Affidavit.

e. "Our most powerful weight loss formula ever!"

NutraCentials WeightOFF Max!

- NutraCentials.com website: A copy of a capture of the NutraCentials WeightOFF Max! "INFO SHEET" taken on January 24, 2020, is attached as **Exhibit 32** to this Affidavit.

- Consumer expo: A copy of the NutraCentials WeightOFF Max! "INFO SHEET" obtained from the Zoomer Show[7] on October 27, 2018, is attached as **Exhibit 33** to this Affidavit.

f. "The nutrients in WeightOFF MAX! naturally combine to deliver 6 key benefits that make weight-loss faster and easier!"

SlimCentials WeightOFF Max!

- SlimCentials.com website: See **Exhibit 28** to this Affidavit.

- SlimCentials.com website: See **Exhibit 18** to this Affidavit.

- Nuvocare.com website: A copy of a capture of the SlimCentials WeightOFF Max! product page taken on February 16, 2020, is attached as **Exhibit 34** to this Affidavit.

g. "6-IN-1 Weight Loss Solution"

SlimCentials WeightOFF Max!

- Nuvocare.com website: See **Exhibit 34** to this Affidavit.

h. "HELPS YOU LOSE WEIGHT 6 WAYS!"

SlimCentials WeightOFF Max!

- Nuvocare.com website: See **Exhibit 23** to this Affidavit.

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[7] The Zoomer Show is described on its website as "Canada's largest consumer show focused on helping adults 45+ live better".

- SlimCentials.com website: See **Exhibit 17** to this Affidavit.
- SlimCentials.com website: See **Exhibit 18** to this Affidavit.
- Facebook page: See **Exhibit 24** to this Affidavit.

i. "CUT 200% MORE WEIGHT THAN DIETING ALONE"

SlimCentials WeightOFF Max!

- Nuvocare.ca website video featuring Mr. Foley: See **Exhibit 14** to this Affidavit.
- SlimCentials.com website: See **Exhibit 17** to this Affidavit.
- YouTube video featuring Mr. Foley: See **Exhibit 5** to this Affidavit.
- Facebook video featuring Mr. Foley: See **Exhibit 15** to this Affidavit.
- SlimCentials.com website video featuring Mr. Foley: See **Exhibit 16** to this Affidavit.
- Product Packaging: A copy of promotional material obtained from a June 2018 product purchase is attached as **Exhibit 35** to this Affidavit

j. "Clinical studies PROVE that WeightOFF MAX! can CUT 200% MORE WEIGHT THAN DIETING ALONE"

SlimCentials WeightOFF Max!

- SlimCentials.com website: See **Exhibit 18** to this Affidavit.
- Nuvocare.ca website video featuring Mr. Foley: See **Exhibit 14** to this Affidavit.
- YouTube video featuring Mr. Foley: See **Exhibit 5** to this Affidavit.
- Facebook video featuring Mr. Foley: See **Exhibit 15** to this Affidavit.
- SlimCentials.com website video featuring Mr. Foley: See **Exhibit 16** to this Affidavit.

k. "Lose-Weight"

SlimCentials WeightOFF Max!

- Instagram page: A copy of a capture of a post from the Nuvocare Instagram page taken on January 27, 2020, is attached as **Exhibit 36** to this Affidavit.

l. "Works in 6 ways for effective weight loss"

SlimCentials WeightOFF Max!

- Nuvocare.ca website video featuring Mr. Foley: See **Exhibit 14** to this Affidavit.
- YouTube video featuring Mr. Foley: See **Exhibit 5** to this Affidavit.
- Facebook video featuring Mr. Foley: See **Exhibit 15** to this Affidavit.
- SlimCentials.com website video featuring Mr. Foley: See **Exhibit 16** to this Affidavit.

m. "3X MORE Weight Control in 90 Days!"

SlimCentials WeightOFF Max!

- Product Packaging: A copy of a photo of SlimCentials WeightOFF Max! from a February 2020 product purchase is attached as **Exhibit 37** to this Affidavit.

n. "The nutrients in WeightOFF MAX! naturally work together to make it one of the most powerful weight loss formulas on the market!"

NutraCentials WeightOFF Max!

- Nuvocare.com website: See **Exhibit 29** to this Affidavit.
- NutraCentials.com website: See **Exhibit 30** to this Affidavit.
- Product Label: See **Exhibit 31** to this Affidavit.

o. "CUTS WEIGHT VIA 3-KEY BENEFITS"

NutraCentials WeightOFF Max!

- Product Label: A copy of a photo of NutraCentials WeightOFF Max! from a February 2020 product purchase is attached as **Exhibit 38** to this Affidavit.

WeightOFF Max! - Other Performance or Efficacy Representations

29. The Respondents have made and continue to make a number of other, related representations about the performance or efficacy of the WeightOFF Max! products on certain Relevant Websites, on certain social media sites, in promotional emails, at consumer expos, in online or print magazines, and on product labels or packaging.

FAT BURN, FAT RELEASE AND FAT BLOCKING Representations

30. The Respondents have made and continue to make representations on certain Relevant Websites, on certain social media sites, at consumer expos, in online or print magazines, and on products labels or packaging that the use of the WeightOFF Max! products will burn fat, release fat, and block fat. These representations include, but are not limited to:

a. "THE ULTIMATE ALL-IN-ONE NATURAL FAT-BURNING SOLUTION"

SlimCentials WeightOFF Max!

- Nuvocare.ca website video featuring Mr. Foley: See **Exhibit 14** to this Affidavit.
- YouTube video featuring Mr. Foley: See **Exhibit 5** to this Affidavit.
- Facebook video featuring Mr. Foley: See **Exhibit 15** to this Affidavit.
- SlimCentials.com website video featuring Mr. Foley: See **Exhibit 16** to this Affidavit.
- SlimCentials.com website: See **Exhibit 18** to this Affidavit.

b. ***"... shown to block carbohydrate usage, making it easier for the body to burn fat as energy"***

SlimCentials WeightOFF Max!

- Nuvocare.ca website video featuring Mr. Foley: See **Exhibit 14** to this Affidavit.
- YouTube video featuring Mr. Foley: See **Exhibit 5** to this Affidavit.
- Facebook video featuring Mr. Foley: See **Exhibit 15** to this Affidavit.
- SlimCentials.com website video featuring Mr. Foley: See **Exhibit 16** to this Affidavit.

c. ***"Burns fat as energy"***

SlimCentials WeightOFF Max!

- Nuvocare. ca website video featuring Mr. Foley: See **Exhibit 14** to this Affidavit.
- YouTube video featuring Mr. Foley: See **Exhibit 5** to this Affidavit.
- Facebook video featuring Mr. Foley: See **Exhibit 15** to this Affidavit.
- SlimCentials.com website video featuring Mr. Foley: See **Exhibit 16** to this Affidavit.

d. ***"Our most powerful fat burner"***

NutraCentials WeightOFF Max!

- YouTube video featuring Mr. Foley: A copy of a capture the video "Interactive Supplement Guide" from the Nuvocare YouTube Channel taken on February 4, 2020, is attached as **Exhibit 39** to this Affidavit.
- Online Magazine: A copy of a capture from a March 2015 issues of *Nelson Salmo Pennywise* magazine taken on October 18, 2019, is attached as **Exhibit 40** to this Affidavit.

e. ***"Increases fat release and burning while also blocking fat storage"***

NutraCentials WeightOFF Max!

- YouTube video featuring Mr. Foley: See **Exhibit 39** to this Affidavit.

- Nuvocare.ca website video: See **Exhibit 19** to this Affidavit.
- YouTube video: See **Exhibit 20** to this Affidavit.
- Facebook video: See **Exhibit 21** to this Affidavit.
- Online Magazine: A copy of a capture from a January 2015 issue of *Now* Magazine taken on October 18, 2019, is attached as **Exhibit 41** to this Affidavit.
- Print Magazine: A copy of a July 2015 issue of *Alive* Magazine is attached as **Exhibit 42** to this Affidavit.

f. ***"Speeds up your metabolism helping you burn fat easier"***

NutraCentials WeightOFF Max!

- NutraCentials.com website: See **Exhibit 32** to this Affidavit.
- Consumer expo: See **Exhibit 33** to this Affidavit.

CUT APPETITE Representations

31. The Respondents have made and continue to make representations on certain Relevant Websites, on certain social media sites, at consumer expos, and on product labels or packaging that the use of the WeightOFF Max! products will cut appetite. These representations include, but are not limited to:

a. ***"CUTS APPETITE"***

SlimCentials WeightOFF Max!

- Product Packaging: See **Exhibit 35** to this Affidavit.

b. ***"Cuts appetite and curbs emotional eating. This leads to reduced calorie intake & reduced snacking by up to 30% daily"***

SlimCentials WeightOFF Max!

- Nuvocare.ca website video featuring Mr. Foley: See **Exhibit 14** to this Affidavit.
- YouTube video featuring Mr. Foley: See **Exhibit 5** to this Affidavit.

- Facebook video featuring Mr. Foley: See **Exhibit 15** to this Affidavit.
- SlimCentials.com website video featuring Mr. Foley: See **Exhibit 16** to this Affidavit.

c. ***"Cut appetite and ignite metabolism"***

NutraCentials WeightOFF Max!

- NutraCentials.com website: See **Exhibit 32** to this Affidavit.
- Consumer expo: See **Exhibit 33** to this Affidavit.

BLOCK CARBOHYDRATES Representations

32. The Respondents have made and continue to make representations on certain Relevant Websites, on certain social media sites, and on product labels or packaging that the use of the WeightOFF Max! products will block carbohydrates. These representations include, but are not limited to:

a. ***"BLOCKS CARBOHYDRATES"***

SlimCentials WeightOFF Max!

- Product Packaging: See **Exhibit 35** to this Affidavit

b. ***"Block carbohydrate usage making it easier for the body to burn fat as energy"***

SlimCentials WeightOFF Max!

- Nuvocare. ca website video featuring Mr. Foley: See **Exhibit 14** to this Affidavit.
- YouTube video featuring Mr. Foley: See **Exhibit 5** to this Affidavit.
- Facebook video featuring Mr. Foley: See **Exhibit 15** to this Affidavit.
- SlimCentials.com website video featuring Mr. Foley: See **Exhibit 16** to this Affidavit.

DECREASE EMOTIONAL EATING Representations

33. The Respondents have made and continue to make representations on certain Relevant Websites, on certain social media sites, in promotional emails, and

in online or print magazines that the use of the WeightOFF Max! products will decrease emotional eating. These representations include, but are not limited to:

a. ***"Decreases emotional eating and reduces appetite"***

NutraCentials WeightOFF Max!

- Print Magazine: See **Exhibit 42** to this Affidavit.

b. ***"Decreases emotional eating and your natural desire to crave sweets"***

NutraCentials WeightOFF Max!

- YouTube video featuring Mr. Foley: See **Exhibit 39** to this Affidavit.
- Online Magazine: See **Exhibit 41** to this Affidavit.

c. ***"Decreasing emotional eating"***

NutraCentials WeightOFF Max!

- Nuvocare.ca website video: See **Exhibit 19** to this Affidavit.
- YouTube video: See **Exhibit 20** to this Affidavit.
- Facebook video: See **Exhibit 21** to this Affidavit.

d. ***"Decrease emotional eating"***

NutraCentials WeightOFF Max!

- Promotional Email: A copy of a capture of an email dated July 14, 2017, received from info@nuvocare.com is attached as **Exhibit 43** to this Affidavit.

e. ***"Cuts appetite and curbs emotional eating"***

SlimCentials WeightOFF Max!

- Nuvocare.ca website video featuring Mr. Foley: See **Exhibit 14** to this Affidavit.
- YouTube video featuring Mr. Foley: See **Exhibit 5** to this Affidavit.

- Facebook video featuring Mr. Foley: See **Exhibit 15** to this Affidavit.
- SlimCentials.com video featuring Mr. Foley: See **Exhibit 16** to this Affidavit.

(b) Forskolin Representations under the SlimCentials and NutraCentials Brands

34. SlimCentials Forskolin+ (NPN 80058127) is a supplement in capsule form. A copy of a capture of the product label's list of ingredients taken from the Nuvocare.ca website on February 16, 2020, is attached as **Exhibit 44** to this Affidavit.

35. NutraCentials Forskolin Nx (NPN 80058127) is a supplement in capsule form. A copy of a capture of the product label's list of ingredients taken from the Nuvocare.ca website on February 16, 2020, is attached as **Exhibit 45** to this Affidavit.

36. The Respondents have made and continue to make a number of representations to the public about the performance or efficacy of the Forskolin products on the Relevant Websites, on social media sites, in promotional emails, at consumer expos, in online or print magazines, and on product labels or packaging.

Forskolin – FAT BURNING Representations

37. The Respondents have made and continue to make representations on certain Relevant Websites, on certain social media sites, in promotional emails, at consumer expos, and on product labels or packaging that the use of the Forskolin products will burn fat. These representations include:

a. "When it comes to burning body fat and preserving muscle, forskolin should be your solution"

SlimCentials Forskolin+

- YouTube video featuring Mr. Foley: See as **Exhibit 39** to this Affidavit.

NutraCentials Forskolin Nx

- YouTube video featuring Mr. Foley: See as **Exhibit 39** to this Affidavit.

b. ***"Clinically proven fat burning solution"***

SlimCentials Forskolin+

- YouTube video featuring Mr. Foley: A copy of a capture of the video "The #1 Forskolin Extract that is BACKED BY SCIENCE and GUARANTEED" from the Nuvocare YouTube channel taken on January 27, 2020, is attached as **Exhibit 46** to this Affidavit.

- Facebook video video featuring Mr. Foley: A copy of a capture of the video "Forskolin" from the Nuvocare Facebook page taken on February 24, 2020, is attached as **Exhibit 47** to this Affidavit.

c. ***"This powerful formula delivers potent fat burning effects"***

SlimCentials Forskolin+

- YouTube video featuring Mr. Foley: See **Exhibit 46** to this Affidavit.

- Facebook video featuring Mr. Foley: See **Exhibit 47** to this Affidavit.

d. ***"DUAL-ACTION effect that stimulates the Body's KEY fat-burning enzyme via 2 distinct mechanisms"***

SlimCentials Forskolin+

- YouTube video featuring Mr. Foley: See **Exhibit 46** to this Affidavit.

- Facebook video featuring Mr. Foley: See **Exhibit 47** to this Affidavit.

e. ***"Stimulates an enzyme in the body responsible for fat burning"***

SlimCentials Forskolin+

- YouTube video featuring Mr. Foley: See **Exhibit 46** to this Affidavit.

- Facebook video featuring Mr. Foley: See **Exhibit 47** to this Affidavit.

NutraCentials Forskolin Nx

- NutraCentials.com website: A copy of a capture of the NutraCentials Forskolin Nx "INFO SHEET" taken on January 24, 2020, is attached as **Exhibit 48** to this Affidavit.

- Consumer expo: A copy of the NutraCentials Forskolin Nx "INFO SHEET" obtained from the Zoomer Show on October 27, 2018, is attached as **Exhibit 49** to this Affidavit.

f. ***"Increases KEY Fat-Burning enzyme"***

SlimCentials Forskolin+

- YouTube video featuring Mr. Foley: See **Exhibit 46** to this Affidavit.

- Facebook video featuring Mr. Foley: See **Exhibit 47** to this Affidavit.

g. ***"Speeds up your metabolism helping you burn fat easier"***

SlimCentials Forskolin+

- YouTube video featuring Mr. Foley: See **Exhibit 46** to this Affidavit.

- Facebook video featuring Mr. Foley: See **Exhibit 47** to this Affidavit.

NutraCentials Forskolin Nx

- NutraCentials.com website: See **Exhibit 48** to this Affidavit.

- Consumer expo: See **Exhibit 49** to this Affidavit.

h. ***"Helps release and burn stored body fat"***

NutraCentials Forskolin Nx

- YouTube video: A copy of a capture of the video "The REAL Forskolin: FORSLEAN – what you need to know" from the Nuvocare YouTube channel taken on February 21, 2020, is attached as **Exhibit 50** to this Affidavit.

- Nuvocare.ca website video: A copy of a capture of the video "The REAL Forskolin: FORSLEAN – what you need to know" from the SlimCentials Forskolin+ product page taken on January 29, 2020, is attached as **Exhibit 51** to this Affidavit.

- SlimCentials.com website video: A copy of a capture of the video "The REAL Forskolin: FORSLEAN – what you need to know" from the SlimCentials Forskolin+ product page taken on January 29, 2020, is attached as **Exhibit 52** to this Affidavit.

- Facebook video: A copy of a capture of the video "FORSKOLIN+ w Razpberi-K" from the Nuvocare Facebook page taken on February 24, 2020, is attached as **Exhibit 53** to this Affidavit.

i. "Stimulates enzyme to Help Burn More Fat"

NutraCentials Forskolin Nx

- Promotional Email: See **Exhibit 43** to this Affidavit.

j. "Lose an average of 9.9 lbs of body fat in 12 weeks"*

NutraCentials Forskolin Nx

- NutraCentials.com website: See **Exhibit 48** to this Affidavit.

- Consumer expo: See **Exhibit 49** to this Affidavit.

k. "Forskolin is lightning in a bottle and a miracle flower to help you fight fat"

NutraCentials Forskolin Nx

- NutraCentials.com website: See **Exhibit 48** to this Affidavit.

- Consumer expo: See **Exhibit 49** to this Affidavit.

l. "... support a key fat-burning enzyme in the body known as HSL"

NutraCentials Forskolin Nx

- Nuvocare.ca: A copy of a capture of the NutraCentials Forskolin Nx product label taken on February 16, 2020, is attached as **Exhibit 54** to this Affidavit.

- Product Label: A copy of a photo of NutraCentials Forskolin Nx taken from a February 2020 product purchase is attached as **Exhibit 55** to this Affidavit.

m. "This potent fat melting nutrient ignites metabolism and fat burning and promotes leaner, tighter muscle tone"

NutraCentials Forskolin Nx

- Nuvocare.com website: See **Exhibit 29** to this Affidavit.
- NutraCentials.com website: See **Exhibit 30** to this Affidavit.
- NutraCentials.com website: See **Exhibit 48** to this Affidavit.
- Consumer expo: See **Exhibit 49** to this Affidavit.

n. "FAT BURNING FORMULA"

SlimCentials Forskolin+

- Product Label: A copy of a photo of SlimCentials Forskolin+ product label taken from a February 2020 product purchase is attached as **Exhibit 56** to this Affidavit.

Forskolin - Other Performance or Efficacy Representations

38. The Respondents have made and continue to make related representations on the Relevant Websites, on social media sites, in promotional emails, at consumer expos, and on product labels or packaging about the performance or efficacy of the Forskolin products.

BELLY FAT Representations

39. The Respondents have made and continue to make representations on certain Relevant Websites, on certain social media sites, and at consumer expos that the use of the Forskolin products will target belly fat. These representations include, but are not limited to:

a. "DUAL BELLY-FAT MELTING REMEDY"

SlimCentials Forskolin+

- YouTube video featuring Mr. Foley: See **Exhibit 46** to this Affidavit.
- Facebook video: See **Exhibit 47** to this Affidavit.

NutraCentials Forskolin Nx

- NutraCentials.com website: See **Exhibit 48** to this Affidavit.
- Consumer expo: See **Exhibit 49** to this Affidavit.
- YouTube video: See **Exhibit 50** to this Affidavit.
- Nuvocare.ca website video: See **Exhibit 51** to this Affidavit.
- SlimCentials.com website video: See **Exhibit 52** to this Affidavit.
- Facebook video: See **Exhibit 53** to this Affidavit.

b. ***"Dual action belly-fat melting remedy is designed to effectively help you shed those extra pounds faster"***

SlimCentials Forskolin+

- YouTube video featuring Mr. Foley: See **Exhibit 46** to this Affidavit.
- Facebook video: See **Exhibit 47** to this Affidavit.

c. ***"Forskolin helps decrease belly fat and overall body fat levels by increasing the enzyme HSL"***

SlimCentials Forskolin+

- YouTube video featuring Mr. Foley: See **Exhibit 39** to this Affidavit.

NutraCentials Forskolin Nx

- YouTube video featuring Mr. Foley: See **Exhibit 39** to this Affidavit.

INCREASE METABOLISM Representations

40. The Respondents have made and continue to make representations on certain Relevant Websites, on certain social media sites, in promotional emails, and at consumer expos that the use of the Forskolin products will increase metabolism. These representations include, but are not limited to:

a. ***"Speeds up your metabolism helping you burn fat easier"***

SlimCentials Forskolin+

- YouTube video featuring Mr. Foley: See **Exhibit 46** to this Affidavit.
- Facebook video featuring Mr. Foley: See **Exhibit 47** to this Affidavit.

NutraCentials Forskolin Nx

- NutraCentials.com website: See **Exhibit 48** to this Affidavit.
- Consumer expo: See **Exhibit 49** to this Affidavit.

b. "This fat melting nutrient ignites metabolism and promotes leaner, tighter muscle tone"

NutraCentials Forskolin Nx

- YouTube video: See **Exhibit 50** to this Affidavit.
- Nuvocare.ca website video: See **Exhibit 51** to this Affidavit.
- SlimCentials.com website video: See **Exhibit 52** to this Affidavit.
- Facebook video: See **Exhibit 53** to this Affidavit.

c. "Speeds up Metabolism"

NutraCentials Forskolin Nx

- Promotional Email: See **Exhibit 43** to this Affidavit.

d. "Forskolin Nx will: speed up your metabolism and burn fat"

- Instagram page: A copy of a capture of a post from the Nuvocare Instagram page taken on February 25, 2020, is attached as **Exhibit 57** to this Affidavit.

(c) Representations made regarding the Combination of Products

41. The Respondents have made and continue to make representations about the performance or efficacy of one or more of the Products in combination on certain Relevant Websites, on certain social media sites, in promotional emails, in online or print magazines, and on product labels or packaging. These representations include, but are not limited to:

a. *"For even more powerful weight loss results, try combining WeightOFF Max! with SlimCentials Forskolin+"*

- Nuvocare.ca website video featuring Mr. Foley: See **Exhibit 14** to this Affidavit.
- YouTube video featuring Mr. Foley: See **Exhibit 5** to this Affidavit.
- Facebook video featuring Mr. Foley: See **Exhibit 15** to this Affidavit.
- SlimCentials.com website video featuring Mr. Foley: See **Exhibit 16** to this Affidavit.

b. *"Weight Loss Results with this Perfect Pair WeightOFF MAX! & Forskolin Nx"*

- Promotional Email: See **Exhibit 43** to this Affidavit.

c. *"INCREASE WEIGHT LOSS EVEN FASTER"*

- Promotional Email: See **Exhibit 43** to this Affidavit.

d. *"Combining Forskolin Nx with WeightOFF! MAX will ignite your metabolism while promoting leaner tighter muscle tone while reducing body fat & curbing your appetite"*

- Promotional Email: See **Exhibit 43** to this Affidavit.

e. *"Burn MORE Body Fat, Maintain MORE Muscle"*

- Product Label: A copy of a photo of NutraCentials WeightOFF Max! from a February 2020 product purchase is attached as **Exhibit 58** to this Affidavit.

f. *"Combine Multi-Award Winning WeightOFF MAX! + Forskolin Nx and Achieve Even More Dramatic LEAN BODY RESULTS!"*

- Product Label: See **Exhibit 58** to this Affidavit.

g. *"MEET YOUR NEW FAT-BURNING DREAM TEAM"*

- Online Magazine: A copy of a capture from the Fall 2015 issue of *Viva Magazine* taken on October 18, 2019, is attached as **Exhibit 59** to this Affidavit.

h. "CLINICAL STRENGTH WEIGHToff MAX! + Forskolin Nx = YOUR DREAM BODY"

- Online Magazine: See **Exhibit 59** to this Affidavit.

i. "This potent combination tackles weight-loss from 7 angles"

- Online Magazine: See **Exhibit 59** to this Affidavit.

IV. GEOGRAPHIC MARKET

42. The Products are available to Canadian consumers nationally through a wide array of retailers and channels. This includes major retail stores and health food retailers, as well as online through the Nuvocare.ca website.[8]

43. The Products are also distributed nationally by Purity Life Health Products LP ("**Purity Life**"). The Purity Life website indicates that they are "Canada's LEADING distributor of natural health products" and indicates Nuvocare Health Sciences in their list of "Brands". A copy of a capture of the Puritylife.com "Brands" page taken on January 22, 2020, is attached as **Exhibit 60** to this Affidavit.

44. According to a statement made by Mr. Foley during the episode of Dragon's Den in 2010, the Respondents' obtained a contract with "the biggest distributor of natural health products in Canada, [...] which opens the door to 2,700 independent health food retailers and 10,000 food, drug and mass accounts". See **Exhibit 6** to this Affidavit.

45. Several Canadian retailers, health food stores, and online retailers are indicated as resellers of Nuvocare products on one or more of the Relevant Websites. These include: Loblaw, London Drugs, Metro, Rexall, Walmart, Ambrosia, Whole Foods Market, Jo Anne's Place Health Foods, Homegrown Health and

[8] When viewing the Products on the other Relevant Websites, consumers that click "buy now" are redirected to the Nuvocare.ca website to purchase the Products.

Wellness, Nature's Emporium, Nature's Fare Markets, Nature's Source Natural Dispensary, Healthy Planet, The Big Carrot, Morning Sun Health Foods, Supplements plus, Well.ca, Vitarock, and vitamart.ca. A copy of a capture of the "Where To Buy" page on the Nuvocare.com website taken on January 24, 2020, is attached as **Exhibit 61** to this Affidavit.

46. I have visited a trade show and a consumer expo where the products are marketed and sold and made purchases of the Products online on the Nuvocare.ca website and at third-party retail stores. I am also informed by other Bureau representatives of additional retail store visits and purchases of the Products in Ottawa, Vancouver, Toronto, Montreal, and Halifax. A table indicating the source of the information, date, location and the Products purchased is attached as **Exhibit 62** to this Affidavit.

47. The Products can also be purchased by Canadian consumers through other online retailers. Copies of captures of online retailer websites taken on January 28 and 29, 2020, where the Products are available for purchase, are attached as **Exhibit 63** to this Affidavit.

V. TARGET MARKET

48. The Respondents make certain representations about the target market of the Products in representations that appear to be intended for health care practitioners and resellers of the Products. These representations indicate that the target market of the Products is anyone looking for a natural health product that will cause weight loss or burn fat. See **Exhibit 39** to this Affidavit.

49. The Respondents identify four (4) specific categories of consumers that the Products are intended to benefit. These categories include: "obese"; "overweight"; "spare tire"; and, "want to lose those last few lbs". The Products are identified as a prescription in all four of these categories. A copy of a photo

of the "Obesity Prescription" taken on September 17, 2017, at the CHFA trade show is attached as **Exhibit 64** to this Affidavit.

50. The Respondents further identify the types of consumers (see **Exhibit 64**) who should use NutraCentials brand products and claim that these Products should be prescribed to:

a. Males and females over the age of 18 who want to lose body fat and maintain muscle;

b. Individuals taking diabetic, heart, thyroid and other medications;

c. Individuals taking vitamins and other medications; and

d. Anyone who wants to use the purest, cleanest, highest quality, most potent nutrients clinically proven to have powerful fat loss benefits while also improving overall health.

51. These representations are also made at consumer expos. A copy of a photo of the "Obesity Prescription" taken at the Zoomer Show on October 27, 2018, is attached as **Exhibit 65** to this Affidavit.

VI. ECONOMIC LOSS TO CONSUMERS

52. SlimCentials WeightOFF Max! is available to Canadian consumers at a cost of $26.95, on sale for $23.95 (See **Exhibit 34**), on the Nuvocare.ca website. The product contains 60 capsules and the recommended dose is 1 capsule 5 times daily. A copy of a capture of the recommended dose on the Nuvocare.com product page taken on February 16, 2020, is attached as **Exhibit 66** to this Affidavit.

53. NutraCentials WeightOFF Max! is sold to Canadian consumers for $29.95 on the Nuvocare.ca website. The product contains 60 capsules and the recommended dose is 2 capsules twice daily. A copy of a capture of the

recommended dose on the Nuvocare.ca product page taken on February 16, 2020, is attached as **Exhibit 67** to this Affidavit.

54. SlimCentials Forskolin+ is available to Canadian consumers at a cost of $24.95 on the Nuvocare.ca website. The product contains 45 capsules and the recommended dose is 1 capsule two times per day. A copy of a capture of the recommended dose on the Nuvocare.ca product page taken on February 16, 2020, is attached as **Exhibit 68** to this Affidavit.

55. NutraCentials Forskolin Nx is available to Canadian consumers at a cost of $29.95 on the Nuvocare.ca website. The product contains 60 capsules and the recommended dose is 1 capsule two times per day. A copy of a capture of the recommended dose on the Nuvocare.ca product page taken on February 16, 2020, is attached as **Exhibit 69** to this Affidavit.

56. The Respondents' offer 15% savings plus free shipping to consumers who purchase their Products through their "AutoShip" program. If consumers purchase the Products through this program, the Respondents will automatically ship the Products to consumers every 15 or 30 days and, as a result, also automatically bill consumers for these purchases. A copy of a capture of the "AUTOSHIP OFFERS" page of the Nuvocare.ca website taken on February 5, 2020, is attached as **Exhibit 70** to this Affidavit.

57. In order to "LOSE 10 LBS. in 60 DAYS" (See **Exhibit 5**), a consumer would need to purchase five bottles of SlimCentials WeightOFF Max! during this period, at a cost of $144.75 based on the sale price of the product, plus any applicable taxes or shipping costs.

58. Based on representations made by the Respondents that combining the Products will achieve "even more powerful weight loss results" (see **Exhibit 5**), a consumer would need to purchase an additional three bottles of SlimCentials Forskolin+ during a 60 day period at a cost of $74.85, plus any applicable taxes or shipping costs.

VII. COMPETITION BUREAU ENFORCEMENT EFFORTS

(a) Bureau Efforts in Addressing Weight Loss Claims

59. Over the years, the Bureau has devoted significant resources to what it considers unsubstantiated weight loss claims, resulting in a number of enforcement actions.[9]

60. Furthermore, the Bureau has made a number of public statements warning consumers to be wary of weight loss representations, including issuing a consumer alert on this topic[10] as well as publishing material in the *The Little Black Book of Scams, 2nd Edition*[11]. This publication warns consumers that "Weight loss scams promise dramatic results with little or no effort" and reminds consumers that "there are no magic pills or miracle cures for achieving quick weight loss". A copy of *The Little Black Book of Scams, 2nd Edition* section on "Health and Medical Scams" is attached as **Exhibit 71** to this Affidavit.

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[9] "Consumers to Receive Full Refund for Bogus Diet Patches" (December 13, 2004), online: Government of Canada <https://www.canada.ca/en/news/archive/2004/12/consumers-receive-full-refund-bogus-diet-patches.html>;
"Competition Bureau Challenges Weight Loss Claims Made by Quebec Companies" (June 8, 2005), online: Government of Canada <https://www.canada.ca/en/news/archive/2005/06/competition-bureau-challenges-weight-loss-claims-made-quebec-companies.html>;
"The Commissioner of Competition and Northern Response International Ltd – Consent Agreement" (October 21, 2008) online: Competition Tribunal <https://www.ct-tc.gc.ca/CMFiles/CT-2008-009_0001_45NFB-_1172008-898.pdf>;
"Archived – Competition Bureau requires maker of Nivea to reimburse customers for misleading claims" (September 7, 2011), online: Competition Bureau Canada <https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03411.html>;
"The Commissioner of Competition and Thane Canada Inc – Consent Agreement" (January 10, 2018) online: Competition Tribunal <https://www.ct-tc.gc.ca/CMFiles/CT-2018-001_Registered%20Consent%20Agreement_2_67_1-10-2018_7967.pdf>.

[10] "Not worth their weight! – Just in time for summer, weight loss scams abound on social media" (June 9, 2014), online: Competition Bureau Canada < https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03749.html>.

[11] The Canadian edition of the Little Black Book of Scams is a publication released by the Bureau that provides consumers and businesses with information they can use to protect themselves against a variety of common scams.

(b) Industry Warning

61. On February 8, 2019, the Bureau issued a warning to sellers and marketers of natural health products in Canada to ensure weight loss claims are not false, misleading, or unsubstantiated. A copy of the warning is attached as **Exhibit 72** to this Affidavit.

(c) Bureau Efforts in Obtaining Testing from the Respondents

62. On March 20, 2019, Josephine Palumbo, Deputy Commissioner of the Deceptive Marketing Practices Directorate, sent a letter by registered mail to Ryan Foley of Nuvocare Health Sciences Inc, at 10 Four Seasons Place, Toronto, ON, M9B 6H7, requesting that testing be provided to the Bureau to substantiate performance claims made about the Products. The letter specifically set out that, under the Act, the onus is on the person making the representations to prove that the claims about the performance or efficacy of a product are based on adequate and proper testing. A copy of the letter is attached as **Exhibit 73** to this Affidavit.

63. The letter further noted that the Bureau is aware that the Products have been licenced by Health Canada for sale in Canada, however, that the licences do not shield the Respondents from the obligation to ensure that all representations made to promote the Products comply with the Act. The letter requested that Mr. Foley respond by April 3, 2019. See **Exhibit 73** to this Affidavit.

64. On or about April 5, 2019, Mr. Foley responded to me by email, requesting clarification of the Bureau's request and offering to "provide claim substantiation back up if claims are supported". A copy of Mr. Foley's email is attached as **Exhibit 74** to this Affidavit.

65. On April 25, 2019, I responded to Mr. Foley by email and provided clarification of the Bureau's request, and reiterated his responsibilities under the Act. I offered to extend the deadline to provide testing to substantiate the performance

claims made about the Products to May 3, 2019. A copy of my email response is attached as **Exhibit 75** to this Affidavit.

66. Despite having indicated that the Commissioner would be treating this as a priority matter, I did not receive a response from Mr. Foley.

67. The Respondents make claims that Nuvocare is a research-based company and that Nuvocare products are supported by research. Some examples include, but are not limited to:

a. The headline that appears on the Nuvocare.ca website is "NORTH AMERICA'S #1 RESEARCH-BASED SUPPLEMENT BRAND!" A copy of a capture of the website headline taken on January 23, 2020, is attached as **Exhibit 76** to this Affidavit;

b. The headline that appears on the SlimCentials.com website is "THE LEADER IN CLINICALLY-PROVEN WEIGHT LOSS NUTRIENTS". A copy of a capture of the website headline taken on January 23, 2020, is attached as **Exhibit 77** to this Affidavit;

c. Mr. Foley states, "[...] at Nuvocare Health Science we're quite different [...] and that's what makes us quite unique is we're a research based company and we won't put anything in our product unless it's seen a tremendous amount of human clinical trials, and we use the exact material in line with the, that was used in the clinical trial and that provide a specific result". A copy of a capture of a video interview with Alive[12] magazine taken on November 28, 2017, is attached as **Exhibit 78** to this Affidavit; and

d. Mr. Foley states, "One of the biggest trends I see, and, you know, we are trying to obviously build this ourselves, is bringing back authenticity to the

[12] "Alive" is a monthly Canadian natural health and wellness magazine. It is distributed in Canadian health retailers and can be purchased through personal subscriptions.

industry. So, basically everything we do is based on a tremendous amount of research. So, authenticity, research based, and being transparent with your customer. You know, full label disclosure, you know, claims that are substantiated by human clinical science. So I really believe authenticity is the future of a sustainable business model in our industry." See **Exhibit 78** to this Affidavit.

68. Despite claims made by the Respondents that Nuvocare products are supported by research, to date, the Bureau has not received a response to the email of April 25, 2019 or any testing to substantiate the Impugned Representations, as was requested.

69. The SlimCentials.com website invites consumers to read three separate "studies" relating to the SlimCentials WeightOFF Max! product.

a. A link called "Study 1" on the website directs consumers to a document that appears to be a summary of the results of a study. The summary of the study does not appear to involve the SlimCentials WeightOFF Max! product. A copy of a capture of the study taken from the website on January 29, 2020, is attached as **Exhibit 79** to this Affidavit.

b. A link called "Study 2" on the website directs consumers to a document that appears to examine the product *Svetol* as an aid to a recommended diet, rather than involving the SlimCentials WeightOFF Max! product. A copy of a capture of the study taken from the website on January 29, 2020, is attached as **Exhibit 80** to this Affidavit.

c. A link called "Study 3" on the website directs consumers to a document that appears to examine the product *MonCam* in conjunction with a hypocaloric diet for weight loss, rather than a study involving the SlimCentials WeightOFF Max! Product. A copy of a capture of the study taken from the website on January 29, 2020, is attached as **Exhibit 81** to this Affidavit.

70. I have reviewed the three "studies" on the SlimCentials.com website, and also note that none of them appear to explicitly address the representations that SlimCentials WeightOFF Max! will block fat storage, cut appetite, block carbohydrates, increase fat release or decrease emotional eating.

71. The NutraCentials.com website invites consumers to read three "studies" relating to the NutraCentials WeightOFF Max! on the product page.

a. A link called "Read Study" on the website directs consumers to a document that appears to be three distinct studies in one document. The first study appears to be the same as the document in the link called "Study 1" on the SlimCentials.com website. A copy of a capture of the document taken from the website on January 29, 2020, is attached as **Exhibit 82** to this Affidavit.

b. The second study appears to be a summary of the results of an experiment on the product *Svetol,* and does not appear to involve the NutraCentials WeightOFF Max! product. See **Exhibit 82** to this Affidavit.

c. The third part of this document appears to be a statistical report on the product *Razpberi-K,* and does not appear to involve the NutraCentials WeightOFF Max! product. See **Exhibit 82** to this Affidavit.

72. I have reviewed the three "studies" on the NutraCentials.com, website, and also note that none of them appear to explicitly address the representations that NutraCentials WeightOFF Max! will block fat storage, cut appetite, block carbohydrates, increase fat release or decrease emotional eating.

73. The SlimCentials.com and NutraCentials.com websites invite consumers to read one "study" relating to the SlimCentials Forskolin+ product and the NutraCentials Forskolin Nx product on each respective product page.

74. A link called "Study 1" on the SlimCentials.com website and a link called "Read Study" on the NutraCentials.com website both direct consumers to one study, which appears to be the same. This study appears to examine the effect

of forskolin by oral ingestion. I have reviewed these "studies" on the SlimCentials.com and NutraCentials.com websites, and also note that they do not appear to explicitly address the representations that SlimCentials Forskolin+ or NutraCentials Forskolin Nx will target belly fat, or increase metabolism. Copies of captures of the study taken from each of the websites on January 29, 2020, are attached as **Exhibits 83** and **84** to this Affidavit.

75. While I have reviewed the studies available on the website, the Respondents have not purported to be relying on any of these studies at this time.

76. Had the Respondents relied on adequate and proper testing of the Products prior to making the representations about the Products, and if this testing were available, it is my belief that the Respondents would have provided it to the Commissioner, given that Mr. Foley was made aware of his obligations in the Bureau's request for this information.

VIII. THE COMMISSIONER'S INQUIRY

77. On February 14, 2020, the Commissioner commenced an inquiry under subparagraph 10(1)(b)(ii) of the Act, on the basis that he has reason to believe that grounds exist for the making of an order under Part VII.1 of the Act, specifically pursuant to paragraphs 74.01(1)(a), 74.01(1)(b) and subsection 74.011(2) of the Act.

78. The Commissioner's Application, in this matter, seeks relief with respect to representations about the performance or efficacy of the Products not based on adequate and proper testing. The Bureau continues however, to investigate a wider range of related issues, including but not limited to representations made online, on product labels or packaging, and in promotional emails that may raise additional issues under the Act.

79. As part of his investigation, the Commissioner has retained an expert who is prepared to assess any testing that the Respondents may provide in the future in response to this Application.

80. Therefore, the Commissioner shall proceed as expeditiously as possible, during the period of interim relief, while having regard for the anticipated need for the use of formal powers to gather additional evidence in order to advance the investigation. The Respondents make a number of similar representations about other similar products that may ultimately form part of the Commissioner's Inquiry.

SWORN BEFORE ME in the City of Gatineau, in the Province of Quebec this day of February 28, 2020

A Commissioner for taking affidavits

Danielle McKenzie

Jody Gregory Currie
A Commissioner for Oaths and Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **1** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 1**"
and is marked as "**Exhibit 1.pdf**"

Commissioner of Oaths

Jody Gregory Currie
A Commissioner for Oaths and
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Exhibit « **2** » of the affidavit of DANIELLE MCKENZIE
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Exhibit « **3** » of the affidavit of DANIELLE MCKENZIE
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Exhibit « **4** » of the affidavit of DANIELLE MCKENZIE
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is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 4**"
and is marked as "**Exhibit 4.mp4**"

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Exhibit « **5** » of the affidavit of DANIELLE MCKENZIE
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Exhibit « **8** » of the affidavit of DANIELLE MCKENZIE
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Exhibit « **9** » of the affidavit of DANIELLE MCKENZIE
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and is marked as "**Exhibit 9.jpg**"

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Exhibit « **10** » of the affidavit of DANIELLE MCKENZIE
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Exhibit « **12** » of the affidavit of DANIELLE MCKENZIE
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in the folder entitled "**Exhibit 12**"
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and is marked as "**Exhibit 22.pdf**"

Commissioner of Oaths

Jody Gregory Currie
A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P144[illegible]

Exhibit « **23** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 23**"
and is marked as "**Exhibit 23.pdf**"

Commissioner of Oaths

Jody Gregory Currie
A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **24** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 24**"
and is marked as "**Exhibit 24.pdf**"

Commissioner of Oaths

Jody Gregory Currie
A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **25** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 25**"
and is marked as "**Exhibit 25.pdf**"

Commissioner of Oaths

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A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P14

Exhibit « **26** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 26**"
and is marked as "**Exhibit 26.pdf**"

Commissioner of Oaths

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A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **27** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 27**"
and is marked as "**Exhibit 27.pdf**"

Commissioner of Oaths

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A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **28** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 28**"
and is marked as "**Exhibit 28.jpg**"

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **29** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 29**"
and is marked as "**Exhibit 29.jpg**"

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **30** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 30**"
and is marked as "**Exhibit 30.jpg**"

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Exhibit « **31** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 31**"
and is marked as "**Exhibit 31.jpg**"

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Exhibit « **32** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 32**"
and is marked as "**Exhibit 32.pdf**"

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\ Commissioner for Oaths and
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sed Paralegal LSO# P14407

Exhibit « **33** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 33**"
and is marked as "**Exhibit 33.pdf**"

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Licensed Paralegal LSO# P14407

Exhibit « **34** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 34**"
and is marked as "**Exhibit 34.jpg**"

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Exhibit « **35** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 35**"
and is marked as "**Exhibit 35.pdf**"

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **36** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 36**"
and is marked as "**Exhibit 36.pdf**"

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Licensed Paralegal LSO# P14407

Exhibit « **37** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 37**"
and is marked as "**Exhibit 37.pdf**"

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Exhibit « **38** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 38**"
and is marked as "**Exhibit 38.pdf**"

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Exhibit « **39** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 39**"
and is marked as "**Exhibit 39.mp4**"

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Affidavits
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Exhibit « **40** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 40**"
and is marked as "**Exhibit 40.pdf**"

Commissioner of Oaths

ody Gregory Currie
ommissioner for Oaths and
Affidavits
Paralegal LSO# P14407

Exhibit « **41** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 41**"
and is marked as "**Exhibit 41.pdf**"

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A Commissioner for Oaths and
Affidavits
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Exhibit « **42** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 42**"
and is marked as "**Exhibit 42.pdf**"

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A Commissioner for Oaths and
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Exhibit « **43** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 43**"
and is marked as "**Exhibit 43.pdf**"

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Exhibit « **44** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 44**"
and is marked as "**Exhibit 44.pdf**"

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Exhibit « **45** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 45**"
and is marked as "**Exhibit 45.jpg**"

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Licensed Paralegal LSO# P14407

Exhibit « **46** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 46**"
and is marked as "**Exhibit 46.mp4**"

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **47** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 47**"
and is marked as "**Exhibit 47.mp4**"

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **48** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 48**"
and is marked as "**Exhibit 48.pdf**"

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **49** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 49**"
and is marked as "**Exhibit 49.pdf**"

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Licensed Paralegal LSO# P14407

Exhibit « **50** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 50**"
and is marked as "**Exhibit 50.mp4**"

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Licensed Paralegal LSO# P14407

Exhibit « **51** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 51**"
and is marked as "**Exhibit 51.mp4**"

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Exhibit « **52** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 52**"
and is marked as "**Exhibit 52.mp4**"

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Exhibit « **53** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 53**"
and is marked as "**Exhibit 53.mp4**"

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Exhibit « **54** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 54**"
and is marked as "**Exhibit 54.jpg**"

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Licensed Paralegal LSO# P14407

Exhibit « **55** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 55**"
and is marked as "**Exhibit 55.pdf**"

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **56** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 56**"
and is marked as "**Exhibit 56.pdf**"

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **57** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 57**"
and is marked as "**Exhibit 57.pdf**"

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **58** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 58**"
and is marked as "**Exhibit 58.pdf**"

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **59** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 59**"
and is marked as "**Exhibit 59.pdf**"

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Licensed Paralegal LSO# P14407

Exhibit « **60** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 60**"
and is marked as "**Exhibit 60.jpg**"

Commissioner of Oaths

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Licensed Paralegal LSO# P14407

Exhibit « **61** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 61**"
and is marked as "**Exhibit 61.pdf**"

Commissioner of Oaths

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A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P[illegible]07

Exhibit « **62** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 62**"
and is marked as "**Exhibit 62.pdf**"

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A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **63** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 63**"
and is marked as "**Exhibit 63.pdf**"

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **64** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 64**"
and is marked as "**Exhibit 64.pdf**"

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Licensed Paralegal LSO# P14407

Exhibit « **65** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 65**"
and is marked as "**Exhibit 65.pdf**"

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Exhibit « **66** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 66**"
and is marked as "**Exhibit 66.pdf**"

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Licensed Paralegal LSO# P14407

Exhibit « **67** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 67**"
and is marked as "**Exhibit 67.pdf**"

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Exhibit « **68** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 68**"
and is marked as "**Exhibit 68.pdf**"

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Licensed Paralegal LSO# P14407

Exhibit « **69** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 69**"
and is marked as "**Exhibit 69.pdf**"

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Exhibit « **70** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 70**"
and is marked as "**Exhibit 70.jpg**"

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Exhibit « **71** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 71**"
and is marked as "**Exhibit 71.pdf**"

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Exhibit « **72** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 72**"
and is marked as "**Exhibit 72.pdf**"

Commissioner of Oaths

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Licensed Paralegal LSO# P14407

Exhibit « **73** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 73**"
and is marked as "**Exhibit 73.pdf**"

Commissioner of Oaths

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Licensed Paralegal LSO# P14407

Exhibit « **74** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 74**"
and is marked as "**Exhibit 74.pdf**"

Commissioner of Oaths

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **75** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 75**"
and is marked as "**Exhibit 75.pdf**"

Commissioner of Oaths

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A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **76** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 76**"
and is marked as "**Exhibit 76.pdf**"

Commissioner of Oaths

Jody Gregory Currie
A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P14407

Exhibit « 77 » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 77**"
and is marked as "**Exhibit 77.pdf**"

Commissioner of Oaths

Jody Gregory Currie
A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P144

Exhibit « **78** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 78**"
and is marked as "**Exhibit 78.MOV**"

Commissioner of Oaths

Jody Gregory Currie
A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **79** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 79**"
and is marked as "**Exhibit 79.png**"

Commissioner of Oaths

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A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **80** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 80**"
and is marked as "**Exhibit 80.png**"

Commissioner of Oaths

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A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **81** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 81**"
and is marked as "**Exhibit 81.png**"

Commissioner of Oaths

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **82** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 82**"
and is marked as "**Exhibit 82.png**"

Commissioner of Oaths

Exhibit « **83** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 83**"
and is marked as "**Exhibit 83.png**"

Commissioner of Oaths

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Affidavits
Licensed Paralegal LSO# P14407

Exhibit « **84** » of the affidavit of DANIELLE MCKENZIE
affirmed before me this 28th day of February 2020,
is included in the USB key marked "**Affidavit of D. McKenzie - Exhibits**",
in the folder entitled "**Exhibit 84**"
and is marked as "**Exhibit 84.png**"

Commissioner of Oaths

Jody Gregory Currie
A Commissioner for Oaths and
Affidavits
Licensed Paralegal LSO# P14407

TAB 3

File No.

COMPETITION TRIBUNAL

IN THE MATTER OF the *Competition Act*, R.S.C, 1985, c. C-34;

AND IN THE MATTER OF an application by the Commissioner of Competition for a temporary order pursuant to section 74.11 of the *Competition Act,* regarding conduct reviewable pursuant to paragraph 74.01(1)(b) of the *Competition Act*.

B E T W E E N :

THE COMMISSIONER OF COMPETITION

Applicant

and

NUVOCARE HEALTH SCIENCES INC. and RYAN FOLEY

Respondents

AFFIDAVIT OF VIRGINIE TREYVAUD AMIGUET

I, VIRGINIE TREYVAUD AMIGUET, of the City of Ottawa, in the Province of Ontario, AFFIRM THAT:

1. I am an employee of Health Canada, currently working as the acting Manager, Product Assessment Division, Bureau of Product Review and Assessment with the Natural and Non-Prescription Health Products Directorate ("NNHPD").

2. I joined Health Canada in 2008 as a scientific evaluator. I was in that position until 2016 when I became a supervisor (Unit Head).

3. My duties include, among other things, providing scientific and regulatory advice on instances of non-compliance with the *Natural Health Products Regulations*, SOR/2003-196 ("NHPR"). For instance, I am responsible for conducting and providing advice on safety and efficacy assessments, monograph revisions, product classification and post-market issues such as risk classification or misleading statements related to Natural Health Products ("NHPs").

4. Accordingly, I have knowledge of the matters affirmed in this affidavit, except where stated to be based on information and belief. Where I made this affidavit based on information obtained from others, I have indicated the source of the information and I believe the information to be true.

A. Natural Health Products

5. Natural health product means a substance set out in Schedule 1 of the NHPR or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1 of the NHPR, a homeopathic medicine or a traditional medicine that is used to restore or maintain good health. NHPs are often made from plants, but can also be made from animals, microorganisms, and marine sources.

6. NHPs include: vitamins and minerals; herbal remedies; homeopathic medicines; traditional medicines like traditional Chinese and Ayurvedic medicines; probiotics; and other products like amino acids and essential fatty acids. Attached as **Exhibit "A"** to this affidavit is Health Canada's webpage entitled "About Natural Health Products".

B. The Regulation of NHPs in Canada

7. NHPs sold in Canada are subject to the NHPR. The NHPR came into force on January 1, 2004.

8. The NHPR was created after consultations with Canadian consumers, academics, health care practitioners and industry stakeholders. It addresses Canadians' concerns about

NHP availability and safety, as well as the House of Commons Standing Committee on Health's 53 recommendations on the regulation of NHPs in Canada. Attached as **Exhibit "B"** to this affidavit is Health Canada's webpage entitled "About Natural Health Product Regulation in Canada".

9. Pursuant to the NHPR, all NHPs are reviewed by Health Canada, more specifically by NNHPD through a product licence application. Once Health Canada has reviewed the information submitted by the applicant and decided it meets the safety, efficacy and quality requirements under the recommended conditions of use, it will issue a product licence for the NHP, along with an eight-digit product number (often called Natural Product Number ("NPN")). Only NHPs that have obtained product licences from Health Canada can be legally sold in Canada.

i. Product Licences for NHPs

10. To obtain a product licence for an NHP, an application must be made to Health Canada. The application must provide information demonstrating that the safety, efficacy and quality requirements are met for the NHP under the recommended conditions of use. The application must include detailed information about the NHP, including its medicinal ingredient(s), source, quantity per dosage unit, potency if any, non-medicinal ingredients and recommended conditions of use.

11. As per the NHPR, the recommended conditions of use means, in respect of a natural health product,

(a) its recommended use or purpose;

(b) its dosage form;

(c) its recommended route of administration;

(d) its recommended dose;

(e) its recommended duration of use, if any; and

(f) its risk information, including any cautions, warnings, contra-indications or known adverse reactions associated with its use.

12. Upon receipt of an application for a product licence, Health Canada's NNHPD will review the information provided as part of the product licence application. The purpose of the review is to determine whether there is sufficient evidence to support the safety and efficacy of the NHP according to the recommended conditions of use as per section 5(g) of the NHPR. Health Canada relies on evidence or information submitted in the product licence application to assess the safety and efficacy of the product formulation. The type and amount of supporting evidence that needs to be provided to Health Canada for an NHP depends on the inherent risk of an ingredient as well as the risk associated with the use of the NHP.

13. As indicated in Health Canada's guidance document "Pathway for Licensing Natural Health Products Making Modern Health Claims", NNHPD also ensures that there is reasonable assurance that benefits of the NHP outweigh any risk(s) inherent in the product's ingredient(s) or associated use(s). Risks related to safety and efficacy include: potential risks due to an ingredient's physical or chemical form; the seriousness of the health claim and the conditions of use; and the health impact from lower than expected performance of the product. A risk-based assessment approach is used to determine the standard of evidence necessary to support the safety and efficacy of a product. Attached as **Exhibit "C"** to this affidavit is Health Canada's guidance document "Pathway for Licensing Natural Health Products Making Modern Health Claims" which describes Health Canada's authorization process in section 2.2 and Health Canada's risk-based approach to safety and efficacy in section 2.3.

14. NNHPD has published a Compendium of Monographs (the "Compendium") based on NHP ingredients. A "monograph" is a written description of a medicinal ingredient setting out the requirements to ensure safety and efficacy. It includes the proper name, common name, source material, quantity per dosage unit, route of administration, dosage form, use or purpose, dose, subpopulation, method of preparation, direction of use, duration of use and risk information. The Compendium is a compilation of monographs based on NHP ingredients.

15. The NNHPD developed the Compendium as a tool for the timely and efficient review of the safety and efficacy of many commonly used NHPs. As per section 6 of the NHPR, the NNHPD product licensing system allows applicants to reference these monographs in support of the safety and efficacy of their product, rather than providing evidence for ingredients that are already known to be safe and efficacious when used under the conditions specified in the monographs. Attached as **Exhibit "D"** to this affidavit is Health Canada's guidance document "Compendium of Monographs".

16. NNHPD uses a monograph attestation process. When the attestation is completed and submitted with the application it means that the applicant for a NHP product licence confirms that the product meets the monograph requirements and that they accept the terms of the attestation. Attached as **Exhibit "E"** to this affidavit is Health Canada's Monograph attestation form.

17. A Product Licence will be issued for applications satisfying regulatory requirements as outlined in the NHPR. The majority of the details of an NHP's product licence are publicly accessible through Health Canada's Licenced Natural Health Products Database ("LNHPD"). The status of the licensed product on the LNHPD will appear as "Active". Attached as **Exhibit "F"** to this affidavit is Health Canada's webpage entitled "Licenced Natural Health Products Database".

ii. <u>Health Claims made by NHPs</u>

18. A health claim is a statement that indicates the intended beneficial effect of a product when used in accordance with its recommended conditions of use. The terms "recommended use or purpose" is often used interchangeably with "health claim" or "indications for use" as explained in section 2.4 of Health Canada's Pathway for Licensing Natural Health Products Making Modern Health Claims (see **Exhibit C** to this affidavit).

19. A person seeking to have an NHP authorized to be sold in Canada must submit the recommended conditions of use which includes its recommended use or purpose (health

claim) for consideration to Health Canada as part of the product licence application. Once a licence is granted, the health claim(s) an NHP can make are explicitly outlined in the NHP's product licence. In general, health claims permitted by an NHP's licence should be verbatim, or convey the exact same meaning as the health claims authorized. An NHP licence holder cannot make health claims about an NHP other than the claim(s) that was authorized, including claims that are false, misleading, convey a stronger claim, or that exceeds the scope of the health claims authorized by Health Canada for the NHP.

20. Health claims beyond those authorized by Health Canada as part of the NHP licence are considered by Health Canada to be "unauthorized claims". Unauthorized claims can pose risks to Canadians, including leading people to use the wrong products for serious conditions or to delay proper treatment. In addition, the sale of an NHP with unauthorized claims is a contravention of section 4 of the NHPR (see **Exhibit A** to this affidavit).

21. For high risk NHPs, meaning those seeking to make health claims of treatment, prevention or cure of serious health conditions, as per section 2.6.1 of the Health Canada's Pathway for Licensing Natural Health Products Making Modern Health Claims, the evidence package submitted to Health Canada as part of the product licence application should include a complete critical summary reflecting the totality of evidence. The evidence should demonstrate statistically significant outcomes, clinically meaningful differences, relevance to the target population and overall consistency of the results across all studies of acceptable quality. Examples of evidence required to support claims under this category include well-designed clinical trials with large number of participants and long duration such as Phase III or IV, Meta-analysis and/or product specific evidence. Weight loss and fat burn claims are examples of high risk claims. The table below, taken from Health Canada's publication Pathway for Licensing Natural Health Products Making Modern Claims (see **Exhibit C** to this affidavit), outlines the type of evidence that Health Canada deems appropriate for each medicinal ingredient and claim associated with high risk NHPs.

Evidence Type	Health Canada Considerations
NHPD published monographs	N/A
Phase III or phase IV clinical trials (randomized, controlled, well-designed)	For treatment, cure, and prevention claims or for health support claims when they imply treatment, cure, prevention, and risk reduction claims if the study is not multi-centred, at least two studies are required.
Meta-analysis (controlled and well-designed)	Conclusions should be based primarily on phase III trials, not phase II trials; primary evidence may be requested.
Prospective observational studies or combinations of one prospective study and one retrospective study	Evidence only meets minimum requirements for prevention and risk reduction claims. Two pieces of evidence of equivalent ranking or higher are required to support efficacy.
Evidence of a positive decision from another regulatory agency	Documentation in the form of an authorization letter or positive decision must be submitted that includes details on what was approved. A description of the regulatory requirements from the other regulatory agency should be provided.

C. Nuvocare Health Sciences Inc.'s Products at Issue

22. I am advised by the Competition Bureau that their application before this Tribunal pertains to the following NHPs licensed to Nuvocare Health Sciences Inc.: NPN 80053895, NPN 80057549, and NPN 80058127.

i. NPN 80053895

23. I am advised by Danielle McKenzie, Competition Law Officer at the Competition Bureau, that NPN 80053895 is marketed and sold by Nuvocare Health Sciences Inc. as NutraCentials Weight OFF Max!.

24. This product was supported by a monograph attestation. The applicant selected the box "My product licence application solely contains information that is supported by NNHPD Monograph(s) information and the above conditions apply to the application in its entirety".

25. NPN 80053895 was issued by Health Canada on September 15, 2014 to Nuvocare Health Sciences Inc. Based on a search of the Licensed Natural Health Products Database on February 19, 2020, the recommended use or purpose for NPN 80053895 as per its product licence is:

> Helps in the function of the thyroid gland. Provides support for healthy glucose metabolism. Helps the body to metabolize carbohydrates and fats. Could be a complement to a healthy lifestyle that incorporates a calorie-reduced diet and regular physical activity for individuals involved in a weight management program. Helps maintain healthy blood pressure levels. Helps support cardiovascular health. Provides antioxidants.

26. The approved claim "Helps the body to metabolize carbohydrates and fats" was supported by an attestation to the NNHPD's Chromium monograph. This claim is not intended to convey that taking these vitamins or minerals helps to boost metabolism, stimulate a bodily system, directly convert food to energy or burn fat or carbohydrates. Inferring such claims would be misleading and is not permitted as it is a contravention of section 4 of the NHPR.

27. The approved claim "Could be a complement to a healthy lifestyle that incorporates a calorie-reduced diet and regular physical activity for individuals involved in a weight management program" was supported by an attestation to the NNHPD's Green coffee

bean extract monograph. This generalized health claim was developed to ensure consumer access and, when worded appropriately, assist consumers in making informed choices thereby supporting the NNHPD's mandate. Since the evidence requirements for this category of claims are lenient, it is important to ensure that the role of the product as it contributes to an overall weight management/maintenance program is not over-emphasized.

28. By attesting to the NNHPD's monographs, the licence holder agrees to the attestations set out in Health Canada's Monograph attestation form (see **Exhibit E**).

29. Health Canada did not approve NPN 80053895 to make weight loss health claims and only approved a lower level claim related to a potential complement to a healthy lifestyle that incorporates a calorie-reduced diet and regular physical activity for individuals involved in a weight management program. General weight management claims are not considered comparable to weight loss claims which would fall under the high risk category.

30. Health Canada also did not approve NPN 80053895 to make claims that it burns fat, releases fat, blocks fat, cuts appetite, blocks carbohydrates or decreases emotional eating.

ii. <u>NPN 80057549</u>

31. I am advised by Danielle McKenzie, Competition Law Officer at the Competition Bureau, that NPN 80057549 is marketed and sold by Nuvocare Health Sciences Inc. as SlimCentials Weight OFF Max!.

32. This product was supported by a monograph attestation. The applicant selected the box "My product licence application solely contains information that is supported by NNHPD Monograph(s) information and the above conditions apply to the application in its entirety".

33. NPN 80057549 was issued by Health Canada on January 21, 2015 to Nuvocare Health Sciences Inc. Based on a search of the Licensed Natural Health Products Database on

February 19, 2020, the recommended use or purpose for NPN 80057549 as per its product licence is:

> Helps in the function of the thyroid gland. Provides support for healthy glucose metabolism. Helps the body to metabolize carbohydrates and fats. Could be a complement to a healthy lifestyle that incorporates a calorie-reduced diet and regular physical activity for individuals involved in a weight management program. Provides antioxidants. Helps (temporarily) to promote alertness and wakefulness, and to enhance cognitive performance. Helps (temporarily) to relieve fatigue, to promote endurance, and to enhance motor performance. Used (temporarily) as a mild diuretic.

34. The approved claim "Helps the body to metabolize carbohydrates and fats" was supported by an attestation to the NNHPD's Chromium monograph. This claim is not intended to convey that taking these vitamins or minerals helps to boost metabolism, stimulate a bodily system, directly convert food to energy or burn fat or carbohydrates. Inferring such claims would be misleading and is not permitted as it is a contravention of section 4 of the NHPR.

35. The approved claim "Could be a complement to a healthy lifestyle that incorporates a calorie-reduced diet and regular physical activity for individuals involved in a weight management program" was supported by an attestation to the NNHPD's Green coffee bean extract monograph. This generalized health claim was developed to ensure consumer access and, when worded appropriately, assist consumers in making informed choices thereby supporting the NNHPD's mandate. Since the evidence requirements for this category of claims are lenient, it is important to ensure that the role of the product as it contributes to an overall weight management/maintenance program is not over-emphasized.

36. By attesting to the NNHPD's monographs, the licence holder agrees to the attestations set out in Health Canada's Monograph attestation form (see **Exhibit E**).

37. Health Canada did not approve NPN 80057549 to make weight loss health claims and only approved a lower level claim related to a potential complement to a healthy lifestyle that incorporates a calorie-reduced diet and regular physical activity for individuals involved in a weight management program. General weight management claims are not considered comparable to weight loss claims which would fall under the high risk category.

38. Health Canada also did not approve NPN 80057549 to make claims that it burns fat, releases fat, blocks fat, cuts appetite, blocks carbohydrates or decreases emotional eating.

iii. NPN 80058127

39. I am advised by Danielle McKenzie, Competition Law Officer at the Competition Bureau, that NPN 80058127 is marketed and sold by Nuvocare Health Sciences Inc. as NutraCentials Forskolin Nx, and SlimCentials Forskolin+.

40. NPN 80058127 was issued by Health Canada on February 13, 2015 to Nuvocare Health Sciences Inc. Based on a search of the Licensed Natural Health Products Database on February 19, 2020, the recommended use or purpose for NPN 80058127 as per its product licence is:

Source of antioxidants.

41. Health Canada did not approve NPN 80058127 to make fat burn health claims, nor did it approve NPN 80058127 to make claims that it targets belly fat or increases metabolism.

AFFIRMED BEFORE ME in the City of Ottawa, in the Province of Ontario this 27th day of February, 2020

A Commissioner for taking affidavits

VIRGINIE TREYVAUD AMIGUET

Exhibit « **A** » of the affidavit
of VIRGINIE TREYVAUD AMIGUET
affirmed before me this
27th day of February 2020.

Commissioner of oaths

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About Natural Health Products

The Natural Health Products Directorate (NHPD) has changed its name to the Natural and Non-prescription Health Products Directorate (NNHPD) subsequent to its recently expanded mandate to include the oversight of non-prescription and disinfectant drugs in addition to natural health products (NHPs). Please note that we are currently modifying documents to reflect this change.

Thank you for your patience and understanding.

Using natural health products can be a good way to maintain or improve your health. But just because a product is natural doesnt mean it is safe for you to use.

This section will tell you more about:

- What natural health products are
- The risks of using natural health products
- How to use natural health products safely
- How to find authorized products
- How to report unwanted side effects

- What Health Canada does to protect you
- Where to get more information

What are natural health products?

Natural health products (NHPs) are naturally occurring substances that are used to restore or maintain good health. They are often made from plants, but can also be made from animals, microorganisms and marine sources. They come in a wide variety of forms like tablets, capsules, tinctures, solutions, creams, ointments and drops.

Natural health products, often called "complementary" or "alternative" medicines, include:

- vitamins and minerals
- herbal remedies
- homeopathic medicines
- traditional medicines like traditional Chinese and Ayurvedic (East Indian) medicines
- probiotics
- other products like amino acids and essential fatty acids

Many everyday consumer products, like certain toothpastes, antiperspirants, shampoos, facial products and mouthwashes are also classified as natural health products in Canada.

Fast fact: 71% of Canadians have used natural health products like vitamins and minerals, herbal products, and homeopathic medicines.

NHPs are used and marketed for a number of health reasons, like the prevention or treatment of an illness or condition, the reduction of health risks, or the maintenance of good health. They must be safe to be used as over-the-counter products. Products needing a prescription are regulated as drugs.

Are there risks to using natural health products?

While natural health products are generally safe and have fewer side effects than medications, they are not risk free. Risks include:

- manufacturing problems (like contamination, incorrect ingredients or dosage)
- unproven claims, which can lead people to use the wrong products for serious conditions or to delay proper treatment
- not enough information for people to make an informed choice (like incorrect instructions or no warnings that a product may not be suitable for certain groups)
- interaction with prescription drugs or other natural health products
- unwanted side effects, like allergic reactions

Fast fact: 12% of Canadians who use natural health products report that they have experienced unwanted side effects (adverse reactions).

Health Canada responded to Canadians' concerns about these risks by creating the Natural Health Products Regulations in 2004. See What is Health Canada doing to protect me? for more.

How can I use natural health products safely?

Take these steps to minimize your risk:

- Talk to a health care professional like a doctor, pharmacist or naturopath before choosing a product. This is especially important for children, pregnant or breast-feeding women, seniors, and people with serious medical conditions.
- To prevent interactions, make sure your health care provider knows what other drugs and natural health products you are using.
- Use approved products. Look for NPN / DIN-HM numbers that identify licensed products.
- Be skeptical of health-related claims that seem too good to be true. Dont rely on ads: do your own research and talk to your health care provider.
- Read and follow all instructions on the product label.
- Report unwanted side effects (adverse reactions) to your health care provider and Health Canada.

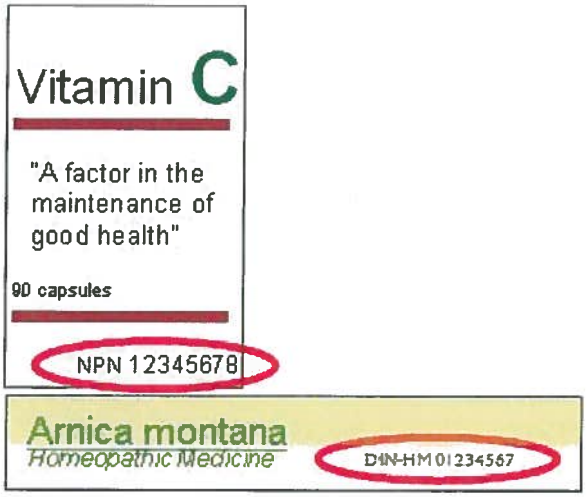
How do I know if a product has been

authorized?

To be licensed in Canada, natural health products must be safe, effective, of high quality and carry detailed label information to let people make safe and informed choices.

You can identify products that have been licensed for sale in Canada by looking for the eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) on the label.

A NPN or DIN-HM means that the product has been authorized for sale in Canada and is safe and effective when used according the instructions on the label.



You can search for licensed natural health products using Health Canadas Licensed Natural Health Products Database.

How do I report unwanted side effects?

You should report unwanted side effects (adverse reactions) to your health care provider and to Health Canada. To report a side effect now, see Adverse Reaction Reporting.

Reporting side effects is important because it helps Health Canada identify rare or serious adverse reactions, make changes in product safety information, issue public warnings and advisories, and/or remove unsafe products from the Canadian market.

Fast fact: Only 41% of Canadians who experienced unwanted side effects (adverse reactions) to natural health products reported them.

What is Health Canada doing to protect me?

Health Canada assures that all Canadians have ready access to a wide range of natural health products that are safe, effective and of high quality.

We assess all natural health products before letting them be sold in Canada. We also assure they are properly manufactured (without contamination or incorrect ingredients). And we do post-market monitoring to make sure that NHP Regulations are being followed.

For more information, please see About Natural Health Product Regulation in Canada.

Where can I learn more?

Related advisories, warnings and recalls

For the most recent advisories, warnings and recalls about NHPs and other health products, see Advisories, Warnings and Recalls.

More about natural health products

- About Natural Health Product Regulation in Canada
- Safe Use of Natural Health Products
- The Safe Use of Natural Health Products During Menopause
- Informing You about Natural Health Products
- Frequently Asked Questions
- Licensed Natural Health Products Database
- Natural Health Products Ingredients Database

Additional resources

- Report a Side Effect (Adverse Reaction)
- Contact the Natural Health Products Directorate
- Stay Connected
- Consumer Safety Portal
- Legislation and Guidelines
- For Industry and Professionals

Date modified:
2016-03-14

Exhibit « **B** » of the affidavit
of VIRGINIE TREYVAUD AMIGUET
affirmed before me this
27th day of February 2020.

Commissioner of oaths

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About Natural Health Product Regulation in Canada

The Natural Health Products Directorate (NHPD) has changed its name to the Natural and Non-prescription Health Products Directorate (NNHPD) subsequent to its recently expanded mandate to include the oversight of non-prescription and disinfectant drugs in addition to natural health products (NHPs). Please note that we are currently modifying documents to reflect this change.

Thank you for your patience and understanding.

All natural health products (NHPs) sold in Canada are subject to the *Natural Health Products Regulations*, which came into force on January 1, 2004.

The Regulations help give Canadians access to a wide range of natural health products that are safe, effective and of high quality.

In this section:

- About the Regulations
- Licensing Requirements

- Adverse Reaction Reporting
- Clinical Trials
- Related Advisories, Warnings and Recalls
- For More Information

About the Regulations

The *Natural Health Products Regulations* were created after many consultations with Canadian consumers, academics, health care practitioners and industry stakeholders. They address Canadians' concerns about NHP availability and safety, as well as the House of Commons Standing Committee on Health's 53 recommendations on the regulation of natural health products (NHPs) in Canada.

To be legally sold in Canada, all natural health products must have a product licence, and the Canadian sites that manufacture, package, label and import these products must have site licences.

To get product and site licences, specific labelling and packaging requirements must be met, good manufacturing practices must be followed, and proper safety and efficacy evidence must be provided.

Licensing Requirements

The licensing requirements of the *Natural Health Products Regulations* apply to any person or company that manufactures, packages, labels and/or imports NHPs for commercial sale in

Canada. They **do not** apply to health care practitioners who compound products on an individual basis for their patients, or to retailers of NHPs.

Product licensing

All natural health products must have a product licence before they can be sold in Canada. To get a licence, applicants must give detailed information about the product to Health Canada, including: medicinal ingredients, source, dose, potency, non-medicinal ingredients and recommended use(s).

Once Health Canada has assessed a product and decided it is safe, effective and of high quality, it issues a product licence along with an eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM), which must appear on the label. This number lets you know that the product has been reviewed and approved by Health Canada.

You can search for licensed natural health products using Health Canada's Licensed Natural Health Products Database. See How do I know if a product has been licensed? for more information.

Evidence requirements for safety and efficacy

The safety and efficacy of NHPs and their health claims must be supported by proper evidence so that consumers and Health Canada know the products are indeed safe and effective. Evidence may include clinical trial data or references to published studies,

journals, pharmacopoeias and traditional resources. The type and amount of supporting evidence required depends on the proposed health claim of the product and its overall risks.

Pathway for Licensing Natural Health Products Making Modern Health Claims
Pathway for Licensing Natural Health Products used as Traditional Medicines

Labelling

All NHPs must meet specific labelling requirements, to help you make safe and informed choices about the NHPs you choose to use. Information required on NHP labels includes:

- product name
- product licence number
- quantity of product in the bottle
- complete list of medicinal and non-medicinal ingredients
- recommended use (including purpose or health claim, route of administration and dose)
- any cautionary statements, warnings, contra-indications and possible adverse reactions associated with the product
- any special storage conditions

More information on labelling and packaging requirements for natural health products is available in the *Labelling Guidance Document*.

Site licensing

All Canadian manufacturers, packagers, labellers, and importers of natural health products must have site licenses. To get a licence, sites must maintain proper distribution records, have proper procedures for product recalls and for the handling, storage and delivery of their products, and demonstrate that they meet good manufacturing practice requirements.

Good Manufacturing Practices

Good Manufacturing Practices make sure proper standards and practices for the testing, manufacture, storage, handling and distribution of natural health products are met. Good Manufacturing Practices for NHPs cover:

- product specifications
- premises
- equipment
- personnel
- sanitation program
- operations
- quality assurance
- stability
- records
- sterile products
- lot or batch samples
- recall reporting

Good Manufacturing Practices are meant to ensure safe and high quality products while giving manufacturers, packagers, labellers, importers and distributors the flexibility to implement quality systems appropriate for their product lines and businesses. More information on Good Manufacturing Practices for NHPs is available in the *Good Manufacturing Practices Guidance Document*.

Adverse Reaction Reporting

The *Natural Health Products Regulations* require product licence holders to monitor all adverse reactions related to their product. License holders *must* report serious adverse reactions to Health Canada. See Adverse Reaction Reporting for more information.

Canadian consumers *should* report unwanted side effects (adverse reactions) to their health care provider and to Health Canada directly. See Adverse Reaction Reporting for more information.

Reporting side effects is important because it helps Health Canada identify rare or serious adverse reactions, make changes in product safety information, issue public warnings and advisories, and/or remove unsafe products from the Canadian market.

Clinical Trials

A clinical trial is when natural health products are tested using human subjects. Clinical trials are intended:

- to discover or verify the product's effects
- to identify any adverse events that are related to its use

- to study its absorption, distribution, metabolism and excretion
- to test its safety or efficacy

The *Natural Health Products Regulations* set out requirements for conducting a clinical trial. Meanwhile, the Natural Health Products Directorate outlines the range of evidence that can be submitted in support of the safety and efficacy of a natural health product and the quality of a natural health product, or of a homeopathic medicine.

More information on the clinical trial process for natural health products is available in the *Clinical Trials for Natural Health Products Guidance Document*.

Related Advisories, Warnings and Recalls

For the most recent advisories, warnings and recalls about food, health and consumer products, see Advisories, Warnings and Recalls.

For More Information

More about natural health product

- About Natural Health Products
  Learn all about natural health products, including how to use them safely.

- Information Kit - Regulation of Natural Health Products in Canada
  A fact sheet on how products are regulated in Canada.
- Information on Homeopathic Products
  Homeopathy is a holistic, health philosophy and practice
- Natural Health Products in Canada - A History
  The history of how natural health products came to be regulated in Canada.
- Natural Health Products - Over 43,000 Products authorized for sale and growing
- Progress Report - Natural Health Products
  An update on the regulation and licensing of natural health products.
- Frequently Asked Questions
  Get answers to questions about natural health products and regulations.
- Licensed Natural Health Products Database
  Use this database to search for NHPs that are licensed for sale in Canada.
- Natural Health Products Ingredients Database
  Search detailed descriptions to learn more about specific NHP ingredients.
- Self-care products
  How self-care products, including natural heath products, cosmetics and over-the-counter drugs, are regulated in Canada.

Additional resources

- Food and Drugs Act Liaison Office
- Report a Side Effect (Adverse Reaction)
- Contact the Natural Health Products Directorate
- Stay Connected
- Consumer Safety Portal
- Legislation and Guidelines
- For Industry and Professionals

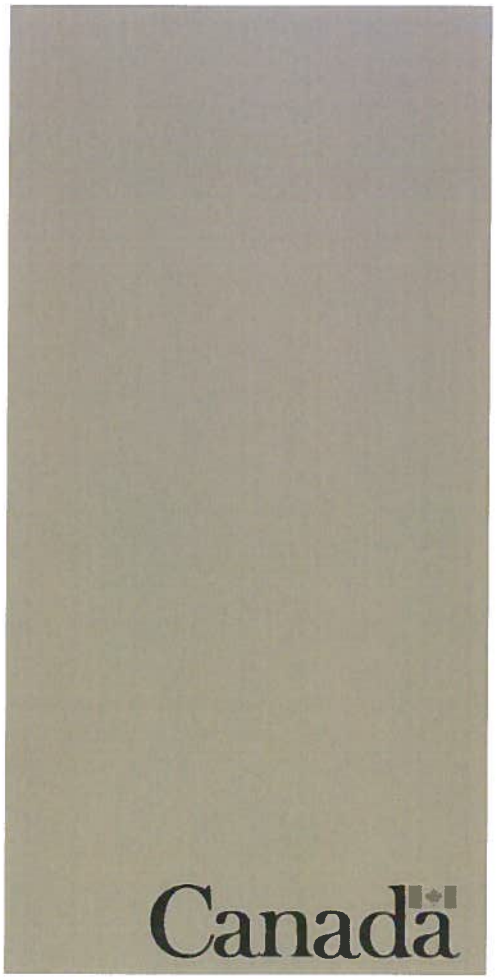
Date modified:
2016-08-11

Exhibit « **C** » of the affidavit
of VIRGINIE TREYVAUD AMIGUET
affirmed before me this
27th day of February 2020.

Commissioner of oaths

Health Canada Santé Canada
Your health and safety... our priority. Votre santé et votre sécurité... notre priorité.

Pathway for Licensing Natural Health Products Making Modern Health Claims



Foreword

Guidance documents are meant to provide assistance to industry and health care practitioners on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

These documents are administrative instruments and therefore allow for flexibility. Alternate approaches to the principles and practices described in this document may be acceptable; licence applicants are invited to discuss these with the Natural Health Products Directorate prior to submitting an application.

As a corollary to the above, it is equally important to note that Health Canada may request information or material, or define conditions not specifically described in this document, in order to enable the Department to adequately assess the safety, efficacy or quality of a health product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the *Natural Health Products Regulations* and relevant sections of other applicable guidance documents.

Document Change Log			
Document	Pathway for Licensing Natural Health Products Making Modern Health Claims, Version 1.0	**Replaces**	Evidence for Safety and Efficacy of Finished Natural Health Products, Version 2.0 Note: this document is also replaced by the following document: Pathway for Licensing Natural Health Products Used as Traditional Medicines, Version 1.0
Date	December 2012	**Date**	December 2006

Change	Location (section, paragraph)	Nature of and/or Reason for Change
Extensive revisions	There were extensive revisions to the content including the addition of revised appendices, annexes and an extensive reorganization of the document.	The December 2006 document, Evidence for Safety and Efficacy of Finished Natural Health Products, Version 2.0, was revised in order to reflect some of the recommendations of the Natural Health Product Program Advisory Committee which were posted on the Health Canada website under the name Report of the Natural Health Products Program Advisory Committee to the Natural Health Products Program, January 26, 2010. It was also split into two guidance documents.

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1.0 Introduction

This guidance document provides information to help product licence applicants determine the evidence (type and amount of data) to provide as part of a product licence application to support the safety (risk) and efficacy (benefit) of natural health products (NHPs) that make modern[1] health claims.

The intent of this document is to ensure that the levels of evidence are rigorous enough to protect public health and maintain consumer confidence, while providing industry with a clearly defined pathway to bring products to market.

While not specifically included in this guidance document, other options for supporting safety and efficacy may be considered depending on the circumstances of a particular NHP.

The *Natural Health Products Regulations* (NHPR) set out the requirements governing the sale, manufacture, packaging, labelling, importation, distribution and storage of NHPs. The objective of the NHPR is to provide reasonable assurance that products offered for sale in Canada are safe, efficacious and of high quality. Evidence submitted as part of a product licence application must support the requirements set out in section 5, paragraphs (a) to (j) of the NHPR.

1.1 Policy Objective

To provide reasonable assurance that NHPs offered for sale in Canada are safe and effective when used under their recommended conditions of use.

1.2 Policy Statement

The level of evidence (type and amount) that can be provided to support the safety and efficacy of an NHP varies depending on the proposed health claim(s) of the product and the overall risk profile of the product or its ingredients.

1.3 Scope and Application

This guidance document applies to product licence applications for NHPs that make modern health claims. It does not apply to product licence applications for:

- Traditional medicines;
- Homeopathic medicines;
- NHPs attesting to Natural Health Products Directorate (NHPD) Labelling Standards; and

[1] Modern is used to describe natural health products that are not used as traditional medicines

- NHPs under the 60-day disposition clause (i.e., those citing a monograph from the NHPD's Compendium of Monographs as the sole source of information supporting the safety and efficacy of the product).

For traditional medicines, refer to the *Pathway for Licensing Natural Health Products Used as Traditional Medicines*.

For medicinal ingredients prepared in accordance with homeopathic pharmacy, refer to the *Evidence for Homeopathic Medicines Guidance Document*.

For more information on the 60-day disposition clause, refer to the *Compendium of Monographs Guidance Document*.

1.4 Background

The *Evidence for Safety and Efficacy of Finished Natural Health Products Guidance Document* (December 2006) is replaced by two new guidance documents: the *Pathway for Licensing Natural Health Products Making Modern Health Claims* and the *Pathway for Licensing Natural Health Products Used as Traditional Medicines*.

Looking for other guidance documents relevant to NHPs?

The current guidance document describes the risk-based levels of evidence for safety and efficacy of NHPs that make modern health claims. The document also includes two annexes:

- *Combination Ingredients* which defines the principles used for assessing multiple-ingredient products; and
- *General Health Claims* which outlines the pathway for using general health claims for NHPs with lower therapeutic impact.

1.5 Definitions

Natural Health Product
An NHP is a substance or a combination of substances described in Schedule 1 of the NHPR, a homeopathic medicine, or a traditional medicine, that is intended to provide a pharmacological activity or other direct effect in:

- diagnosing, treating, mitigating, or preventing a disease, disorder, or abnormal physiological state or its symptoms in humans;
- restoring or correcting organic functions in humans; or
- modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

Schedule 2 of the NHPR sets out substances which do not fall within the meaning of an NHP.

Medicinal Ingredient
A medicinal ingredient is a substance which is set out in Schedule 1 of the NHPR, is biologically active and is included in an NHP for the purposes of:

- diagnosing, treating, mitigating, or preventing a disease, disorder, or abnormal physical state or its symptoms in humans;
- restoring or correcting organic functions in humans; or

- modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

A medicinal ingredient is characterized by its physical form, its chemical attributes, its source, its preparation, as well as its dose and pharmacological action.

Non-medicinal Ingredient
A non-medicinal ingredient is defined as any substance that is added to a product to confer suitable consistency or form to the medicinal ingredients (suitable as per dosage form and route of administration). Non-medicinal ingredients:

- should not exhibit pharmacological effects;
- should not have any effect contradictory to the product's recommended purpose;
- should not exceed the minimum concentration required for the formulation;
- should not adversely affect the bioavailability, pharmacological activity, or safety of the medicinal ingredients; and
- should be safe.

Recommended Conditions of Use
The recommended conditions of use are defined as:

- recommended use or purpose;
- dosage form;
- recommended route of administration;
- recommended dose (including sub-population, amount, dosage unit, frequency, and directions of use);
- recommended duration of use, if any; and
- risk information, including cautions, warnings, contraindications, or known adverse reactions associated with the use of the product or its medicinal ingredients.

Modern Health Claims
Claims based on evidence from a range of sources, including (but not limited to) clinical studies, animal and *in vitro* studies, pharmacopoeias, textbooks, peer-reviewed published articles, and regulatory authority reports.

Traditional Health Claims
Claims based on the sum total of knowledge, skills, and practices based on theories, beliefs, and experiences indigenous to a specific culture, used in the maintenance of health, as well as prevention, diagnosis, improvement, or treatment of physical and mental illness. For a claim to be categorized as "traditional use," it should be founded upon the theories, experiences and beliefs embodying the respective ancient practice of medicine.

2.0 Guidance for implementation

2.1 Roles and Responsibilities

Product licence applicant:
It is the responsibility of the applicant to provide a complete product licence application, including evidence demonstrating that safety (risk) has been established and any risks

sufficiently mitigated; that efficacy (benefit) has been demonstrated; and that quality is supported.

Natural Health Products Directorate:
It is the responsibility of the NHPD to review the information provided as part of the product licence application in order to assess the safety, efficacy and quality of an NHP, to ensure benefits outweigh risks, and to clearly document the product licensing decision.

Did you know that you can meet with staff of the Natural Health Products Directorate before submitting your application if you have questions? For more information, see the *Management of Product Licence Applications for NHPs*.

For further information on roles see the *Management of Product Licence Applications for Natural Health Products*. It explains how applicants can meet with the NHPD prior to submitting a product licence application and communicate with their submission coordinator throughout the application review process.

2.2 Health Canada Authorization Process

In order to obtain authorization to sell an NHP in Canada, a product licence application must be submitted to Health Canada. As part of this product licence application, evidence supporting the safety and efficacy of the NHP according to its recommended conditions of use must be included.

You may be able to get a product licence quickly by using our pre-cleared information: check out our monographs and labelling standards via the Natural Health Products Ingredients Database

The purpose of the assessment is to determine whether the evidence supports the safety and efficacy of the product, including whether there is reasonable assurance that benefits of the product outweigh any risk inherent in the product's ingredients or associated use of the product. The assessment of safety (risk) for a product depends on a variety of factors, including the conditions of use and the physical form and pharmacology of each ingredient in the product as well as the product as a whole. The benefit-to-risk profile of a product is always considered prior to a product licensing decision being made (i.e., licence issuance or refusal).

Refer to the *Management of Product Licence Applications for NHPs* for more information on the product application and assessment process.

2.3 Risk-Based Approach to Safety and Efficacy

Risks related to safety and efficacy includes potential risks due to:

- An ingredient's physical or chemical form;
- The seriousness of the health claim and the conditions of use implied; and
- The health impact from lower than expected performance of the product.

A risk-based assessment approach is used to categorize evidence recommendations into three levels of risk: low, medium, and high. These levels are proportionate to the standard of evidence necessary to support safety and efficacy of a product.

Figure 1 outlines the decision process for determining the category of safety and efficacy evidence recommended for NHPs making modern health claims.

Low Level of Risk:

This level applies to those products/ingredients that, through their intended use, present a low risk to health. This category includes NHPs with wide safety margins, including 1) NHPs used for treatment, cure, risk reduction or prevention of minor diseases or conditions (including symptoms or risk factors of those conditions), which naturally resolve in a timely manner or for which lower than expected performance of the product should not pose a major risk to the person taking it under the recommended conditions of use (refer to section 2.4.1. for the definition of minor disease/condition claims), 2) NHPs for the treatment of minor symptoms or risk factors of major conditions or the risk reduction of these conditions, and 3) NHPs for general health maintenance, support, or promotion that refer to modification of a biochemical or physiological function of a nutritional nature or imply benefit to a minor disease or health condition.

Medium Level of Risk:

This level applies to those products/ingredients that, through their intended use, present a significant risk to health. This category includes NHPs used for treatment, cure, or prevention of major diseases or health conditions which are not naturally resolved within a timely manner or have undesirable effects that may persist or worsen if proper care is not pursued in a timely manner (refer to section 2.4.1. for the definition of major disease/condition claims). It also includes NHPs for the treatment of risk factors of serious conditions or the risk reduction of these conditions.

Did you know that you can meet with staff of the Natural Health Products Directorate before submitting your application if you have questions? For more information, see the *Management of Product Licence Applications for NHPs*.

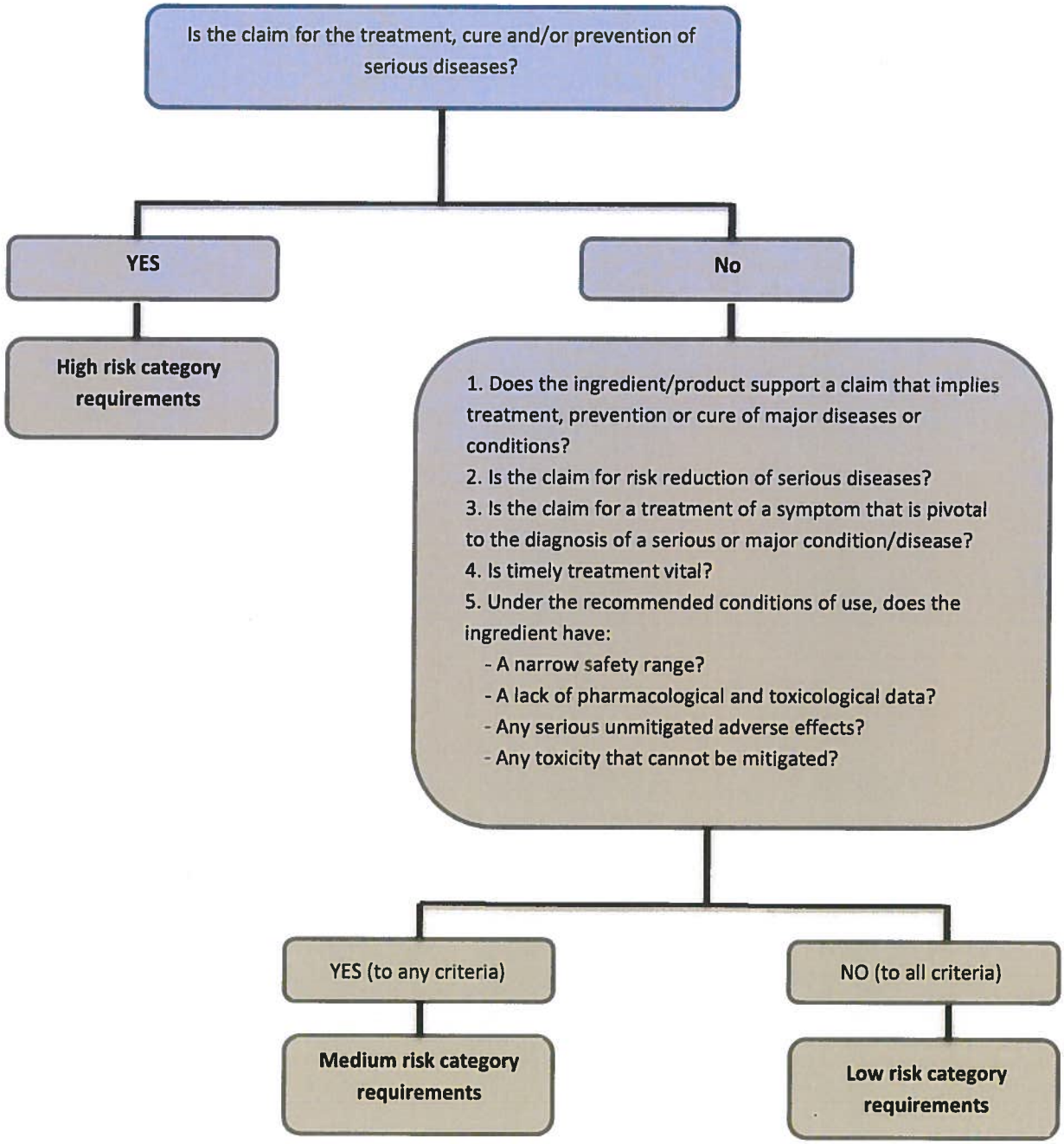
High Level of Risk:

This level applies to those products/ingredients that, through their intended use, present a serious health risk. This category includes NHPs with the narrowest safety margin and effective dose range, as well as those used for treatment, cure, and prevention of serious diseases that require supervision by a health care practitioner, or are debilitating or potentially life threatening without effective treatment (refer to section 2.4.1. for the definition of serious disease/condition claims). High level of risk includes, but is not limited to, schedule A disease/conditions.

At any level of risk, additional evidence may be necessary to substantiate safety and efficacy for:

- Vulnerable sub-populations (e.g., children, pregnant and breastfeeding women, elderly);
- Any known interaction among ingredients;
- Any known interaction with any other product/medication; and/or
- Any indication that the product/ingredient(s) may alter diagnostic testing.

Figure 1: Risk-Based Approach for Determining Safety and Efficacy Evidence for NHPs Making Modern Health Claims



Note: This decision process should be followed for each medicinal ingredient individually, for each claim individually, and for the product as a whole. Based on identified safety concerns for any ingredient, the evidence recommendations may be elevated to a higher category.

2.4 Types of Health Claims

A health claim is a statement that indicates the intended beneficial effect of a product when used in accordance with its recommended conditions of use. The term "recommended use or purpose" is often used interchangeably with "health claim" or "indications for use."

2.4.1 Claim by Health Condition

NHP claims can be categorized into three main categories based on the characteristics of the health condition:

- **Serious disease/condition claims** are for products indicating treatment, prevention or cure of diseases/conditions that require supervision by a health care practitioner, or are debilitating or potentially life threatening without effective treatment. Treatment is vital to mitigate the health impact.
- **Major disease/condition claims** are for products indicating treatment, prevention, or cure of diseases/conditions that are not naturally resolved within a timely manner or have potentially undesirable effects that may worsen or persist if proper treatment or care is not pursued in a timely manner.
- **Minor disease/condition claims** are for products indicating treatment, prevention, risk reduction, or cure of diseases/conditions or symptoms that are expected to naturally resolve within a timely manner or for which lower than expected performance of the product should not pose a major risk to the person taking it under the recommended conditions of use.

Refer to Appendix A for examples of health claims by health condition.

2.4.2 Claim by Health Effect

Health claims can be further classified as those intended to help diagnose, treat or prevent a health condition or symptom, those intended to reduce the risk of a health condition or symptom, or those intended to have a more general health-related function:

- **Diagnostic claims** relate to the diagnosis of a disease, disorder, or abnormal physical state or its symptoms in humans (e.g., indicated for the detection of glucose intolerance in the diagnosis of diabetes mellitus).
- **Treatment claims** relate to the treatment or partial treatment and mitigation of a disease, disorder, or abnormal physical state or its symptoms (e.g., symptomatic relief claims) in humans.
- **Cure claims** describe a therapeutic effect that results in the elimination of a disease, disorder, or abnormal physical state in humans, either permanently or for a significant length of time.
- **Risk reduction claims** are based on significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect in preventing the health condition. The presentation of risk reduction claims should ensure that consumers do not interpret them as prevention claims. This can be accomplished, for example, by use of appropriate language and reference to other risk factors.
- **Prevention claims** relate to interventions which are proven to significantly reduce the incidence of the disease.

- **General health maintenance, support and promotion claims** describe the effect of a medicinal ingredient on restoration, correction, or modification of a structure or physiological function in the human body in a manner that maintains, supports or promotes health. Health function claims can vary from health maintenance (e.g., maintains healthy gums) to treatment of the symptoms or risk factors of a disease or condition (e.g., reduces plaque build-up along the gum line).
- **Antioxidant claims** are for products with at least one medicinal ingredient that has antioxidant properties. Antioxidant claims should be worded as general health support claims when the medicinal ingredient is an essential nutrient (e.g., "provides antioxidant(s) for the maintenance of good health") or as "source of" claims for other types of antioxidant ingredients (e.g., "source of antioxidants"). If a more specific antioxidant claim is desired, the claim will be evaluated according to the conditions/diseases specified or implied within the claim.

A wide range of evidence can be used to support the safety and efficacy of an NHP – use the flow chart in Figure 1 to find the risk level of your product.

2.4.3 General Health Claims

Products with general health claims include those that have low therapeutic impact and are therefore subject to the appropriate evidence requirements.

Annex I outlines a regulatory pathway for NHPs with general health claims. These claims can be used provided that the health and safety of Canadians would not be at risk; this is consistent with a risk-based product approach where health claims are indexed against the level of evidence provided to support the safe use of the products. For more information on general health claims, see Annex I.

2.5 Safety Evidence Recommendations

All products should be safe under their recommended conditions of use. Safety evidence recommendations are based on the identified risks, including but not limited to:

- Severity and seriousness of adverse effects;
- Probability or frequency of adverse effects;
- Severity and seriousness of the disease or condition for which the product is indicated for use;
- Health impact associated with a lower than expected performance of the product;
- Use by potentially vulnerable sub-populations (e.g., infants, children, pregnant and breastfeeding women, elderly); and
- Inherent risks of the medicinal ingredients in the product.

When necessary, safety evidence may also need to support:

- Chemistry and manufacturing information;
- Characterization of the disease implicated in the recommended use or purpose;
- Characterization of the risk factors associated with the disease implicated in the recommended use or purpose;
- Assessment of the potential for interactions;
- An independent causality assessment of adverse reactions;
- A description of the post-market surveillance program (for active surveillance data);

- Consumer research to support labelling; and/or
- A detailed benefit-to-risk assessment.

For additional information see the guidance document Schedule A - Section 3 to the Food and Drugs Act

Previous marketing data including summaries of adverse reaction reports and precautionary labelling may be submitted to support the safety of products but will not be accepted as the sole piece of evidence to support safety.

Only safety risks that can be mitigated by advisory information such as warning statements or contraindications for mild to moderately harmful outcomes are acceptable for licensed NHPs. Serious or severe outcomes that only occur in a very limited and specific population **and** which can be clearly contraindicated on the product licence application form and product label are the exception to this rule. All other risks should be mitigated by appropriate conditions of use. For instance, risk mitigation strategies may include:

Did you know that demonstrated food use of a medicinal ingredient can support the safety of that ingredient?

- Using a different method of preparation of the ingredients (e.g., choice of extraction solvent);
- Using an appropriate route of administration;
- Specifying a dose regimen;
- Qualifying health conditions with terms such as "mild,", "transient,", or "temporary" (to reflect the supporting evidence);
- Using more specific claims to more closely reflect evidence;
- Limiting to a sub-population who will benefit;
- Excluding vulnerable persons from the sub-population;
- Using clear directions of use so that the product can be used in a safe way;
- Not including ingredients with a lack of evidence for safety; and
- Limiting the amount of time that a product may be taken (including a specific duration of use).

As a general rule, risk statements should be based on human evidence or established risks and are necessary when the awareness of these risks is required to help consumers make an informed choice. Additionally, advisory information should be based on moderately intolerable or unexpected adverse reactions and not on mild transient reactions (e.g., nausea). Evidence of risk in animals can contribute to understanding the mechanism of action, but does not commonly form the basis for including a risk statement when non-corroborative human evidence is submitted. Risk statements based on animal evidence may be necessary when the risks are serious.

Within any risk category, the evidence may be sufficient to support both safety and efficacy when it is appropriate for the claim and when it fully reflects the product's recommended conditions of use.

For the low and medium categories, methodologically weak safety evidence should be supplemented to demonstrate consistency in results and plausibility.

For the high risk category, product specific evidence is recommended. Additionally, the evidence package should include a complete critical summary reflecting the totality of evidence and should usually reflect more than one type of evidence.

The minimum safety and efficacy evidence for each risk category – high, medium, low – is outlined in Table 1.

2.5.1 Safety Evidence Recommendations for Non-Medicinal Ingredients

It is important to note that non-medicinal ingredients listed in the Natural Health Products Ingredient Database (NHPID) have not necessarily been reviewed for safety or suitability in NHPs. Additional information may be requested to support the safety or nature of any non-medicinal ingredient. Information to support the recommended conditions of use for all non-medicinal ingredients should be available upon request, such as quantity, purpose in formulation, alternative formulations and specifications, identity information, safety information or other manufacturing information.

When evidence to support safety is requested, it should reflect the daily dose and purpose of the non-medicinal ingredient, should be appropriate to the route of administration, and should consider exposure. Non-medicinal ingredients should not be indiscriminately included within a product's formulation. The safety requirements for non-medicinal ingredients generally mirror those of medicinal ingredients. However, when risk or uncertainty is identified, additional evidence may be requested to help characterize the risk.

Manufacturers may add substances to their medicinal ingredients to aid stability or manufacturing processes. If these remain in significant quantities in the finished NHP (e.g., including any quantity that still provides a technical effect), they must be declared as non-medicinal ingredients on the product licence application form and label. It may be necessary to communicate with the manufacturer directly in order to identify these types of ingredients.

> Did you know that you can provide evidence to support non-medicinal ingredients that are not present in the Natural Health Products Ingredient Database with the NHPID Issue Form?

The individual components of mixtures should be listed separately except when the mixture has a common name in the NHPID (exceptions may be made when the NHPID does not adequately describe the components of the mixture) or the mixture is a proprietary blend of flavours that may be qualitatively described (e.g., artificial strawberry kiwi flavour).

2.6 Efficacy Evidence Recommendations

All products must have at least one health claim. Efficacy evidence should support the reasonable association of the medicinal ingredient(s) with the health claim(s) and demonstrate that therapeutic efficacy of the product will be supported by at least one medicinal ingredient or the combination of more than one.

To do this, the evidence should support the claim with respect to the specific target population intended, the specific directions of use and the specific system of medicine, when appropriate.

The efficacy evidence should be able to support the health context of the product and, when necessary, provide enough background information to describe the characterization of the health condition implied by the claim and the health context of the recommended use.

Within any risk category, the same evidence may be sufficient to support both safety and efficacy when it is appropriate for the claim and when it fully reflects the product's recommended conditions of use.

The minimum type of evidence from a higher risk category may be used to support a claim in a lower category as long as it is appropriate for the condition.
For the low and medium categories, methodologically weak efficacy evidence should be supplemented to demonstrate consistency in results and plausibility.

Table 1 outlines the minimum safety and efficacy evidence for each risk category (high, medium, low).

2.6.1 Efficacy Evidence for the High Risk Category

NHPs making claims for the treatment, prevention or cure of serious health conditions should meet the evidence criteria for the high risk category.

The evidence package should include a complete critical summary reflecting the totality of evidence. Evidence should be presented in the form of a systematic review outlining the validity and causality elements for each reference by providing a critical analysis of the study design types, and the quality and quantity of each evidence type that supports and refutes the claim. Product-specific evidence is recommended. Evidence provided should demonstrate statistically significant outcomes, clinically meaningful differences, relevance to the target population, and overall consistency of the results across all studies of acceptable quality. Data should support the characterization of the disease.

Additional evidence to support interactions and a complete summary reflecting the totality of evidence should be provided in addition to evidence recommendations listed in Table 1.

2.6.2 Efficacy Evidence for the Medium Risk Category

NHPs making claims for major health conditions and diseases should meet the evidence criteria of the medium risk category. The evidence for products or ingredients in this category can be submitted as individual references, although additional information or evidence is recommended to help support: the recommended conditions of use, the health context of the product, and the comparability of the ingredient forms. Evidence should ideally demonstrate:

- A well described study population;
- A record of the flow of subjects through the trial;
- Power analysis to determine proper number of subjects;
- Random allocation;
- Blinded assessment of outcome;
- Intention to treat analysis;
- Should usually be assessed compared to current standard therapy; and
- In addition to validity, evidence should demonstrate reasonable causality supporting the efficacy of the product.

2.6.3 Efficacy Evidence Requirements for the Low Risk Category

NHPs making claims for minor health conditions and diseases should meet the evidence criteria of the low risk category. This risk category also includes NHPs for the treatment of symptoms or risk factors of serious or major conditions or the risk reduction of these conditions; and NHPs for general health maintenance, support, or promotion that refers to modification of a biochemical or physiological function of a nutritional nature or implies benefit to a minor disease or health condition. Evidence requirements for this category reflect the low risk nature of these products; however, evidence should still demonstrate key aspects of validity and be appropriate for the recommended conditions of use.

This category includes most vitamins, minerals, essential nutrients, and other nutrients recommended for use by healthy adults. These types of ingredients are often associated with NHPD pre-cleared information.

For additional guidance on appropriate claims for low risk products, refer to Annex I: General Health Claims.

Table 1. Acceptable Minimum Safety and Efficacy Evidence by Risk Category

For a description of each risk category, refer to section 2.3. For each medicinal ingredient and claim associated with the risk category, at least one of the following types of evidence meets the minimum criteria.

High Risk Category:	
Evidence type	**Considerations**
NHPD published monographs	N/A
Phase III or phase IV clinical trials (randomized, controlled, well-designed)	For treatment, cure, and prevention claims or for health support claims when they imply treatment, cure, prevention, and risk reduction claims if the study is not multi-centred, at least two studies are required.
Meta-analysis (controlled and well-designed)	Conclusions should be based primarily on phase III trials, not phase II trials; primary evidence may be requested.
Prospective observational studies or combinations of one prospective study and one retrospective study	Evidence only meets minimum requirements for prevention and risk reduction claims. Two pieces of evidence of equivalent ranking or higher are required to support efficacy.
Evidence of a positive decision from another regulatory agency	Documentation in the form of an authorization letter or positive decision must be submitted that includes details on what was approved. A description of the regulatory requirements from the other regulatory agency should be provided.
Medium Risk Category:	
All acceptable minimum evidence requirements for the high risk category	N/A
Systematic review other than meta-analysis	Conclusions should be based primarily on phase III trials, not phase II trials; primary evidence may be requested.
Published, peer-reviewed, detailed narrative reviews which cite detailed primary evidence	Detail should include: defining characteristics of the ingredient; primary endpoints/outcomes with statistical and clinical significance; the studied sub-population's age, gender, and health state; the dosing regimen and dosage form; the route of administration; the directions of use; any restrictions to study entry of participants based on interactions/risk; any identified adverse reactions

Phase II clinical trials	Two pieces of evidence of equivalent ranking or higher are required to support efficacy. When the evidence provided to support the claim is methodologically weak, it should be supplemented to demonstrate consistency in results and plausibility.
Epidemiological studies	Evidence only meets minimum requirements for prevention and risk reduction claims. Two pieces of evidence of equivalent ranking or higher are required to support efficacy.
Published compilations referring to traditional use	Evidence can be used to support safety only.
Low Risk Category:	
All acceptable minimum evidence requirements for the high and medium risk categories	N/A
Phase II clinical trials	One piece of evidence of equivalent ranking or higher is required to support efficacy. When the evidence provided to support the claim is methodologically weak, it should be supplemented to demonstrate consistency in results and plausibility.
Epidemiological studies	Evidence only meets minimum requirements for prevention and risk reduction claims. One pieces of evidence of equivalent ranking or higher are required to support efficacy.
Pilot and open label studies	Two pieces of evidence of equivalent ranking are required to support efficacy. The two different studies may be of equivalent or higher ranking. When the evidence provided to support the claim is methodologically weak, it should be supplemented to demonstrate consistency in results and plausibility.
Reputable textbooks	Textbook should reflect human in vivo data if the ingredient is an essential nutrient.
Demonstration of food use	Evidence can be used to support safety only.

2.6.4 Qualifying Claims

When necessary, qualifying statements may be necessary to add context to support a claim and to help consumers make informed decisions. The need to qualify a claim is based on the characteristics of the ingredients, the seriousness and severity of the health claim, the need for specificity within the claim, as well as the value that the wording will provide to the consumer.

Examples of claims that should be qualified include:

- When the evidence refers to one risk factor in a risk reduction claim, the claim should be qualified with other modifiable factors that should be considered (e.g., "calcium intake, when combined with sufficient Vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis"); and
- Risk reduction claims in which a biomarker was used should indicate that the biomarker, the factor which contributes to the efficacy of the claim, is only one of many that may contribute to the development of the disease to which it has been linked.

For additional guidance on claim qualifiers, refer to Annex I: General Health Claims.

Traditional Use Claims may appear in all Natural Health Products

Traditional use claims may appear on non-traditional use products; these products should be formulated based on the following principles:

- The medicinal ingredient(s) supporting the traditional claim(s) should meet the requirements for traditional use claims as per the *Pathway for Licensing Natural Health Products Used as Traditional Medicines*.
- Evidence should support the dose information and the method of preparation as those traditionally used within the given traditional system of medicine.
- To prevent the product from being represented as a "traditional medicine," any indicated traditional use claim should refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates.
    - This includes products with claims based on modern evidence and claims supported by traditional use. E.g., "Helps to promote sleep" *(based on modern evidence)*. "Passionflower is traditionally used in Herbal Medicine as a sleep aid" *(based on evidence for traditional use)*.
    - It also includes products with claims from multiple systems of traditional medicine. E.g., "Ashwagandha is traditionally used in Ayurveda to balance aggravated Vata (nervine tonic, sedative)" and "Passionflower is traditionally used in Herbal Medicine as a sleep aid."
- When an additive combination of ingredients within a single traditional system of medicine has been used to support the traditional use claim(s), all ingredients supporting the traditional use claim should be disclosed in the recommended use or purpose(s). E.g., "Passionflower, hops, and chamomile are traditionally used in Herbal Medicine as sleep aids"

2.7 Combination Ingredients

For information on products with multiple ingredients, including sub-therapeutic ingredients, and combinations of medicinal ingredients individually supported by NHPD pre-cleared information, see Annex II.

2.8 Linking Evidence to Conditions of Use, Ingredient Form and Use of Extracts

Refer to Appendix B for recommendations on how to link safety and efficacy evidence to a product's conditions of use.

Refer to Appendix C for recommendations on how to link safety and efficacy evidence to an ingredient's chemical and physical form.

Refer to Appendix D for information on linking safety and efficacy evidence to the use of an extract (i.e., comparability of an extract to the evidence).

2.9 Additional Guidance

More information can be found in Appendix E.

2.10 Final Check before Submitting Product Licence Application

Refer to Appendix F for evidence criteria, which can be used as a final check before submitting a product licence application to ensure that the application is not critically deficient and meets a minimum level of validity.

Appendices

Appendix A: Examples of Health Claims by Health Condition
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Annexes

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Appendix A: Examples of Health Claims by Health Condition

Table 2: Examples of Health Claims by Health Condition

Health Condition	Examples
Serious disease/ condition	Helps prevent rheumatoid arthritis. For the treatment of cerebrovascular disease. For the treatment of depressive disorders. Used to prevent diabetic neuropathy. For the treatment of prostate cancer. For the treatment of high blood pressure. Used to treat diabetes.
Major disease/ condition	Helps to reduce serum triglycerides/triacylglycerols. Helps to lower blood/plasma cholesterol levels. For reducing acid reflux during pregnancy. Helps to restore cognitive function/memory. Helps in the prevention of nausea and vomiting associated with conventional cancer management (chemotherapy and radiation treatment). Helps attenuate the rise in blood sugar levels following a meal. Helps improve insulin sensitivity. Helps to regulate blood glucose levels. Helps prevent glucose intolerance. Helps prevent osteoporosis. Improves joint function in osteoarthritis of the knee. Helps prevent recurrent urinary tract infections. Prevents against cavities. Helps cure migraine headaches. Helps prevent macular degeneration. Helps treat erectile dysfunction.

Health Condition	Examples
Minor disease/ condition	Reduces the number and severity of acne pimples. Helps relieve nervousness. Helps relieve minor pain associated with menstruation. Used as a mild sedative (for jet lag). Soothes sore throat. Short-term relief of occasional constipation/laxative. Helps relieve minor burns including sunburn. Used for the temporary relief of muscle and joint pain associated with rheumatoid arthritis or osteoarthritis (symptom). Helps to relieve the symptoms (e.g., sore throat, runny nose) of the common cold. Used as a decongestant to relieve nasal congestion due to hay fever. Helps to reduce the recurrence of cold sores. Relieves symptoms such as heartburn and dyspepsia associated with gastric hyperacidity (i.e. antacid). For the removal of corns and calluses. Helps prevent nausea and vomiting associated with motion sickness and seasickness.

Appendix B: Linking Evidence to Conditions of Use

Evidence is required to support the claim and all of the recommended conditions of use. Table 3 provides a summary of important recommendations.

Table 3: Linking Evidence to the Conditions of Use

Condition of Use	Safety Requirements	Efficacy Requirements
Dosage form	• Evidence specific to less common dosage forms should be provided when possible or when ingredients have stability concerns (i.e., extended-release dosage forms or immediate-release dosage forms).	• When pharmacokinetics may be influenced by dosage form, information may be required regarding the potential impact of the efficacy of the product. • The reference dosage form should be comparable to that recommended, unless an acceptable justification is provided to show that the difference in dosage form is unlikely to affect product efficacy.
Route of administration	• The reference route of administration should be the same as that recommended (except for throat sprays/lozenges for which swallowed dosage forms will be considered). • Topical use in adults should not be extrapolated to children; evidence should support specific use by children unless an acceptable justification is provided. • Evidence for other routes of administration may be considered when specific knowledge of the ingredient mechanism of action is known, (e.g., sublingual use may help support oral use, if evidence of the specific mechanism of action is provided).	• The route of administration in the evidence should be the same as that recommended. • A minimum concentration for efficacy should be assumed.

Condition of Use	Safety Requirements	Efficacy Requirements
Dosing Information (including dose frequency, daily dose)	• The reference daily dose should be equal to or greater than the recommended daily dose. • The dose should be appropriate for the vulnerability of the target population; • The reference frequency of use should be the same as that recommended if the frequency of use has an effect on the safety profile (e.g., consuming 4 x 200 mg of caffeine per day is likely to induce different physiological effects than 1 x 800 mg of caffeine per day). • Evidence supporting use in children or infants should either be clinical or represent a long-standing history of safe use. • The product risk profile, including the nature of the ingredient and how it is being used, should be considered when deciding how closely the safety evidence should match the ingredient. For example, the higher the risk profile, the more closely the dosing information should match the evidence.	• The reference daily dose should be less than or equal to the recommended daily dose. • The reference frequency of use should be the same as that recommended when frequency of use and circulating concentrations over time is required for achieving specific pharmacological effects. • A reference dose by weight is more appropriate than a reference dose by age for children. • For children, age brackets should also include a weight (e.g., "children aged 1 to 2 years of age, weighing at least 9 kg").
Duration of use	• A duration of use statement based on the conditions in the evidence should be provided when the evidence demonstrates a risk to health that supports occasional use only or if the nature of the condition requires a limited duration of use. • The duration of use should be limited in cases where there is an established risk to health due to the long-term use of an ingredient/product. • For ingredients with uncertainty relating to risk (e.g., novel ingredients), an unlimited duration of use without sufficient	• A duration of use statement should be provided when the efficacy evidence suggests a minimum duration of use is necessary before an effect can be seen. If evidence demonstrates that efficacy is consistently observed at the first time point studied, a minimum duration of use is not usually necessary.

Condition of Use	Safety Requirements	Efficacy Requirements
	advisory information should be supported by at least 6 months of use without significant identified adverse effects.	
Target population	• The risk of using a specific sub-population in the evidence to support a wider population should be justified by the product's benefit-to-risk profile. This includes consideration of the ingredient's risk profile, the method of action, the quality and type of evidence and the specificity of the recommended target population. • Evidence (particularly for treatment claims) for adults should not be extrapolated to children or infants (age 0-11years), and evidence for children (age 2-11 years) should not be extrapolated to infants (under age 2 years). • As necessary, specific evidence may be needed to support the dosing of vulnerable groups such as infants, children and elderly (over 65 years of age) and other vulnerable groups. • Specific evidence should be provided for pregnant or breastfeeding women. • A history of food use may not support safety in infants; evidence supporting a history of safe food use specifically in infants may be required. • Extrapolation of evidence to adolescents from adults or children or vice versa should be considered on a case-by-case basis, depending on the type of product, the conditions of use, and the quality of the evidence. • The age range should be restricted when the age group in	• The dose should be appropriate for the recommended population. • The recommended age bands for infants, children and adolescents should reflect the ages specified in the evidence. For example, evidence for use in children age 2-10 years of age is insufficient to support the use in children under age 2. • The age bands should appear on the label even when the evidence does not specify an age range. • The health impact of lower than expected efficacy should be considered when deciding if extrapolation from a specific health condition to a more general use in healthy consumers would be acceptable. • The pathology and aetiology of the health condition in the evidence should be considered before extrapolating to healthy consumers.

Condition of Use	Safety Requirements	Efficacy Requirements
	the evidence does not match that of the product. • The use by the target population should not be considered too risky based on the assessment of the benefit-to-risk profile of the product.	
Direction of use	• The vulnerability of the target population should be considered when deciding how the directions of use should be specified on the label. • Additional safety evidence should be provided when there is uncertainty regarding a product's safety based on the recommended directions of use (e.g., when a nasal spray uses a high pressure nasal bulb for delivery). • When necessary, the directions of use should be clear enough to allow a third person, such as a parent, to safely administer the product.	• The directions of use should be specific enough to provide the guidance for the proper administration of the product (e.g., "take before going to bed,", "take on an empty stomach"). • When necessary, the directions of use should be clear enough to allow a third person, such as a parent, to effectively administer the product (i.e. specific instructions to crush a tablet or empty contents of a capsule into food or drink to ensure administration to young children or groups who cannot swallow a whole capsule).
Precautionary labelling	• As necessary, the risk information should be appropriate for ingredients with a therapeutic dose; ingredients with a sub-therapeutic dose; and for non-medicinal ingredients. • All precautionary labelling should be based on human evidence or established risks; however certain statements based on theoretical evidence may be necessary when the risks are serious. • A precaution for use with other medications and or conditions/diseases should be included when one or more ingredient(s) in the product is known to alter the effectiveness of the medication or progression of the disease (e.g. alters	• Risk information should prevent over medication when pharmacological effects are additive.

Condition of Use	Safety Requirements	Efficacy Requirements
	effectiveness of treatment, increases risk of developing the disease, worsen the course of the disease or mask symptoms of the disease)	

Appendix C: Linking Evidence to Ingredient Form

Table 4 provides recommendations for ensuring that evidence will support the ingredient's chemical and physical form.

Table 4: Linking Evidence to Ingredient Form

Ingredient Characteristic	Recommendations for Safety and Efficacy Evidence
Identity	Evidence should support: • The unambiguous Latin binomial name or chemical name; • The part or derivative used; and • The specificity of the ingredient's action. For example, for probiotics the evidence should be specific to the organism strain number as well as the genus and species; for botanicals, the evidence should be specific to the part of the plant used; if the evidence indicates "leaf" then "aerial parts" would not likely be supported unless evidence was provided to show that stem and other relevant components have the same ingredient at the same concentration.
Source material	Evidence should: • Support the source material when changing the source material might influence the safety or efficacy of the ingredient; • Describe the source material for isolates when there is a known safety concern; • For isolates that represent a defined molecule (e.g., caffeine), pharmacological activities do not vary depending on their biological source. Therefore, the evidence for these isolates does not need to be source specific. • Isolates that are either polymers (like collagen and hyaluronic acid) or groups of molecules (like polyphenols) have variable pharmacological activity depending on the biological source. Therefore, source-specific evidence is required for these isolates.
Blends of ingredients	Efficacy evidence should: • Describe a blend of medicinal ingredients (X, Y, Z) only when X, Y, Z are all present in the recommended product at a similar dose.
Chemical form	Evidence should : • Support the ingredient form as much as possible when the ingredient has undergone chemical processes that could affect its safety or efficacy (e.g., oxidation, reduction, purification, emulsification, etc.).

Physical form	Evidence should: • Support the ingredient form as much as possible when the ingredient has undergone physical processes that could affect its safety or efficacy (e.g., micronization, extraction, binding, stabilization, microencapsulation, etc.).
Dosage form	Evidence should: • Support the ingredient form as much as possible when the dosage form has been altered in a way that could affect safety or efficacy (e.g., addition of coatings, etc.)

Types of evidence that may be useful to describe the form of the ingredient in the evidence or in the recommended product include: technical information sheets, raw material specifications, bioequivalence studies, other details obtained directly from the author of a clinical trial, information describing the method of preparation, phytochemical composition studies.

Appendix D: Linking Evidence to Use of Extracts

To support the comparability of an extract to the evidence, whether it is of plant, animal or microbial origin, information about the extract standardization or extract solvent system and the extract ratios should be provided. Considerable discrepancy in the methods of preparations could mean that the extracts are not comparable. Also, in order to compare scientific studies on whole materials, or to relate the applicability of a study material to a commercial product, the study materials have to be adequately characterized.

In general, if the extract is standardized, the evidence provided to support the safety and efficacy of the extract should be of the same standardization. In this case, the Quantity Crude Equivalent (QCE) and solvent system is not required to support safety and efficacy but may be provided as additional information. The QCE, extract ratio and solvent system can be used to support a standardized extract when the quantity of the extracts match and the extract ratio and extraction solvents used are comparable.

If the extract is not standardized and is prepared from a known QCE or extract ratio, starting material, solvent and method of preparation (e.g., decoction), the evidence provided to support the safety and efficacy of the extract should match.

An evidence-based justification may be required to support comparability of extracts to one another. This rationale may include the methods of manufacture (e.g., comparisons of the solvents used), the characterization of the extracts (e.g., comparisons of phytochemical profiles), and different studies that compare different extract types.

Appendix E: Additional Guidance

Refer to Table 5 for additional guidance on a variety of topics. This table will be updated on a regular basis.

Table 5: Additional Guidance

Issue	Source of Information	Web Link
Antiseptics	Human Use Antiseptic Drugs Guidance Document	http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/antiseptic_guide_ld-eng.php
Nanotechnology	Policy Statement on Health Canada's Working Definition for Nanomaterial	http://www.hc-sc.gc.ca/sr-sr/pubs/nano/pol-eng.php
Schedule A	Schedule A and Section 3 of the *Food and Drugs Act* Guidance Document	http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/scha_guide_ld-eng.php
Health Canada's Decision-Making Framework for Identifying, Assessing, and Managing health Risks- August 1, 2000	Health Canada Guidance Document on how to Identify, Assess and Manage Health Risks	http://hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/risk-risques_tc-tm-eng.php#aa

Appendix F: Evidence Criteria for Modern Health Claims

Prior to submitting evidence-based Product Licence Applications (PLAs), cross check supporting evidence against the evidence criteria below to ensure that it meets a minimum level of validity.

1. Evidence must be provided for all the medicinal ingredient(s) [XXX and YYY].

Example of missing evidence:

- The PLA indicates that the product is composed of medicinal ingredients X, Y and Z. However, the evidence provided supports the safety and efficacy of medicinal ingredients X and Y, but no evidence has been provided to support the safety of medicinal ingredient Z.

2. The product and/or medicinal ingredient on the PLA form must be comparable to the product and/or medicinal ingredient included in the evidence.

Examples where the medicinal ingredient(s) in the evidence does not adequately represent the medicinal ingredient(s) listed on the PLA form, may include differences in:

- Medicinal ingredient (e.g., collagen vs. hydrolyzed collagen)
- Chemical derivative (e.g., glucosamine HCl vs. glucosamine sulphate);
- Source organism or species (e.g., protease sourced from *Aspergillus niger* vs. protease sourced from *Aspergillus oryzae* or *Panax quinquefolius* vs. *Panax ginseng*);
- Bacterial strain (e.g., *Lactobacillus rhamnosus* AB-123 vs. *Lactobacillus rhamnosus* GG);
- Source material (e.g., *Echinacea angustifolia* leaf vs. *Echinacea angustifolia* root);
- Extract/isolate vs. crude material (e.g., Green tea leaf extract standardized to 15% EGCG vs. Green tea leaf); and,
- The evidence provided is for a blend of medicinal ingredients X, Y, Z, but the medicinal ingredients listed on the PLA are A, B, C.

3. Some evidence is not considered adequate on its own to support safety and efficacy of the product and/or the medicinal ingredient.

Examples of evidence that is not considered adequate as sole support for the safety and efficacy of products include:

- Compilations of evidence that have not been critically reviewed (e.g., Natural Medicines Comprehensive Database, Physicians' Desk Reference (PDR) Health, general information websites);
- Evidence without relevance to, or that cannot support safety of the medicinal ingredient(s)/product and/or efficacy of the product for use in humans (e.g., biochemical characterization study, pharmacokinetic study)

4. Animal or in vitro evidence is provided as the sole source of safety or efficacy evidence for the product and/or medicinal ingredient.

At least some evidence should come from human use; animal or in vitro experimental evidence may be considered as additional, supporting information but is not recommended to form the basis for product authorization. While animal and *in vitro* studies can provide plausible

explanations of how a medicinal ingredient will work, they are not sufficient evidence on their own to support efficacy in humans.

5. The daily dose indicated on the PLA form for the product and/or medicinal ingredient is not captured within the safety and efficacy evidence provided.

Example of missing evidence:

- The recommended daily dose of Medicinal Ingredient X in the PLA is 300 mg; however, the evidence provided supports a daily dose of 60 mg. The evidence may support efficacy but would not support safety.

Example of missing evidence:

- The recommended daily dose of Medicinal Ingredient Y in the PLA is 50 mg; however, the evidence provided supports a daily dose of 150 mg. The evidence may support safety but would not support efficacy.

6. Dosing information must be provided/contained within the evidence submitted.

Example of missing evidence:

- The evidence provided is a general review article that discusses a variety of studies but does not indicate the doses used in the studies.

7. The claim(s) supported by the safety and efficacy evidence must have direct relevance to the claim(s) for the product OR the evidence does not support at least one of the claims.

Examples of missing evidence:

- The evidence provided supports the safety and efficacy of product X when used to relieve osteoarthritic pain. However, the PLA indicates that the product is to be used for cognitive function.
- The evidence provided supports the safety and efficacy of product X when used for headache relief. However, the PLA indicates that the product is to be used to aid digestion.

Example of relevance:

- The evidence describes the effect of treatment on LDL cholesterol whereas the claim indicated on the PLA is for "Cardiovascular health." This is acceptable.

8. The route of administration supported by the safety and efficacy evidence must be the same as the route of administration indicated in the recommended conditions of use section of the PLA.

Example of missing evidence:

- The evidence provided supports the safety and efficacy of product X/medicinal ingredient(s) when taken as an intravenous solution/injection but the PLA indicates that the route of administration for the product is oral. Furthermore, as per Schedule 2 of the *Natural Health Products Regulations*, products administered by injection are prohibited.

Appendix G: Expert Opinions

An expert opinion may be used to supplement information that is not available in the literature, (e.g., duration of use for an ingredient) or as supplementary information to support a new use for a previously approved ingredient. When using expert opinions, factors such as experience, education, the number of experts, and conflicts of interest should be considered. These factors, along with any other relevant information provided, will contribute to the weighting of the expert opinion.

An expert should have:

- Training in the field or healing paradigm related to the proposed NHP or medicinal ingredient(s);
- Scientific qualifications, including experience in research methods and/or training in evidence-based health care; and
- No conflicts of interest or must disclose all conflicts of interest.

Annex I: General Health Claims

Intent:

This annex outlines a regulatory pathway for natural health products (NHPs) with general health claims. These claims can be used provided that the health and safety of Canadians would not be at risk; this is consistent with a risk-based product approach where health claims are indexed against the level of evidence provided to support the safe use of the products.

What is meant by a general health claim? There are several types of general health claims. The main type of general health claim is known by the fact that the claims are more limited in describing the effect of the NHP and present the component as having a therapeutic effect as it relates to a disease or health condition without classical definition of the effect or outcome. As such, the first type of general health claims does not address mitigation, treatment, prevention or cure of serious or major conditions. Instead, they relate to modifying organic functions in a manner that maintains or promotes health, including nutrient structure-function and quality of life health claims.

What type of evidence is required for a general health claim? The information or data used to support a general health claim should be appropriate to the strength of the health claim. This includes the fact that the evidence standards could be different than those presented in the main body of the 'Pathway for Licensing Natural Health Products Making Modern Claims' or 'Pathway for Licensing Natural Health Products Making Traditional Claims' guidance documents.

General health claims must not be false or misleading and their accuracy must be established through an established methodology to meet the appropriate standard of evidence. Further, the claims must not lead to unsafe or inappropriate use of an NHP, nor to the sale or advertising of NHPs for use outside of their approved indications and conditions of use.

An NHP, its associated claim(s) and its packaging, labelling and advertising must be consistent with the terms of market authorization. Additionally, a claim made through the product name, the brand name or the name of the manufacturer will be considered false or misleading if it indicates or implies an unauthorized indication and/or use of the NHP that was not included in the terms of market authorization.

Types of general claims that have low therapeutic impact include:

- For health maintenance (e.g., maintains healthy gums)
- For relief of minimally bothersome symptoms (e.g., runny nose)
- For self-limiting conditions (e.g., colds)
- For purposes that will cause little or no harm if an NHP is ineffective in a particular consumer (e.g., anti-flatulent).

It is important to note that while the previous paragraphs focus on the main types of general health claims, there are also a few other types of general health claims for which there is a different relationship between the claim and the intended therapeutic effect. In these other types, the information used to support the claim exists, but there are challenges in determining the therapeutic effect, leading to the need for generalization.

- *Pattern of evidence:* In some instances it is not a single trial, text, or study that suggests that the product has a therapeutic effect. Rather, there is a positive pattern of evidence of benefit from the product. In these instances, because

information on the product's benefit is drawn from multiple sources, there needs to be generalization in the claim to assure that it is accurate to the patterns of demonstrated benefit(s). As such, the claim will be generalized to a therapeutic effect that is evidenced throughout the sources used to support the benefit of the product.

- *Specific end-points:* In some instances there is some certainty regarding the health benefits of a given ingredient, but the therapeutic outcome is either less clear or is very specific and not readily relatable or understandable. As it relates to specificity, this could include a situation whereby the information shows a mechanism of action for which the therapeutic benefit of that action is not readily known or understood. For instance, information relating to a benefit provided to support a health claim shows benefits on a health system rather than a more common treatment, prevention or cure claim for a specific disease. As such, generalization may be necessary to support the licencing of the product. As another example, the information showing a benefit to support licencing of a product may relate to a specific mechanism of action within the human body, but the health outcome of that mechanism of action may not be clearly known or understood by a consumer.

- *Qualifications:* In some other cases qualification of the claim may be necessary in order to support the addition of a claim. Qualification should be reserved for occasions where there could be concern of a benefit not being achieved, creating a known risk. In these cases, a qualifier such as "could," or "likely," or "when used in addition to x or y" may be added to the claim to convey that a benefit was not as strong as other instances whereby a qualifier was not used. An example of this includes a situation where the product is treating a symptom of a disease that, if not treated, could have an impact on health and safety. This also assures that there is fairness in the strength of a claim for a product licence being directly proportional to the strength of the benefit. More direction on qualification of claims can be found within the body of the annex and in Section 2.6.4 of the 'Pathway for Licensing Natural Health Products Making Modern Claims' guidance document.

Qualification can also occur in instances whereby the product is intended to be used within a system of medicine, such as within the context of traditional medicine. Refer to the main body of the annex for more direction on these types of claims.

This demarks an important distinction between the main types of general health claims, such as source of claims, and the three types of general health claims listed above. While a "source of" claim has a lower therapeutic effect and a less specific general health claim as a result of that, other general health claims could be supported by higher levels of evidence.

1.0 Purpose

The purpose of this annex is to provide guidance on the use of general health claims for NHPs, such as those demonstrating a lower therapeutic effect, to ensure that the standards of evidence for those NHPs reflect the therapeutic outcome and the allowable health claim.

The approach follows these principles:

- Evidence requirements are proportional to the level of risk of the NHP:
  - Higher intrinsic risk, higher therapeutic impact, higher level claim NHPs must be supported by evidence that is of a higher standard and level of certainty.
  - Conversely, lower intrinsic risk, lower therapeutic impact, lower health claim NHPs can be supported by lower level or less certain evidence of efficacy so long as there is high certainty of safety under the recommended conditions of use.
- Mitigate risks to the health of consumers and support access to NHPs that are safe and are likely to do what the health claim on the label states.
- Focused decision making, grounded in a risk-benefit analysis that recognizes degrees of appropriate evidence in relation to the NHP's safety and positive health outcomes.
- Provide stakeholders (internal and external) with predictability and transparency in evidence requirements for health claims.

2.0 Scope

The following list outlines NHPs that fall outside the scope of this annex:

- NHPs that contain ingredients that are intrinsically higher risk. This includes NHPs associated with a higher level of uncertainty and/or seriousness of effect, as well as safety concerns that cannot be mitigated sufficiently through the authorized conditions of use (e.g., with dosage and duration limitations, cautionary labelling, etc.).
- NHPs that have a demonstrated lack of quality control as evidenced by inspection or complaints made to Health Canada and could be contaminated with bacteria, adulterated or hyper potent.
- NHPs that have been the subject of controversial or inconclusive science related to the safety of the ingredient(s).
- NHPs that have been identified through post-market monitoring as having potential safety concerns, such as the number of reported adverse drug reactions for a given ingredient or product.
- Licensed NHPs that have a demonstrated history of being advertised outside their terms of market authorization (e.g., through internet advertising).

NHPs marketed with statements that are not considered to be health claims under the *Natural Health Products Regulations* (NHPR) could fall outside of the scope of this annex. Any other consideration that negatively changes the risk/benefit profile of the NHP could lead to a decision that an NHP is outside of scope of this annex.

NHPs that are intended for use in vulnerable sub-populations, such as children and pregnant/breastfeeding women, would not be categorically excluded from this annex; however, a greater attention to risk mitigation may be required (including appropriate cautionary statements or dosage limitations) to allow for a general health claim.

This annex should only apply to those general claims not already specified in other NHPD recognized forms of pre-cleared information (PCI). This guidance is intended to support and not supplant or supersede any other policies or guidance documents related to standards of evidence or health claims.

3.0 Background

Although Health Canada has developed PCI to support efficient authorization of many products and/or claims, there are NHPs that do not meet the current evidence requirements within the established PCI and as such require a full review.

General health claims can provide a clearer pathway to market through a streamlined application process while remaining consistent with the principles of the risk-based approach to NHP licensing.

A general health claim is one that applies broadly to a set of circumstances where there may be a benefit to health, but that benefit may not relate to a specific structure or function being affected, and may not indicate a disease, disorder or abnormal physical state or its symptom(s) that is/are being treated or prevented. Instead, general health claims relate to modifying organic functions in a manner that maintains or promotes health, including nutrient structure-function and quality of life health claims.

4.0. General Health Claims

The following categories are those general health claims that may be authorized if all required conditions/considerations are met.

"Source of/Provides/Contains" Claims

A "source of" claim is a factual representation that identifies a constituent or ingredient within a product. This approach is already utilized for food. Thus, the recommended use or purpose to be authorized for the NHP is as a source of that substance. A health benefit is generally implied by identifying the product as a source of the constituent/ingredient, and this must not be false or misleading, i.e., such claims will relate to nutrients or other constituents/ingredients generally known to be beneficial to health and should not be in reference to inert or ubiquitous substances. These claims can be prefixed by "source of,", "provides" or "contains."

Examples

- Source of fibre
- Provides antioxidants
- Source of probiotic
- Source of protein
- Source of a vitamin or mineral
- Source of an essential fatty acid
- Source of an essential amino acid
- Contains digestive enzymes
- Provides non-essential amino acid
- Contains non-essential fatty acid
- Source of carbohydrates

Evidence requirements

Applicants wishing to apply for a "source of" claim are required to test for the presence of the constituent or ingredient (i.e., identification testing) and may be asked to provide evidence for quantification such as an assay at the finished product or raw material stage; however, this will not be a requirement upon submission. Applicants should have the results of the aforementioned tests maintained such that they could be provided to Health Canada in a timely manner upon request.

The NHPD is adopting a standard with respect to essential nutrient content in NHPs modelled after the Food and Drug Regulations' (FDR) vitamin and mineral minimum dose requirements as per Sections D.01.004 and D.02.002. If a Recommended Dietary Allowance (RDA) or an Adequate Intake (AI) exists for the nutrient (excluding chloride, fluoride, potassium, sodium and sulphate), the daily dose of the NHP should contain at least 5% of the RDA or AI and the NHP would qualify for a "source of" claim.

When the constituent is not an essential nutrient, data does not need to be provided to support the dose as any amount greater than zero will confer efficacy. Evidence is required to support the safety of each ingredient at the specified dose.

Claims Based on Constituents

Many medicinal ingredients of NHPs have constituents that on their own can support a specific health claim. Products that are standardized as a source of such a constituent at a relevant quantity can have a more specific claim based on that constituent.

Examples

- Helps maintain eyesight, skin membranes and immune function
    - Cod liver oil is known to contain vitamin A (palmitate), vitamin D3 (cholecalciferol), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)
- Helps to support eye health in conditions (associated with sunlight damage), such as cataracts and age-related macular degeneration
    - Marigold extracts that are standardized to lutein

Evidence requirements

Applicants applying for these types of claims must provide evidence in the form of identification testing (for the constituent) as well as assays to determine the quantity of the constituent. To support the more specific claim, applicants can attest to a Natural Health Product Monograph such as the Multi-Vitamin-Mineral Supplement Monograph. The applicant can also provide clinical evidence as well as supporting evidence from animals or *in vitro* evidence to support the more specific claim. Applicants should include the name of the constituent in the claim or list it as a constituent of the medicinal ingredient so that consumers know the claim is not false or misleading and can make informed choices.

Claims for the Maintenance of Good Health

Applicants can apply for the claim "for the maintenance of good health" providing the product contains an essential nutrient. These essential ingredients may be isolated ingredients or constituents of ingredients.

Examples

- A source of vitamin x for the maintenance of good health
- A source of mineral x for the maintenance of good health

- A source of dietary fibre for the maintenance of good health
- Provides essential fatty acid x for the maintenance of good health
- A source of essential amino acid x for the maintenance of good health

Evidence requirements
To apply for one of these claims the ingredient must be present in the product and will be identified and assayed for in the product. If the essential nutrient is a constituent of an ingredient, the applicant will be asked to identify through constituent testing (identification testing and assay) which ingredient contains the specific nutrient at the finished product stage; however this will not be a requirement upon submission. An applicant can also apply, for the product as a whole, to use the claim "for the maintenance of good health" without identifying the essential nutrient in the claim if it is listed as a constituent of the medicinal ingredient so that it is clear to the consumer that the product contains that nutrient.

General Claims to Help/Support/Maintain/Promote Health

Structure-function health claims imply the modification of an organic function related to a specific body structure. These general health claims are prefixed by either "supports," "maintains" or "promotes" versus "treats," "prevents" or "cures." "Supports" and "maintains" are claims usually referring to the maintenance of a steady state whereas "promotes" usually implies an improvement to the state or condition. The low therapeutic impact claim qualifier "helps" is used to indicate that the product addresses or treats only one/some components of the disease or intended health benefit. These claims must not be to treat or cure Schedule A diseases but may support mechanisms of action associated with reduction of the risk of a Schedule A disease. These claims differ from general health maintenance claims in that there is an implied relationship between the claim and the product, and the claim and health outcome, whereas the general health maintenance claim does not contain such a relationship. It should be noted that a general health maintenance claim does not necessarily equate to poor evidence; on the contrary, most general health maintenance claims are supported by higher levels of evidence including clinical trials and text book evidence.

Examples
- Supports the immune system
- Promotes liver function
- Supports cognitive function
- Maintains vision
- Supports digestion
- Supports glucose metabolism
- Supports cardiovascular health

Evidence requirements
These claims are often supported by clinical trials and observational or epidemiological studies in humans, but other forms of evidence could be considered acceptable. The minimum evidence required to support these types of claims includes at least some human evidence (clinical and/or epidemiological), clinical text books that describe how constituents work in the body, and supporting evidence such as animal and *in vitro* studies that provide more information surrounding the mechanism of action.

Where supported by the evidence, it is beneficial to the consumer to provide more detail on the mechanisms of action by relating that to a body system or function.

Examples

- Support liver function by aiding in carbohydrate metabolism
- Helps support digestion by adding to the body's natural micro flora

Generalized claims based on mechanism of action

When clinical endpoints/markers discussed in the evidence are not clearly recognizable, are not well known, or could not be easily understood by the public, claims must be generalized for the average consumer to understand. In the case of biomarkers, evidence should be provided for the validation of the biomarker.

Examples

- Helps to reduce blood C reactive protein levels, a clinical marker of inflammation.

When evidence to support a claim describes a biochemical pathway the claim may be generalized to discuss organ function or health. It should be noted that a generalized claim based on a mechanism of action does not necessarily equate to poor evidence.

General Claims for the Relief or Resolution of Low Therapeutic Impact Conditions

General claims are also appropriate for the resolution of less serious conditions (self-diagnosable, self-treatable and/or self-resolving) where a consumer can easily tell if a product is effective. These claims cannot be for the treatment of serious conditions such as those outlined in Schedule A but may be for relief of non-unique symptoms of such serious diseases such as treatment of the pain from osteoarthritis. These claims can be prefixed by "Helps to."

Examples

- Relieves dry eyes
- Helps to relieve the pain associated with osteoarthritis
- Reduces the symptoms associated with the common cold
- Helps to relieve runny nose
- Helps to relieve upset stomach

Evidence requirements

The minimum evidence required to support these types of claims includes at least some human evidence (e.g., clinical and/or epidemiological), clinical text books that describe how constituents work within the body, and supporting evidence such as animal and *in vitro* studies that provide more information surrounding the mechanism of action. The clinical evidence provided to support these claims may be weak in methodological design and may represent trends in evidence.

General Claims for Risk Reduction of Low Therapeutic Impact Conditions

General claims are also appropriate for the prevention of less serious conditions (self-diagnosable, self-treatable and/or self-resolving) where a consumer can easily tell if a product is effective. These claims cannot be for the treatment of serious conditions such as those outlined in Schedule A. These claims are usually prefixed by "Helps to prevent" or "Reduces the risk of."

Examples

- Helps to prevent dry eyes
- Helps to prevent drowsiness

Evidence requirements

The minimum evidence required to support these types of claims includes at least some human evidence (clinical and/or epidemiological), clinical text books that describe how constituents work within the body, and supporting evidence such as animal and *in vitro* studies that provide more information surrounding the mechanism of action. The clinical evidence provided to support these claims may be weak in methodological design and may represent trends in evidence.

Herbal Medicine

When the primary support for treatment of minor conditions comes from a specified paradigm of medicine such as herbalism, the claim should be prefixed with the paradigm such as "Used in Herbal Medicine."

Examples

- Used in Herbal Medicine to help relieve upset stomach
- Used in Herbal Medicine as a sleep aid
- Used in Herbal Medicine to help relieve pain and/or inflammation in muscles and joints (e.g., sprains, bruises, joint pain)

Evidence requirements
In order to apply for a "used in herbal medicine" claim, an applicant must provide two independent references that support the product's use within the specified healing paradigm. At least one of the references must support the product's extraction information and the recommended conditions of use such as dose, duration, sub-population and specified risk statements.

The paradigm of Herbal Medicine may also be appropriate for both the treatment and prevention of self-limiting conditions where all requirements as previously described are met.

Aromatherapy- Essential Oils

The NHPD has adopted the following definition as a basis for decision-making regarding essential oil products: *Aromatherapy is a branch of botanical medicine which uses essential oils and other volatile/aromatic plant extracts for therapeutic or medicinal effect.*

There are three routes by which essential oils are commonly administered:

1. Topical: external skin via massage, compress, bath, creams/ointments
2. Internal: mucous membranes via inhalation, mouthwashes, douches, pessaries, suppositories
3. Oral: ingestion in gelatin capsules, on activated charcoal tablets or diluted in honey or alcohol

The general claims for these classes of products are "Used in Aromatherapy" or "Aromatherapy product." When the evidence to support a more specific claim becomes available in the paradigm of Aromatherapy, the claim should be prefixed by "Used in Aromatherapy."

Evidence requirements
In order to apply for an Aromatherapy claim, an applicant must provide two independent references that support the product's use within Aromatherapy. The references should be route of administration-specific. At least one of the references must support the product's

extraction information and the recommended conditions of use such as dose, duration, directions of use, sub-population and specified risk statements.

General Claims for Traditional Products

The NHPD definition of a traditional product is outlined in the guidance document *Pathway for Licensing Natural Health Products Used as Traditional Medicines*. In the cases where the product meets the requirements for a traditional medicine, the product may make a claim "For use in traditional XXX Medicine" where the paradigm of the traditional medicine is included in the general claim. Additionally, these claims can be used for products where there has been a modification from the original formula. Essentially, this may represent a personalized formula or manufacturer/practitioner-specific formula.

Examples

- Remedies/Products based on Herbal Medicine
- Remedies/Products based on Traditional Ayurvedic Medicine
- Remedies/Products based on Traditional Chinese Medicine

Evidence requirements
In order to apply for a general traditional health claim, an applicant must provide two independent references that support the medicinal ingredient's use within the specified traditional paradigm. At least one of the references must support the product's extraction information and the recommended conditions of use such as dose, duration, sub-population and specified risk statements.

Claims that are Only Effective When Used in Combination with Other Treatments

When the clinical evidence provided to support claims demonstrates that a product is only efficacious when used in conjunction with an activity or other constituents, the claims should reflect those additional requirements.

Examples

- Helps in weight maintenance when used in conjunction with adequate exercise and a calorie-reduced diet
- Helps reduce the risk of developing osteoporosis when taken with adequate amounts of calcium and vitamin D
- When used in conjunction with good oral hygiene helps reduce the risk of developing gingivitis

Evidence requirements
The minimum evidence required to support these types of claims includes limited human evidence (clinical and/or epidemiological), clinical text books that describe how constituents work within the body, and supporting evidence such as animal and *in vitro* studies that provide more information surrounding the mechanism of action.

Building Health Claims

Licensees are encouraged to seek greater specificity and strength in the health claims for their products as additional evidence becomes available. Additionally, consumers seeking

a higher therapeutic impact should be directed to health claims that are more specific and strong, as the specificity of the claim relates to the sufficiency of the evidence provided in the product licence application.

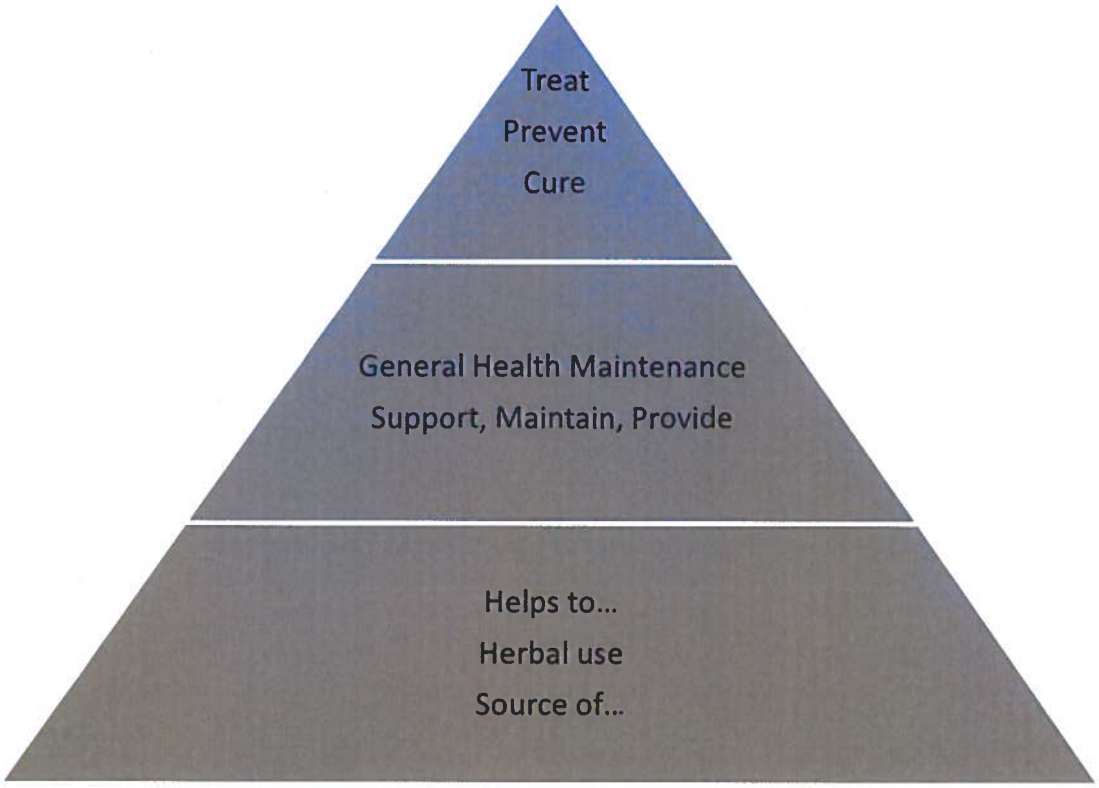

Figure 2. Building Health Claims

As such, through product licence amendments, the claim for a lower therapeutic impact product can evolve over time as additional studies, supplemental literature, clinical use, and other sources of evidence provide more conclusiveness as to the benefits of the product. As the link between the condition, the NHP and the therapeutic outcome becomes more definitive, the applicant can provide that evidence to modify the product licence to allow for more specific and stronger health claims.

Applicants providing evidence that supports a stronger or more specific health claim will be supported. This annex applies more specifically to situations whereby the evidence supports a more general health claim. As science and available evidence evolves, a stronger health claim could be applied for, and if the evidence is sufficient, received.

Having a General Health Claim Revoked

An NHP with a general health claim could be affected if the low risk nature of the product changes, effectively making a product or ingredient ineligible for a general health claim.

The reasons for removing a general health claim can be found in section 3 of this annex. Additionally, a general health claim may be invalidated if:

- There is heightened uncertainty regarding the safety of the ingredient or product.
- New evidence suggests the product could pose a risk to health.
- New evidence indicates that the product is not conforming to the general nature of the claim authorized in the product licence.
- Post-market evidence effectively elevates the risks of the product above the benefits conferred by use of the NHP.

In the event of a potential need to revoke a general health claim, the following process will be adhered to so that immediate steps are taken to address the potential safety concern.

1. Issuance of a non-regulatory letter to affected stakeholders providing an opportunity for the impacted parties to address Health Canada's concerns of a potential risk to health, including a risk assessment by the impacted stakeholder. For the issue to be resolved, evidence would be required to show that Health Canada's safety concerns are groundless or to provide appropriate risk mitigation measures.

2. If the safety concern persists, Health Canada will move forward with the issuance of a regulatory letter requesting information from the impacted party (or parties) to address the safety concern. Acceptable outcomes at this stage could include a withdrawal of the concern due to sufficient evidence provided by the regulated party, risk mitigation measures to address potential safety concerns, or additional steps required by Health Canada.

3. If a significant risk to health and safety is identified, section 17 notices could be issued effectively mitigating the risks. As such, the general health claim would no longer be acceptable for such a product.

This annex documents the current practice, and it will continue to be in effect. However, during the consultation period, stakeholders provided differing viewpoints about how the practice is represented to consumers. These important viewpoints will be considered in the on-going modernization efforts for health products. Any future changes to this annex will be made available for consultation.

Annex II: Combination Ingredients

Combinations of the substances listed in Schedule 1 of the *Natural Health Products Regulations* (NHPR) are permitted, provided that:

- There is no increased risk (e.g., additive risk, over-medication, altered bioavailability or pharmacological activity) that cannot be mitigated;
- There is no decrease in efficacy (e.g., contradictory effects); and
- There are no incompatible recommended conditions of use (e.g., contradictory claims, durations of use, risk information).

Sub-therapeutic Ingredients

Sub-therapeutic ingredients are those that are commonly recognized to have medicinal properties but are present in a product below known effective doses. These ingredients can be classified as follows:

- A sub-therapeutic ingredient should be listed as non-medicinal when it is added to confer suitable consistency or form to the medicinal ingredients as per the definition of a non-medicinal ingredient.
- A sub-therapeutic ingredient should be listed as medicinal:
    - When its combination with other ingredients supports the recommended use or purpose(s) of the product as demonstrated by evidence of an additive effect; or
    - When an additive effect cannot be demonstrated and it does not meet the definition of a non-medicinal ingredient.

Combinations of Medicinal Ingredients Individually Supported by Natural Health Products Directorate (NHPD) Pre-Cleared Information (PCI)

When NHPD PCI is cited for all individual medicinal ingredients in a multiple medicinal ingredient product, licensing will be facilitated. Certain basic criteria should be met, such as, but not limited to:

- All of the elements reflecting the conditions of use of the PCI being cited should be the same or compatible (i.e., route of administration, dosage form, use or purpose, dose,

sub-population, potency, frequency, directions of use, duration of use, risk information). In cases where specific recommended conditions of use are required for efficacy, these should be clearly represented for each of the different uses or purposes of the product.

- **Recommended use or purpose**: Efficacy of at least one medicinal ingredient is required while safety of all medicinal ingredients is required within a multiple-ingredient product. Restrictions from risk statements for the product should not conflict with the product's claims.

The NHPD may request additional evidence in support of the safety and/or efficacy of any multiple ingredient products when necessary, when adverse reactions are reported, when new evidence becomes available or when consumer concerns are raised.

Exhibit « **D** » of the affidavit
of VIRGINIE TREYVAUD AMIGUET
affirmed before me this
27th day of February 2020.

Commissioner of oaths

Health Canada Santé Canada

COMPENDIUM OF MONOGRAPHS

NATURAL HEALTH PRODUCTS DIRECTORATE

June 13 2013
Version 3.0

Canada

FOREWORD

Guidance documents are meant to provide assistance to industry and health care practitioners on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments and therefore allow for flexibility. Alternate approaches to the principles and practices described in this document may be acceptable; licence applicants are invited to discuss these with the Natural Health Products Directorate prior to submitting an application.

As a corollary to the above, it is equally important to note that Health Canada may request information or material, or define conditions not specifically described in this document, in order to enable the Department to adequately assess the safety, efficacy or quality of a health product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the *Natural Health Products Regulations* and relevant sections of other applicable guidance documents.

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INTRODUCTION

The Compendium is a compilation of monographs based on natural health product (NHP) ingredients. The Natural Health Products Directorate (NHPD) developed the *Compendium of Monographs* as a tool for the timely and efficient review of the safety and efficacy of many commonly used NHPs.

The NHPD allows applicants to reference NHPD monographs in support of the safety and efficacy of medicinal ingredients as part of their Product Licence Application (PLA). This process is efficient for both applicants and Health Canada, since there is no need to evaluate the safety and efficacy of NHP ingredients that are already known to be safe and efficacious when used under the conditions specified in the NHPD monographs.

For more information on the product licence application process and the evidence required to support the safety (risk) and efficacy (benefit) of NHPs, please refer to the *Pathway for Licensing Natural Health Products Making Modern Health Claims* and the *Pathway for Licensing Natural Health Products Used as Traditional Medicines*.

The Compendium consists of single ingredient monographs, product monographs and criteria for the combination of monographed ingredients.

For a list of published NHPD Single Ingredient and Product Monographs, see the Natural Health Product Ingredient Database (NHPID).

For acceptable non-medicinal ingredients that can be used in natural health products, see the NHPID.

1.0 ABOUT THE COMPENDIUM

1.1 Compendial Applications

Natural Health Products Regulations

Part 1: PRODUCT LICENCES
Sixty-Day Disposition
Section 6

6. (1) Subject to subsection (2), the Minister shall dispose of an application submitted under section 5 within 60 days after the day on which it is submitted if, in support of the application, the only information submitted by the applicant under paragraph 5(g) is that which is

a. in the case of an application respecting a natural health product that has only one medicinal ingredient, contained in a monograph for that medicinal ingredient in the Compendium; and

b. in the case of an application respecting a natural health product that has more than one medicinal ingredient, contained in a monograph for that combination of medicinal ingredients in the Compendium.

(2) If the Minister requests that additional information or samples be submitted under section 15, the 60-day period referred to in subsection (1) does not include the number of days beginning on the day on which the request is made and ending on the day on which the additional information or samples are received.

(3) For the purposes of this section, the Minister disposes of an application on the earlier of the day on which

a. the licence is issued in accordance with section 7; and

b. the applicant is sent a notice under subsection 9(1).

A compendial application cites NHPD monographs in the Compendium to support the safety and efficacy of medicinal ingredient(s) in a NHP. All other aspects of manufacturing and preparing the product for sale, including good manufacturing practices and labelling, must comply with the *Natural Health Product Regulations* (NHPR). For more information, see the *Quality of Natural Health Products Guide*, the *Labelling* guidance document, the *Good Manufacturing Practices* guidance document and the relevant sections of the *Product Licensing* guidance document.

1.2 Elements of a Monograph

When submitting a compendial application, several items on the PLA form must match the monograph content exactly or fall within its parameters, including the proper name, common name, source material, route of administration, dosage form and recommended dose. The remaining sections of the monograph - use or purpose, directions of use, duration of use and risk information - may use a "statement to the effect of", unless otherwise stated on the monograph. This allows applicants to alter the

wording, but not the intent, of the monograph elements. Any 'statement to the effect of' wording may be evaluated to determine whether it has the same intent as the monograph.

The following are the parameters for the use of a NHPD monograph.

- **Proper name:** The proper name must be chosen from one of the proper name options provided in the monograph.
- **Common name:** The common name must be chosen from one of the common name options provided in the monograph.
- **Source material:** The source material must be chosen from the options provided in the monograph. More than one source material is acceptable, provided that all source materials listed in the PLA form reflect the same dose and/or use or purpose on the referenced monograph.
- **Route of administration:** The route of administration must be chosen from the options provided in the monograph. Please see the Controlled Vocabulary section of the NHPID for a description of the routes of administration.
- **Dosage form:** The dosage form must be chosen from the options provided on the monograph and must reflect the route of administration for the product. The dosage form must be chosen from the list of recognized dosage forms, found in the NHPID under the Controlled Vocabulary section.

  Please note that an NHP in a liposomal formulation is not considered equivalent to an NHP in a non-liposomal formulation. Therefore applicants cannot attest to a monograph for safety and efficacy of an ingredient unless the monograph specifically states that liposomal formulations are acceptable. Products with liposomal formulations must be submitted through the appropriate non-compendial assessment stream with specific evidence to support the liposomal formulation.
- **Recommended use or purpose:** Claims have been identified for each monographed ingredient based on NHPD's evaluation of the safety and efficacy data. Applicants may choose one or more claims provided in the monograph or create an alternative using a "statement to the effect of", unless otherwise stated. Applicants must ensure that any conditions surrounding the claim (dose, source material, etc.) are met.
- **Dose:** The total daily dose must be equal to that noted in the monograph, or, when a range is specified, fall within the range indicated in the monograph. The dose indicated on the monograph may be specific to:
  - **Subpopulation:** All monographs are intended for adults, unless otherwise specified.
  - **Method of preparation:** Must be chosen from the list of acceptable methods, if indicated. Furthermore, to make a traditional use claim, the method of preparation must be one that was traditionally used. Please see

the *Pathway for Licensing Natural Health Products Used as Traditional Medicines* guidance document for a list of traditional methods of preparation.

- **Potency:** When a monograph includes potency, it must be included in the PLA, unless otherwise specified.
- **Frequency:** The frequency must be the same as or fall within the range of the frequency on the monograph, when specified. When the monograph specifies a divided dose the frequency must be more than once daily. If no frequency is specified, the applicant may select an appropriate frequency.
- **Directions of use:** Where specified, all directions of use must be included in the PLA. The directions of use may be identical to that on the monograph or may be a "statement to the effect of", unless otherwise stated.

- **Duration of use:** When the monograph includes a duration of use, it must be included on the PLA.
- **Risk information:** All risk information contained in the monograph must be included in the PLA, as applicable. The risk information may be identical to that on the monograph, or may be a "statement to the effect of", unless otherwise stated.
- **Non-medicinal ingredients:** Only non-medicinal ingredients listed in the NHPID may be used with an appropriate excipient purpose. Any applicable restrictions indicated in the database must be met.

  The presence of non-medicinal ingredients without conditions on the List of Prohibited and Restricted Cosmetic Ingredients (the Cosmetic Ingredient Hotlist), indicates that there are potentially significant safety issues with these ingredients. If the hotlist indicates that additional evidence is required for an ingredient or if an ingredient is listed with no specified conditions, it is not permitted in a topical product submitted in the compendial stream. If the hotlist specifies certain conditions for an ingredient, or label requirements, it is the responsibility of the license holder to ensure that the ingredient meets the conditions outlined.

  Requirements for non-medicinal ingredients are outlined in the *Quality of Natural Health Products Guide*, *Pathway for Licensing Natural Health Products Making Modern Health Claims* and *Pathway for Licensing Natural Health Products Used as Traditional Medicines* guidance documents.
- **Storage conditions:** When the monograph includes storage conditions, they must appear on the product label as per Section 87 of the *NHPR*.
- **Specifications:** Note that certain monographs include additional specifications relevant to that ingredient or product. This information should be considered when establishing product specifications.

1.3 References Used in NHPD Monograph Development

The Compendium is comprised of monographs based on information obtained from modern and traditional sources with regard to the safety and/or efficacy associated with the use of NHPs.

Developing the monographs involves considering information gathered from sources such as:

- published compendia such as those of the World Health Organization, European Scientific Cooperative on Phytotherapy, British Herbal Pharmacopoeia, Pharmacopoeia of the People's Republic of China, European Medicines Agency: Committee on Herbal Medicinal Products (HMPC), and the German Commission E;
- articles published in peer-reviewed journals;
- information published in national pharmacopoeias such as the *United States Pharmacopeia*, *British Pharmacopoeia*, *European Pharmacopoeia, Pharmacopée Française*;
- other published expert committee reports such as the Dietary Reference Intakes (1997-2011), and the U.S. Agency for Health Care Research and Quality (ongoing); and
- Health Canada publications such the Therapeutic Products Directorate's *Category IV Monographs* and *Labelling Standards*.

1.4 Revising and Adding Monographs

Monographs are revised periodically. If new information is published or if a safety or efficacy issue is identified, a monograph will be updated accordingly. A notice to affected stakeholders requesting information may be issued when a monograph is revised for safety reasons and a risk has been identified. Regarding any other monograph revisions, product licence holders are expected to align products affected by the revision(s) with the current monographs, as applicable. This can be accomplished by submitting a post licensing change. Please see the *Post Licensing* guidance document for more information on these types of changes and how to submit such changes to the NHPD. Any new PLA's referencing a NHPD monograph will be expected to comply with the current version of the monograph published in the Compendium, found in the NHPID.

The NHPD considers the following when determining which monographs may be developed or revised:

- High proportion of applications in queue with NHPD that contain specific ingredients.
- Changes to safety and/or efficacy profile of an ingredient.
- Amount of safety and/or efficacy data available for a particular ingredient.
- Directorate, Department and/or Government strategic priorities.

- Signals from international associations, agencies and/or regulatory bodies.
- Suggestions from stakeholders.

Suggestions for revisions to currently published monographs and suggestions for ingredients that should be the subject of a monograph and included in the Compendium can be submitted to NHPD at ingredient_support@hc-sc.gc.ca via the *Ingredient Database Issue Form*. The form should include the name of the monograph being amended along with the rationale and supporting scientific data for consideration.

2.0 TYPES OF MONOGRAPHS

2.1 Single Ingredient Monographs

Applicants may reference a single ingredient monograph that supports the safety and efficacy of a NHP as part of their PLA in the compendial stream.

Safety-only monographs address only the safety of the medicinal ingredient. No recommended uses or purposes are associated with these monographs and on their own cannot support the licensing of a product via the compendial stream. The NHPD strives to revise safety-only monographs periodically. When the available body of evidence supports the inclusion of a recommended use or purpose, safety-only monographs will be revised. Applicants cannot reference safety-only monographs in the compendial application stream for single ingredient products; however safety-only monographs, like all monographs, can be used to support the safety of individual ingredients in non-compendial PLA's, provided that the conditions of use on the monographs are met.

2.2 Product Monographs

Product monographs are composed of more than one medicinal ingredient and may outline the conditions of use based on a product category (e.g. antiseptic hand cleansers, diaper rash products, Multi-Vitamin/Mineral Supplements, etc.) and not the ingredient. As such, a single ingredient may appear on several product monographs. Therefore, the conditions of use for that ingredient, such as dose, recommended use or purpose and risk information, will differ depending on the product category.

Upon the coming into force of the *NHPR* and the classification of certain ingredients as NHPs, the NHPD adopted relevant Therapeutic Product Directorate (TPD) *Category IV Monographs* and *Labelling Standards (LS)* into NHPD product monographs, and has incorporated them in the NHPD *Compendium of Monographs*. Work is ongoing to convert all relevant Category IV monographs and LS to compendial monographs.

2.3 Combination of NHPD Pre-cleared Information

Please refer to the Pathway for *Licensing Natural Health Products Making Modern Claims* for more information regarding combining pre-cleared information.

3.0 SPECIFICATIONS

The submission of a signed PLA will be regarded as an attestation acknowledging the licence holder's responsibility to meet the requirements set out in the *NHPR* and associated guidance documents relating to quality and Good Manufacturing Practices.

The *Quality of Natural Health Products Guide* and the *Good Manufacturing Practices* guidance document outline expectations and approaches relating to the quality requirements for NHPs. Furthermore, individual monographs and the NHPID may also include ingredient specific considerations pertinent to the quality of the product.

By submitting a PLA, the applicant is attesting to meeting the general specifications included in the *Quality of Natural Health Products Guide.* If the product specifications fall outside the general specifications provided in the *Quality of Natural Health Products Guide*, the applicant must submit their own product specifications. Any product specifications submitted should be established in accordance with the requirements and principles described in the *Quality of Natural Health Products Guide*. Applicants are responsible for ensuring that all information is documented, maintained, relevant, accurate, and sufficient to support the quality of their NHPs. This documentation could be requested by the NHPD at any time.

Exhibit « **E** » of the affidavit
of VIRGINIE TREYVAUD AMIGUET
affirmed before me this
27th day of February 2020.

Commissioner of oaths

Monograph Attestation Form

Primary Brand Name(s):

Application Type

☐Product licence application ☐Post-licence amendment

Attestation Conditions

When submitting a product licence application in respect of a natural health product for which one or more Natural and Non-prescription Health Products Directorate (NNHPD) monographs exist in the Compendium of Monographs:

(a) I attest that the information provided in this product licence application [proper name(s), common name(s), source material(s), route(s) of administration, dosage form(s), use(s) or purpose(s), dose(s), duration of use, risk information, etc.] respects the information contained in one or more NNHPD monograph(s);

(b) I attest that the non-medicinal ingredients in the product are present and compliant with the Natural Health Product Ingredients Database (NHPID) and do not exhibit pharmacological effects, do not have any effect contradictory to the product's recommended purpose, do not exceed the minimum concentration required for the formulation, do not adversely affect the bioavailability, pharmacological activity or safety of the medicinal ingredients, and that they are safe;

(c) I attest that the label text is acceptable as per sections 86-94 of the Natural Health Products Regulations and that the information on the label text is consistent with the information provided in this product licence application;

(d) I attest that the natural health product's brand name(s) submitted in this product licence application is consistent with the information provided in this product licence application (e.g. recommended purpose, quantities, etc.), does not pose a risk to health and safety, and is not false and misleading;

(e) I attest to selling this product within the conditions of this attestation and the terms of market authorisation (product licence). I fully understand that if I were to operate outside of this attestation that I may be subject to compliance and enforcement.

☐ My product is supported solely by NNHPD Monograph(s) and the above conditions apply to the application in its entirety; OR

☐ My product is supported by a combination of NNHPD Monograph(s) and evidence which I have provided in support of the product's safety, efficacy and/or quality that is subject to assessment. Condition (a) of this attestation applies to the medicinal ingredients in support of safety, efficacy and/or quality as indicated in the table on page two of this form.

Signature Block

Name (Print)	Company	Position
Signature	Date (yyyy/mm/dd)	

Primary Brand Name(s):

Condition (a) of this attestation applies to the following medicinal ingredients in support of safety, efficacy and/or quality as indicated in the table below:

Medicinal Ingredient	Safety	Efficacy	Quality	If efficacy, list claim in full
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	
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	☐	☐	☐	
	☐	☐	☐	
	☐	☐	☐	

Exhibit « **F** » of the affidavit
of VIRGINIE TREYVAUD AMIGUET
affirmed before me this
27th day of February 2020.

Commissioner of oaths

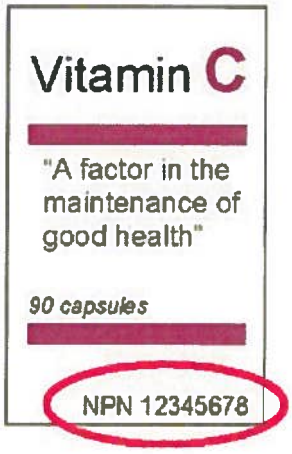
Government of Canada / Gouvernement du Canada

Licensed Natural Health Products Database (LNHPD)

What Is It?

The Licensed Natural Health Products Database contains information about natural health products that have been issued a product licence by Health Canada.

Products with a licence have been assessed by Health Canada and found to be safe, effective and of high quality under their recommended conditions of use. You can identify licensed natural health products by looking for the eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) on the label.



This Licensed Natural Health Products Database is managed by Health Canada and includes information on **licensed** natural health products, including:

- vitamin and mineral supplements

- herb and plant-based remedies
- traditional medicines like Traditional Chinese Medicines or Ayurvedic (Indian) Medicines
- omega 3 and essential fatty acids
- probiotics
- homeopathic medicines
- many everyday consumer products, like certain toothpastes, antiperspirants, shampoos, facial products and mouthwashes

What Information Can I Find Here?

For every licensed product listed in this database, the following details are provided:

- product name
- product licence holder
- Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM)
- product's medicinal ingredients
- product's non-medicinal ingredients
- product's dosage form
- product's recommended use or purpose (i.e. its health claim or indication)

- risk information associated with the product's use (i.e. cautions, warnings, contra-indications and known adverse reactions)

Additional information about this database:

- the data is updated nightly
- use the **User Guide** for help navigating the database
- use the **Terminology Guide** to understand the words and terms used in the database

Access the Licensed Natural Health Products Database

Access the Licensed Natural Health Products Database Data Extract

For More Information

- For **technical support** or for general questions about the content of this database, please contact the Natural and Non-prescription Health Products Directorate (NNHPD) at nhp_initiative_psn@hc-sc.gc.ca
- To search detailed descriptions of specific NHP ingredients, see the Natural Health Products Ingredients Database.
- For more information about how natural health products are licensed, see About Natural Health Product Regulation in Canada.

- **Self-care products**

  How self-care products, including natural heath products, cosmetics and over-the-counter drugs, are regulated in Canada.

Date modified:

2019-01-04

TAB 4

CT-

THE COMPETITION TRIBUNAL

IN THE MATTER OF the *Competition Act*, R.S.C. 1985, c. C-34;

AND IN THE MATTER OF an application by the Commissioner of Competition for an order pursuant to section 74.11 of the *Competition Act* regarding conduct reviewable pursuant to paragraph 74.01(1)(b) of the *Competition Act*;

BETWEEN:

COMMISSIONER OF COMPETITION

Applicant

-and-

NUVOCARE HEALTH SCIENCES INC. and RYAN FOLEY

Respondents

TEMPORARY ORDER

FURTHER TO the application of the Commissioner of Competition (the "**Commissioner**") pursuant to section 74.11 of the *Competition Act*, RSC 1985, c. C-34 (the "**Act**"), for an order directing that Nuvocare Health Sciences Inc. and Ryan Foley (the "**Respondents**"), not to engage in certain reviewable conduct, as set out herein, or substantially similar reviewable conduct;

THE TRIBUNAL ORDERS THAT:

1. the Respondents shall, from the date of this order, until the Commissioner completes his inquiry, be prohibited from:

    a) making, by any means whatsoever, any representation to the public in the form of a statement, warranty or guarantee of performance or efficacy of any product that is not based on adequate and proper testing;

b) making, by any means whatsoever, any representation to the public in the form of a statement, warranty or guarantee of performance or efficacy that is not based on adequate and proper testing about the products WeightOFF Max! under the NutraCentials and SlimCentials brands, the product Forskolin+ under the SlimCentials brand, and the product Forskolin Nx under the NutraCentials brand, as well as any other variation of these products (collectively, the "**Products**"); and

a. Without limiting the generality of the foregoing, making, by any means whatsoever, any representation to the public in the form of a statement, warranty or guarantee of performance or efficacy that is not based on adequate and proper testing about the Products' capacity to:

i. cause weight loss;

ii. burn fat;

iii. increase fat release;

iv. block fat storage;

v. block carbohydrates;

vi. cut appetite;

vii. decrease emotional eating;

viii. target belly fat; or

ix. increase metabolism.

2. The Respondents shall, within 20 days of the issuance of this Order, provide a report to the Commissioner's authorized representative setting out all actions it has taken to comply with this order.

3. The Commissioner's costs of this application as against the Respondents ordered payable forthwith.

DRAFT

DATED this _____day of _____, 2020.

SIGNED on behalf of the Tribunal by the Presiding Judicial Member

_____

DRAFT

CT-

THE COMPETITION TRIBUNAL

IN THE MATTER OF the *Competition Act*, R.S.C. 1985, c. C-34, as amended;

AND IN THE MATTER OF an application by the Commissioner of Competition for an order pursuant to section 74.11 of the *Competition Act* regarding conduct reviewable pursuant to paragraph 74.01(1)(b) of the *Competition Act*;

BETWEEN:

COMMISSIONER OF COMPETITION

Applicant

– and –

NUVOCARE HEALTH SCIENCES INC. and RYAN FOLEY

Respondents

APPLICATION RECORD

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