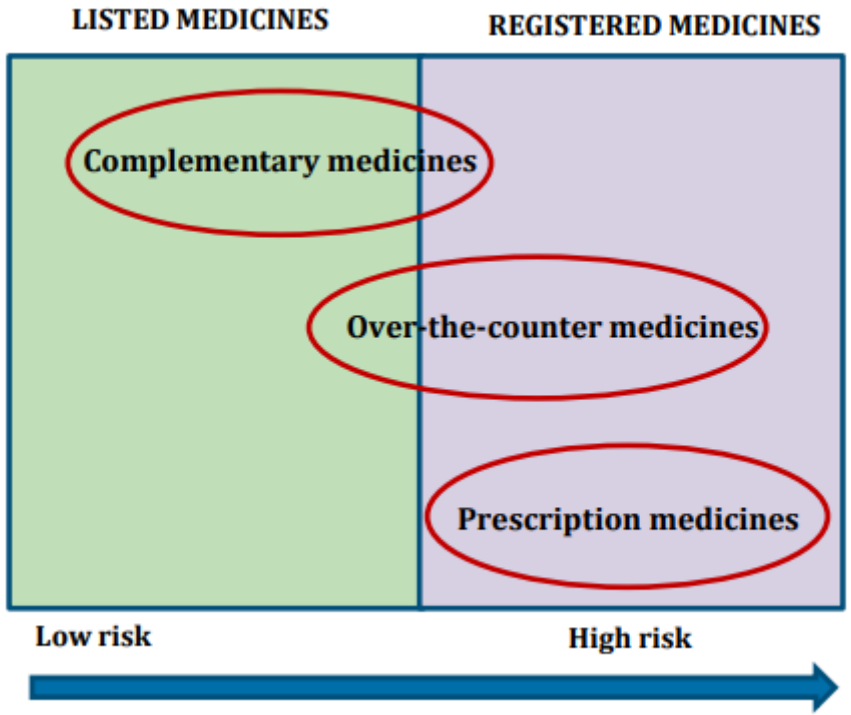
26.12.2023

AU/ USA/CA


Australian Government
Department of Health
Therapeutic Goods Administration

- Complementary medicines (also known as 'traditional' or 'alternative' medicines) include vitamin, mineral, herbal, aromatherapy and homoeopathic products.



Australian Register of Therapeutic Goods (ARTG) Unless exempt (refer to Medicines exempt from certain TGA regulation)
medicines must be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be legally imported, exported, manufactured or supplied for use in Australia.
Each medicine included in the ARTG has a unique ARTG identification which starts with 'AUST', is followed by 'R', 'L' or L(A)

Classification of medicines as registered or listed

Australia has a two-tiered system for the regulation of medicines. Within the regulatory framework, medicines are classified as either:

- lower risk medicines that are **listed** in the ARTG (either **AUST L** listed medicines or **AUST L(A)** assessed listed medicines)
- higher risk medicines that are **registered** in the ARTG (**AUST R** registered medicines)

How to list a complementary medicine ?

[Interactive decision tool]

[ARTG search]

[Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2021]

Listed medicine compliance reviews

Listed medicines are included in the Australian Register of Therapeutic Goods (ARTG) without undergoing a full pre-market evaluation by the TGA. This relies on the medicine satisfying certain criteria for low risk medicines and certification by the sponsor that their medicine meets all of the requirements of section 26A of the *Therapeutic Goods Act 1989*.

Australian Government
Department of Health
Therapeutic Goods Administration

Compliance review process for listed medicines

We conduct compliance reviews of listed medicines that are on the market to check whether they meet regulatory requirements. The typical steps in the review process are:

Review stage	*Actions*
Initiation	1. **We** send a *Request for Information* notice to the sponsor requesting selected information about the medicine. 2. The **sponsor** supplies the requested information to us by the due date. If the sponsor does not provide an adequate response, we may cancel the medicine under section 30 of the Act.
Review	1. We assess the information provided against relevant legislation; this assessment may be broad or focused on a limited set of selected legislated requirements. 2. If we do not find any compliance deficiencies based on the information provided at that time, the TGA will go to the Decision Stage. No further action is taken. 3. If we identify medicine compliance deficiencies, we send a Proposal to Cancel notice to the sponsor notifying them of the deficiencies.
Response	1. The **sponsor** considers the deficiencies identified in our *Proposal to Cancel* notice and may make a submission to us with evidence or justification that the compliance deficiencies we identified are invalid. The **sponsor** may also respond to any questions we have about the deficiencies identified. They may also include actions they have already taken in the interim to remedy the compliance deficiencies. 2. **We** consider the sponsor's submission. If no submission is provided, there is no additional information to consider and the medicine remains non-compliant.
Decision	1. **We** make a final decision about the deficiencies of the medicine as at the time of the review. We notify the sponsor of our final decision, and any regulatory action, in our final letter to them. We will also provide a copy of the information outlining the results of the review that will be published on the TGA website. 2. Under certain circumstances, we may provide additional time for the **sponsor** to rectify the deficiencies identified to bring their medicine into compliance and allow it to remain on the ARTG. 3. If, after consideration of the sponsor's submission, we are not satisfied that the deficiencies were adequately addressed, or the sponsor did not make a submission, the medicine is considered to be non-compliant and we cancel the medicine from the ARTG. 4. The **sponsor** can request for our decision to be reconsidered under section 60 of the Act if they do not agree with it. This must be done within 90 days of the decision being made.
Publication	1. **We** currently publish details of medicines that are cancelled from the ARTG on the TGA website. From December 2019 we will publish the outcome of each individual compliance review on the TGA website. 2. The outcomes of compliance reviews are also included in the TGA Annual Performance Statistics Report.

November 2019

For more resources and further information go to:
https://www.tga.gov.au/publication/australian-regulatory-guidelines-complementary-medicines-argcm
or email: *Complementary.Medicines@health.gov.au*

How the TGA selects medicines for a compliance review

There are approximately 12,000 medicines listed on the ARTG at any one time and over 1000 are newly listed each year. Given the low risk nature of listed medicines, the TGA selects only some of those in the ARTG for review each year. Listed medicines may be subject to any number of compliance reviews while they remain in the ARTG.

Targeted reviews

The TGA may select listed medicines with suspected or potential issues in meeting regulatory requirements for targeted review according to a risk-based approach. Priority is given to issues that:

- may result in an immediate or potential health risk to consumers
- could significantly mislead the Australian public, particularly where there is a health impact
- involve a new or emerging issue of concern
- are likely to become widespread if we do not intervene
- are the subject of public or media scrutiny and concern
- are of national or international significance
- could lead to a loss of stakeholder confidence in the Government's regulatory scheme or in therapeutic goods.

Priority may also be given to medicines that:

- are a 'relisting' of a medicine that was recently cancelled from the ARTG (by either the sponsor or the TGA)
- belong to a sponsor with a history, based on past compliance reviews, of their medicines being non-compliant
- a particular type of product (e.g. medicines with particular ingredients or indications) for which there are concerns of non-compliance.

Regulations at a Glance

FDA-regulated products	Pre-market approval (FDA)	Pre-market notification (FDA)	Labeling (FDA)	Mandatory adverse event reporting (FDA)	GMPs (FDA)	Facility registration (FDA)	Advertising (FTC or FDA)
Foods		✓	✓		✓	✓	✓ FTC
Dietary supplements		✓	✓	✓	✓	✓	✓ FTC
Drugs	✓		✓	✓	✓	✓	✓ FDA
Biologics	✓		✓	✓	✓	✓	✓ FDA
Medical devices	✓		✓	✓	✓	✓	✓ FDA

USA

- DSHEA -1994
- 2017-2020 – ODS – תכנית להעמקת ידע בתחום תוספי התזונה
- אחריות על המוצרים היא אצל היצרנים בהתאם לGMP
- מ2004 החזרות מוגברות מהשוק של מוצרים המכילים תוספי תזונה מעורבבים עם רכיבים פרמצבטיים.
- NDI – מסגרת רגולטורית רוויית ביקורת על שלא נאכפת מספיק

50 Packs of Happy Hour Vitamins SALE

~~$69.00~~ $39.00 Sale

ADD TO CART

$10 Off Until 9/21!

The perfect party favor, gift, or vacation must pack. Take a dose before/while drinking to help prep your body for the negatives of alcohol.

50 Packs of Happy Hour Vitamins

FREE SHIPPING & 100% Satisfaction Guarantee

FDA Sends Warning Letters to Seven Companies Illegally Selling Hangover Products

Constituent Update

July 29, 2020

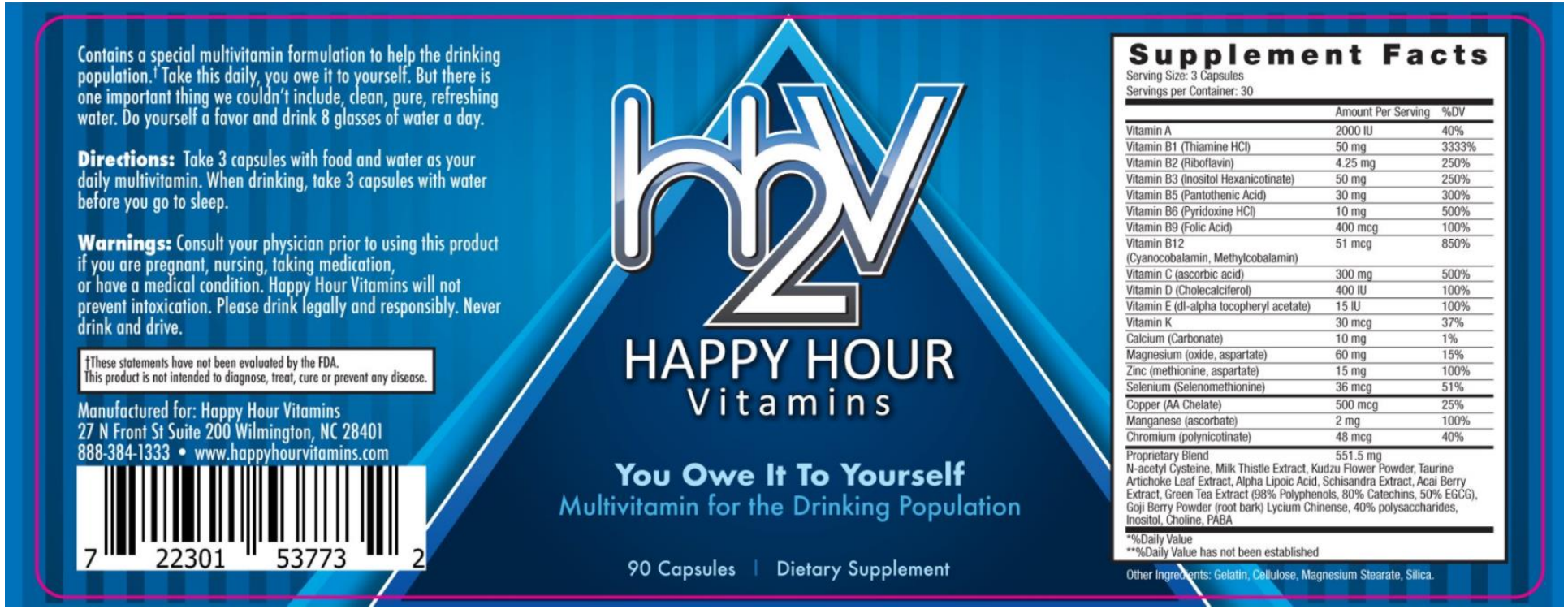
On July 29, 2020, the U.S. Food and Drug Administration (FDA) issued warning letters to seven companies whose products claim to cure, treat, mitigate, or prevent hangovers. A hangover can occur after alcohol intoxication. Alcohol intoxication, like all poisonings, causes dose-related dysfunction and damage, ranging from mild impairments to death. Alcohol intoxication causes temporary damage to brain function, causing impairments of judgment, attention, reflexes, and coordination. The products outlined in these letters, which are labeled as dietary supplements, are unapproved new drugs and have not been evaluated by the FDA to be safe and effective for their intended use.

Dietary supplements that claim to cure, treat, mitigate, or prevent hangovers could potentially harm consumers, particularly young adults, who may be led to believe that using these products, rather than drinking in moderation or not at all, can prevent or mitigate health problems caused by consuming too much alcohol. Consumers should not rely on these products as an alternative to responsibly limiting their consumption of alcoholic beverages.

Warning letters were sent to the following companies:

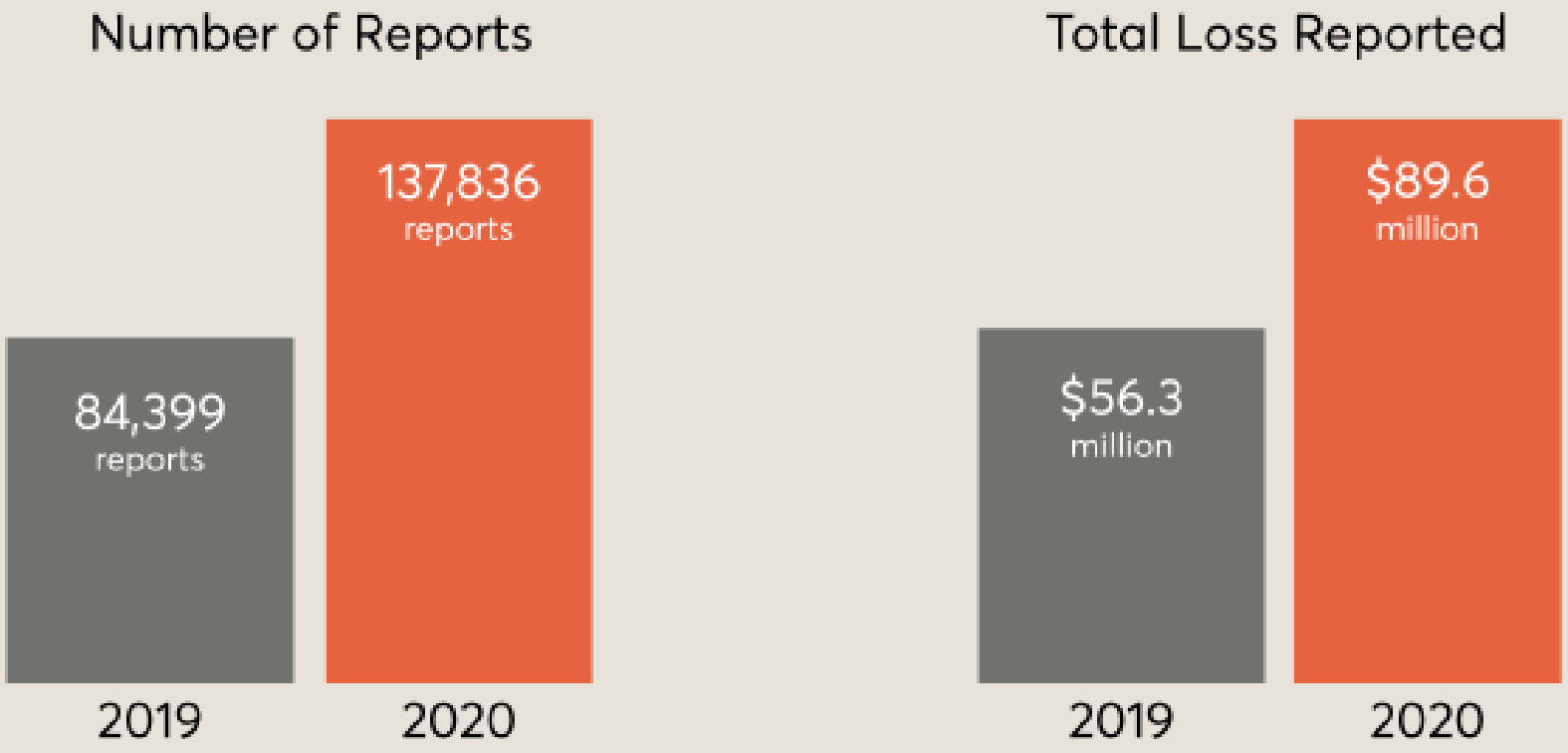
- Double Wood LLC
- Ebnsol Inc.
- Vita Heaven, LLC dba Hangover Heaven
- Happy Hour Vitamins

האם מדובר ברכיב חדש???



Fraud Reports Are on the Rise

The number of reported cases of online shopping fraud reported to the Federal Trade Commission jumped by more than 60 percent in the first two quarters of 2020, after the 2019 coronavirus outbreak occurred, compared with the same time period in 2019.



Source: Federal Trade Commission.

- Dietary supplements – information for consumers

- **CFR - Code of Federal Regulations Title 21**

A) Dietary supplement containing multiple vitamins (see 21 CFR 101.36(e)(10)(i)):

Supplement Facts

Serving Size 1 Tablet

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	5000 IU	100%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D (as cholecalciferol)	400 IU	100%
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU	100%
Thiamin (as thiamin mononitrate)	1.5 mg	100%
Riboflavin	1.7 mg	100%
Niacin (as niacinamide)	20 mg	100%
Vitamin B_6 (as pyridoxine hydrochloride)	2.0 mg	100%
Folate (as folic acid)	400 mcg	100%
Vitamin B_{12} (as cyanocobalamin)	6 mcg	100%
Biotin	30 mcg	10%
Pantothenic Acid (as calcium pantothenate)	10 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, propylparaben, and sodium benzoate.

B) Dietary supplement containing multiple vitamins for children and adults (see 21 CFR 101.36(e)(10)(ii)):

Supplement Facts

Serving Size 1 Tablet

Amount Per Serving		% Daily Value for Children Under 4 Years of Age	% Daily Value for Adults and Children 4 or more Years of Age
Calories	5		
Total Carbohydrate	1 g	†	< 1%*
Sugars	1 g	†	†
Vitamin A (50% as beta-carotene)	2500 IU	100%	50%
Vitamin C	40 mg	100%	67%
Vitamin D	400 IU	100%	100%
Vitamin E	15 IU	150%	50%
Thiamin	1.1 mg	157%	73%
Riboflavin	1.2 mg	150%	71%
Niacin	14 mg	156%	70%
Vitamin B_6	1.1 mg	157%	55%
Folate	300 mcg	150%	75%
Vitamin B_{12}	5 mcg	167%	83%

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Sucrose, sodium ascorbate, stearic acid, gelatin, maltodextrins, artificial flavors, dl-alpha tocopheryl acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, beta-carotene, folic acid, cholecalciferol, and cyanocobalamin.

C) Multiple vitamins in packets (see 21 CFR 101.36(e)(10)(iii)):

Supplement Facts

Serving Size 1 Packet
Servings Per Container 10

Amount Per Serving	AM Packet	% Daily Value	PM Packet	% Daily Value
Vitamin A	2500 IU	50%	2500 IU	50%
Vitamin C	60 mg	100%	60 mg	100%
Vitamin D	400 IU	100%		
Vitamin E	30 IU	100%		
Thiamin	1.5 mg	100%	1.5 mg	100%
Riboflavin	1.7 mg	100%	1.7 mg	100%
Niacin	20 mg	100%	20 mg	100%
Vitamin B_6	2.0 mg	100%	2.0 mg	100%
Folic Acid	200 mcg	50%	200 mcg	50%
Vitamin B_{12}	3 mcg	50%	3 mcg	50%
Biotin			30 mcg	10%
Pantothenic Acid	5 mg	50%	5 mg	50%

Ingredients: Sodium ascorbate, ascorbic acid, calcium pantothenate, niacinamide, dl-alpha tocopheryl acetate, microcrystalline cellulose, artificial flavors, dextrin, starch, mono- and diglycerides, vitamin A acetate, magnesium stearate, gelatin, FD&C Blue #1, FD&C Red #3, artificial colors, thiamin mononitrate, pyridoxine hydrochloride, citric acid, lactose, sorbic acid, tricalcium phosphate, sodium benzoate, sodium caseinate, methylparaben, potassium sorbate, BHA, BHT, ergocalciferol and cyanocobalamin.

D) Dietary supplement containing dietary ingredients with and without RDIs and DRVs (see 21 CFR 101.36(e)(10)(iv):

Supplement Facts

Serving Size 1 Capsule

Amount Per Capsule	% Daily Value
Calories 20	
Calories from Fat 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 4250 IU	85%
Vitamin D 425 IU	106%
Omega-3 fatty acids 0.5 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

		RDI			
Nutrient	Unit of measure	Adults and children ≥ 4 years	Infants[1] through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Vitamin D	Micrograms (mcg)[2]	20	10	15	15
Calcium	Milligrams (mg)	1,300	260	700	1,300
Iron	Milligrams (mg)	18	11	7	27
Potassium	Milligrams (mg)	4,700	700	3,000	5,100
Vitamin A	Micrograms RAE[3] (mcg)	900	500	300	1,300
Vitamin C	Milligrams (mg)	90	50	15	120
Vitamin E	Milligrams (mg)[4]	15	5	6	19
Vitamin K	Micrograms (mcg)	120	2.5	30	90
Thiamin	Milligrams (mg)	1.2	0.3	0.5	1.4
Riboflavin	Milligrams (mg)	1.3	0.4	0.5	1.6
Niacin	Milligrams NE[5] (mg)	16	4	6	18
Vitamin B_6	Milligrams (mg)	1.7	0.3	0.5	2.0
Folate[6]	Micrograms DFE[7] (mcg)	400	80	150	600
Vitamin B_{12}	Micrograms (mcg)	2.4	0.5	0.9	2.8
Biotin	Micrograms (mcg)	30	6	8	35
Pantothenic acid	Milligrams (mg)	5	1.8	2	7
Phosphorus	Milligrams (mg)	1,250	275	460	1,250
Iodine	Micrograms (mcg)	150	130	90	290
Magnesium	Milligrams (mg)	420	75	80	400
Zinc	Milligrams (mg)	11	3	3	13
Selenium	Micrograms (mcg)	55	20	20	70
Copper	Milligrams (mg)	0.9	0.2	0.3	1.3
Manganese	Milligrams (mg)	2.3	0.6	1.2	2.6
Chromium	Micrograms (mcg)	35	5.5	11	45
Molybdenum	Micrograms (mcg)	45	3	17	50
Chloride	Milligrams (mg)	2,300	570	1,500	2,300
Choline	Milligrams (mg)	550	150	200	550
Protein	Grams (g)	N/A	11	N/A	[8]71

§101.36 Nutrition labeling of dietary supplements.

Government of Canada

Natural Health Product Regulation in Canada

CANADA

- NNHPD – רגולציה קרובה יותר לתרופות
- חובה להוכיח יעילות ובטיחות, אולם סטנדרטים בינוניים וחובת ההוכחה היא על היצרנים והמפיצים.
- אישור פוזיטיבי של כל המוצרים בדומה לישראל
- נהלים ברורים לעבודה מול הרגולטור

Natural Health Products Ingredients Database

monographs

Quality of Natural Health Products Guide

licensed natural health products

Requirements	Application type							Notification
	Class I		Class II or III			Class III		
	Compendial	Amendment	General	Traditional	Amendment	Homeopathic	Amendment	
Natural Health Product Licence Application form	✓	Not applicable	✓	✓	Not applicable	✓	Not applicable	Not applicable
Amendment and Notification Form	Not applicable	✓	Not applicable	Not applicable	✓	Not applicable	✓	✓
Label text	✓	If applicable to the proposed changes	✓	✓	If applicable to the proposed changes	✓	If applicable to the proposed changes	If applicable to the proposed changes
Summary Report (Evidence, Safety and/or Quality)	Not applicable	If applicable	Recommended	Recommended	Recommended	Recommended	Recommended	Not applicable
Evidence	See section 5.1.1.4	See section 5.1.1.4	✓	✓	✓	✓	✓	Not applicable
Animal Tissue Form (if applicable)	✓	✓	✓	✓	✓	✓	✓	Not applicable
Finished Product Specifications	See section 5.1.1.6	If applicable to the proposed changes	✓	✓	If applicable to the proposed changes	✓	If applicable to the proposed changes	Not applicable

Amendment

11 (1) If the licensee makes any of the following changes in respect of the natural health product, the licensee shall not sell any lot or batch of the natural health product affected by the change unless the product licence is amended accordingly:

(a) a change to its recommended dose;

(b) a change to its recommended duration of use;

(c) the deletion or modification of risk information shown on any of its labels, including the deletion or modification of a caution, warning, contra-indication or known adverse reaction associated with its use;

(d) a change of its recommended use or purpose;

(e) a change of the source material of any of its medicinal ingredients;

(f) changing any of its medicinal ingredients to or from being synthetically manufactured;

(g) a change to the potency of any of its medicinal ingredients;

(h) a change affecting its safety or efficacy that does not arise as a result of

(i) a change to the quantity of a medicinal ingredient per dosage unit,

(ii) the addition or substitution of a medicinal ingredient,

(iii) a change to its dosage form, or

(iv) a change to its recommended route of administration; or

(i) one or more of the following changes to its specifications, namely,

(i) the removal of a test method set out in the specifications,

(ii) the modification of a test method set out in the specifications in a manner that widens the purity tolerances of the natural health product or the quantity, identity or potency tolerances of any of its medicinal ingredients, or

(iii) the modification of a test method set out in the specifications in a manner that renders it less precise, accurate, specific or sensitive.

Class I

Class I applications are those that must comply with all of the parameters of an individual NNHPD monograph (exactly as worded in the monograph). Applicants can only reference one NNHPD monograph per application in Class I. Modifications to any of the parameters of a monograph are not permitted (e.g. the use of "statements to the effect of" will not be accepted in Class I).

Class II

Class II applications are general and traditional applications supported entirely by a combination of 2 or more NNHPD monographs as well as the following scenarios:

- Applications supported entirely by an individual NNHPD monograph with a deviation to one or more monograph statements which maintains the intent of the monograph(s) statements (e.g. "statements to the effect of");
- Applications supported entirely by a combination of NNHPD monographs with a deviation to one or more monograph statements which maintains the intent of the monograph(s) statements (e.g. "statements to the effect of");
- Products supported entirely by a combination of NNHPD monographs with the addition of common fruits or vegetables listed in the Canadian Nutrient File, excluding source materials listed as "refuse", with a daily dose of up to 10 g (of crude material or quantity crude equivalent for non-standardized extracts).

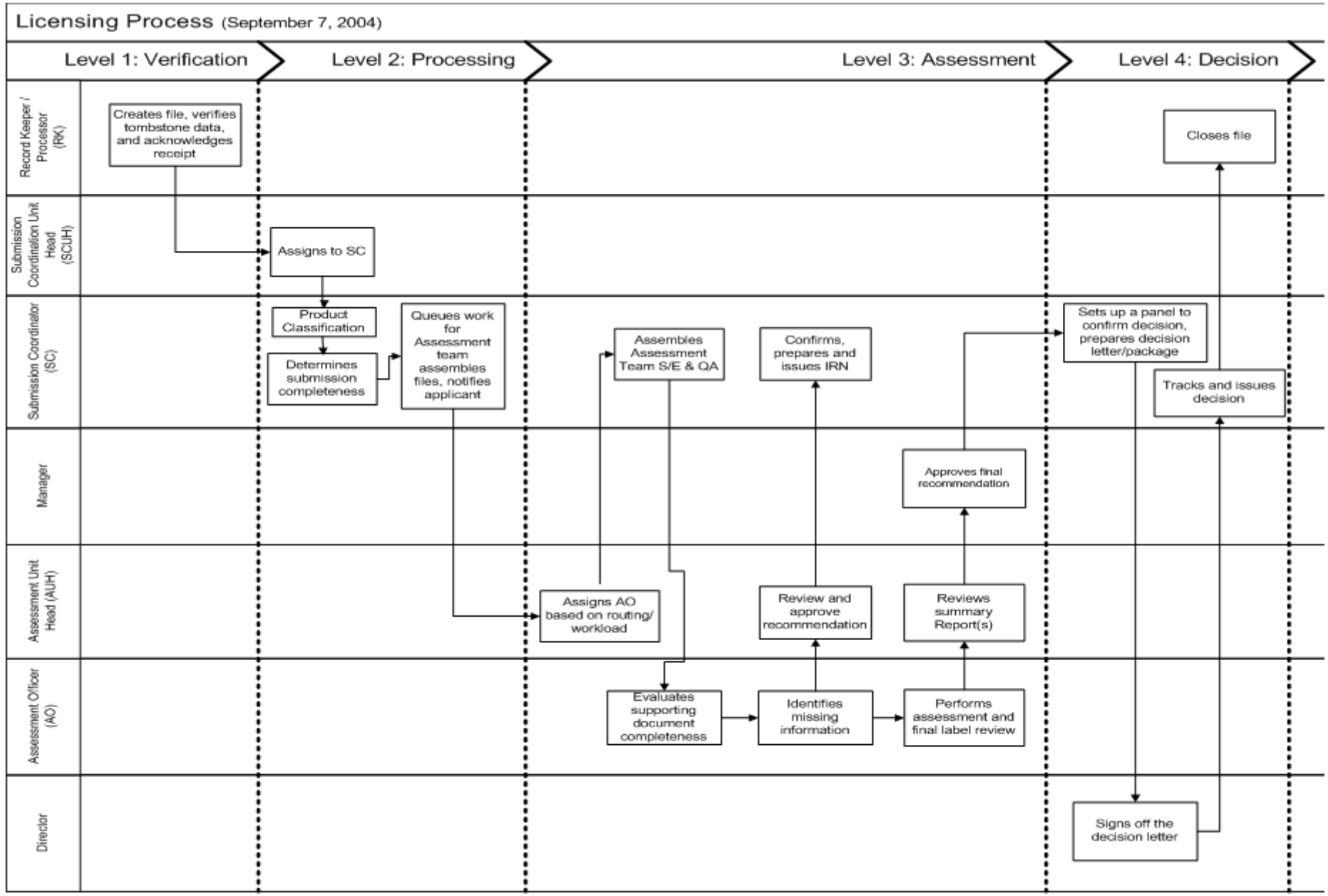
Homeopathic applications with specific claims are not accepted in Class II.

Class III

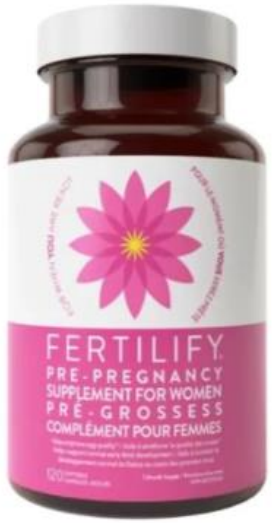
Cla applications are comprised of general, traditional and homeopathic applications requiring full assessment (not captured above in Class I or II) and include, but are not limited to, the following scenarios:

- Products with a novel preparation and/or dosage delivery system presenting unique safety and/or efficacy profiles;
- Applications referencing a Master File to support safety, efficacy and/or quality (see section 4.5 for information on Master Files, including a definition).
- Products with ingredient combination issues (including those covered by a monograph) that may require safety assessment. These combinations include but not exclusive to the following lower certainty combinations and combination risk factors (e.g. stimulant laxatives combined with diuretics, weight management ingredients/claims in combination with diuretics, combination hormonal effect products, combination sedative ingredients). These combinations are reviewed on a case by case basis.
- Applications partially referencing monograph information but going beyond the parameters established in the relevant monograph(s). For example, a dosage form or route of administration not indicated on the monograph(s) that requires further assessment.
- Homeopathic applications with specific claims.

Please refer to section 4.1 for guidance and supporting documents regarding the safety, efficacy and quality requirements for Class III applications.


Licensing Process (September 7, 2004)
Level 1: Verification
Level 2: Processing
Level 3: Assessment
Level 4: Decision
Record Keeper / Processor (RK)
Submission Coordination Unit Head (SCUH)
Submission Coordinator (SC)
Manager
Assessment Unit Head (AUH)
Assessment Officer (AO)
Director
Creates file, verifies tombstone data, and acknowledges receipt
Assigns to SC
Product Classification
Determines submission completeness
Queues work for Assessment team assembles files, notifies applicant
Assembles Assessment Team S/E & QA
Confirms, prepares and issues IRN
Sets up a panel to confirm decision, prepares decision letter/package
Closes file
Tracks and issues decision
Approves final recommendation
Assigns AO based on routing/ workload
Review and approve recommendation
Reviews summary Report(s)
Evaluates supporting document completeness
Identifies missing information
Performs assessment and final label review
Signs off the decision letter

Variations of 'fertility' in supplement names



The Montreal-based maker of Fertil Pro says its products "boost fertility." Fertilify says its products are designed to "support fertility." In both cases, CSPI said the evidence the companies provided didn't come close to backing those claims. (Yad-Tech, Fertilify)

Toronto's Fertilify says on its website that its products are designed to "support fertility." The product page for its pre-pregnancy supplement until recently said it "supports fertility when trying to conceive naturally." The Montreal-based maker of Fertil Pro says its products "boost fertility." In both cases, CSPI said the evidence the companies provided didn't come close to backing those claims.

1.5370249https://www.cbc.ca/news/health/canadian-fertility-supplements-targeted-

A: Misleading

Question added: May 8, 2020

Vitamin C is an essential nutrient that is naturally found in some vegetables and fruits, particularly oranges and other citrus fruits. While some individuals treat the common cold with vitamin C, there is little evidence to support its efficacy. There is currently **no evidence that vitamin C is effective in the prevention or treatment of COVID-19.** High doses especially may cause stomach upset and diarrhea. However, more research is underway to study the effects of using large doses of vitamin C to treat COVID-19, including a Canadian trial.

(Source: iHealthfacts - Can large doses of vitamin C prevent or treat COVID-19?)

Q: Does taking vitamin D supplements prevent COVID-19? I heard people with vitamin D deficiencies have more severe COVID-19 symptoms.

A: Misleading

Question added: May 1, 2020; updated May 7, 2020

Vitamin D is produced naturally when you are exposed to sunlight. While there is some evidence that points to vitamin D in helping to protect against respiratory tract infections, there are only clinical trials still being undertaken to see if vitamin D has a role in COVID-19 prevention or treatment. There is currently no reliable evidence that vitamin D supplements can be used to prevent or treat symptoms of COVID-19.

However, as many are staying indoors adhering to public health guidance, vitamin D levels may be lower than usual. As such, if a person cannot reach healthy levels of vitamin D through sun exposure and/or a healthy diet, some governments advise taking (no more than) the recommended levels of vitamin D supplements.