Invest NOVA SCOTIA

TRADE MARKET INTELLIGENCE REPORT

Natural Health & Personal Care Product Regulations in Canada and the U.S.

Prepared for Invest Nova Scotia - May 2025

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Natural Health & Personal Care Product Regulations in Canada and the U.S.

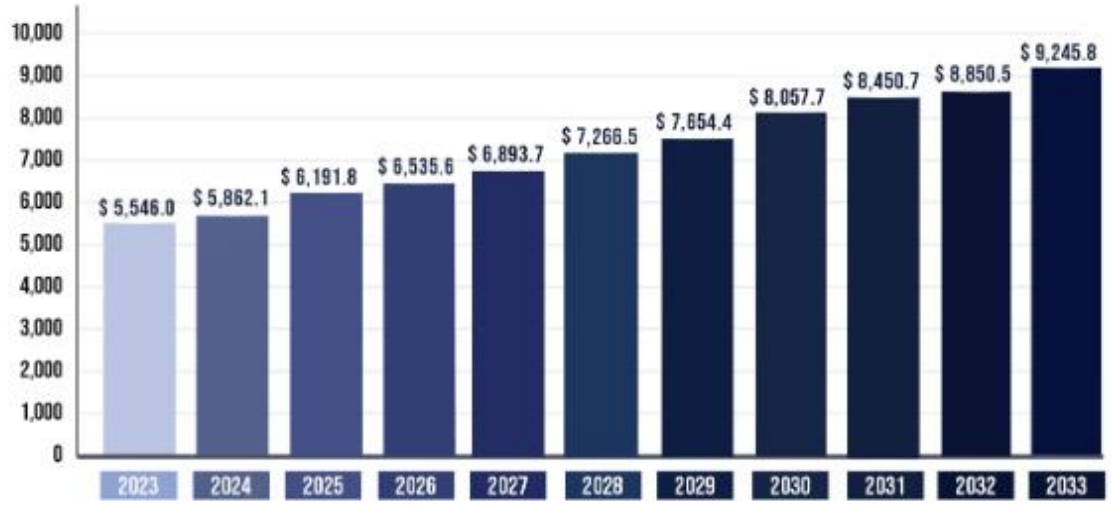
Overview

Consumers are spending more on wellness than they ever have before. Wellness is now a $1.5 trillion USD market globally – and it's growing at a rate of 5 to 10 percent each year. McKinsey research shows that consumers are most interested in six wellness categories: health, fitness, nutrition, appearance, sleep, and mindfulness. In the future, executives predict that consumers will seek more control and personalization in wellness products and services.

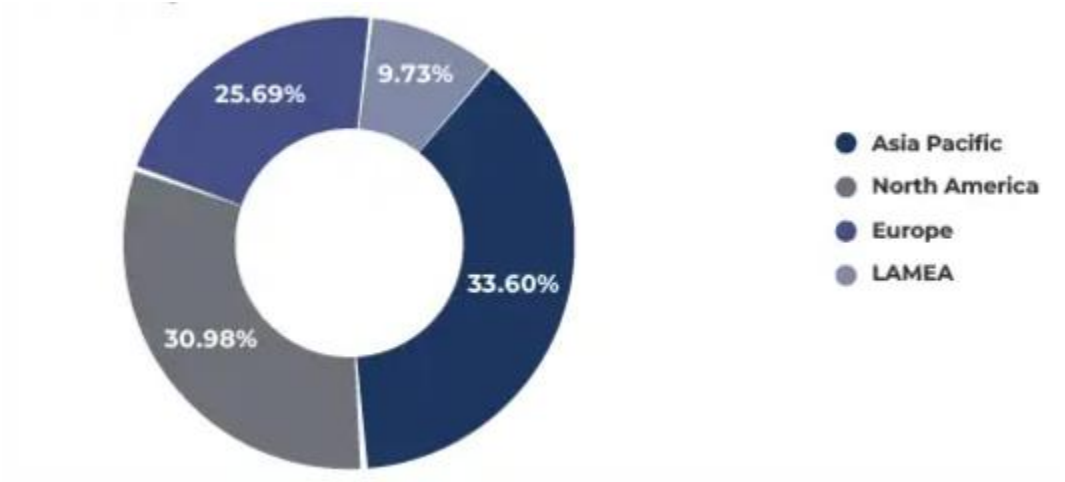
The demand for natural and "clean" products is steadily growing. Digital and social channels are becoming more influential, and consumers are increasingly looking for wellness-related services, not just products. According to Precedence Research, the global health and wellness market size was estimated at $5,546 billion USD in 2023 and is predicted to grow from $5,862 billion USD by 2024 to approximately $9,245 billion USD by 2033.

North America is expected to be the most opportunistic during the forecast period. The health and wellness industry in North America is growing as consumer disposable income rises, health consciousness grows, and demand for healthy products increase. The presence of leading industry players, as well as their development plans, have a substantial impact on market growth. The rising incidence of chronic illnesses, along with restricted activity time, highlights the need for the supply of diet, lifestyle, and fitness instruction to reduce the impact of these ailments.[i]

Graph 1: Health and Wellness Market Size 2023 to 2033 (USD Billion) ii



Graph 2: Health and Wellness Market Share, By Region, 2023 (%)iii



With growing demand, there are broad opportunities for nutraceutical, supplement, and personal care product manufacturers in Nova Scotia. However, understanding how a product is legally defined and what related regulations apply can be a challenge. Companies interested in exporting to the United States (U.S.) must also understand the differences between U.S. and Canadian regulatory compliance.

This report is meant to provide an introduction and overview of how Canada and the U.S. regulate natural health and personal care products. This pertains to supplements, nutraceuticals, cosmeceuticals, vitamins, and beauty products with wellness benefits. This report will not cover the regulations for prescription or controlled drug/pharmaceutical products, or for Canadian over-the-counter drugs, as the regulatory requirements for these types of products is much more extensive than is often required for natural health and personal care products. However, it is important to understand the line between these product categories and how the use of some ingredients or therapeutic claims may cause a natural product to be regulated as a drug. This report also aims to help clarify how these distinctions are made.

Please note that this report does not constitute legal advice regarding the interpretation of any of the laws, acts, or regulations mentioned. Companies with questions about their legal obligations and responsibilities should seek the advice of legal counsel.


Canada

Canadian Classification

Personal care products and products such as supplements may fall under three basic categories of regulation: **drugs, cosmetics**, or **natural health products**. The ingredient content, how the product is represented for sale, and its intended purpose determines how a product is classified.[iv]

A "**drug**" is classified as any substance or mixture of substances manufactured, sold or represented for use in:

- the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals;
- restoring, correcting or modifying organic functions in human beings or animals; or,
- disinfection in premises in which food is manufactured, prepared or kept.[v]

A "**cosmetic**" includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes.[vi] Products claiming therapeutic effects or that contain certain active ingredients are not considered cosmetics.[vii]

Under the Natural Health Products Regulations, which came into effect on January 1, 2004, **natural health products** (NHPs) are defined as:

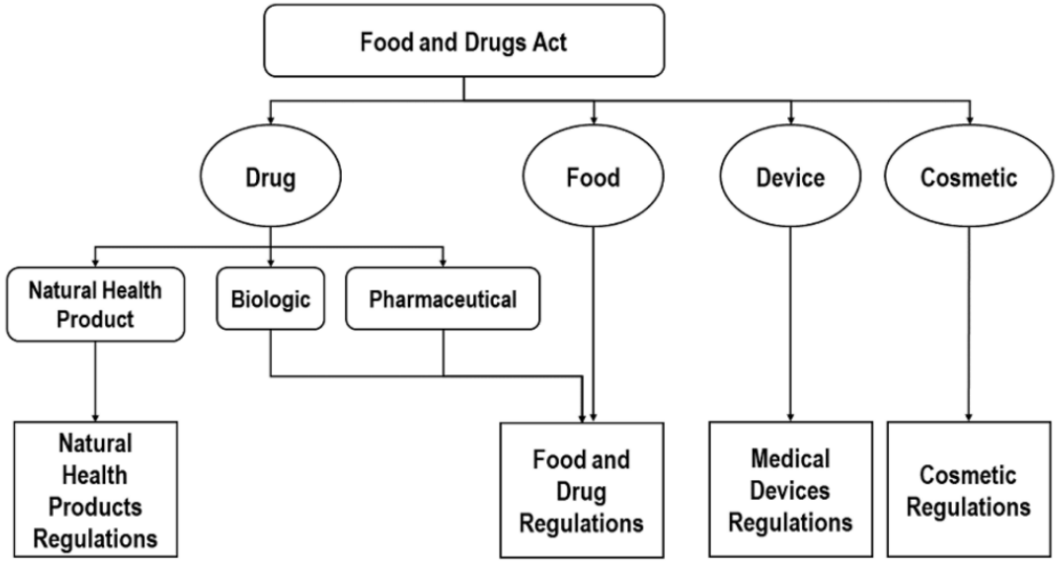
- probiotics
- herbal remedies
- vitamins and minerals
- homeopathic medicines
- traditional medicines such as traditional Chinese medicines
- other products like amino acids and essential fatty acids[viii]

NHPs are defined as a substance set out in Schedule 1: Included Natural Health Product Substances of the *Natural Health Products Regulations;* a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1; a homeopathic medicine; or a traditional medicine, that is manufactured, sold or represented in:

- The diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal state or its symptoms in humans
- Restoring or correcting organic functions in humans; or
- Modifying organic functions in humans

A natural health product does not include a substance set out in Schedule 2: Excluded Natural Health Products Substances.

Figure 1: Visual Overview of Regulations that apply to each Product Line[ix]



Representation of Sale

The way a product is represented for use and the claims presented on labels, packaging, and in advertisements will affect how it is classified and regulated. This included both explicit and implied representation through words, symbols and pictures.

The *Food and Drugs Act* clearly states that a classification decision is made on the definition and the representation for sale of a given product. For **drugs**, misleading or deceptive claims are general offences under the *Food and Drugs Act*. For **cosmetics**, a certain degree of discretion and judgement is exercised with respect to "puffery" (hyperbole about a product that does not contain factual claims of merit), unless is strays into the therapeutic area. False or misleading claims for cosmetics are offences under section 7(1) of the *Consumer Packaging and Labelling Act*. Products for which therapeutic claims are made are evaluated.

Another main distinguishing feature of representation is the aspect of specific dose instructions to ensure efficacy which is generally associated with drug products. Proof of efficacy is essential to drugs to ensure that the benefits outweigh the risks. There should be no risk from the lack of cosmetic efficacy, which are applied on an as-desired basis. This should not be confused with directions for safe use, which are required for all products pursuant to the *Food and Drugs Act*.[x]

Cosmetics

Regulations

All cosmetics sold in Canada must be safe to use and must not pose any health risk. They must meet the requirements of the *Food and Drugs Act* and the *Cosmetic Regulations*. Requirements under other legislation must also be met, if applicable.[xi]

The *Cosmetic Regulations* and the *Food and Drugs Act* require that cosmetics sold in Canada are manufactured, prepared, preserved, packed and stored under sanitary conditions. The manufacturer and importer must:

- provide a list of the product's ingredients
- notify Health Canada that they are selling the product

Requirements such as the *Consumer Packaging and Labelling Act (CPLA),* the *Canadian Environmental Protection Act, 1999 (CEPA)* and the *Cannabis Act*, must also be met, if applicable.

Registration

According to section 30 of the *Cosmetic Regulations*, all cosmetic manufacturers and importers must notify Health Canada within 10 days after they first sell a cosmetic in Canada. Failure to notify may result in a product being denied entry into Canada or removed from sale. Under section 31, any changes to the product information provided under section 30 requires manufacturers and importers to update Health Canada.

Some examples of changes include:

- modification of the cosmetic formulation
- update to product name
- new company name, address or contact information
- discontinuation of sale

To notify Health Canada of a new cosmetic, amendment to an existing notification, or to discontinue the sale of a cosmetic, you must fill out and submit a Cosmetic Notification Form (CNF).

The completed CNF provides specific information to Health Canada, including:

- product brand and name
- the name and address of the person who submits the cosmetic notification
- manufacturing and importing information
- label contact information
- type of product (leave-on or rinse-off) *New*
- area of application
- function of the cosmetic
- form of the cosmetic (for example: cream, gel or powder)
- ingredients of the cosmetic
- concentration of each ingredient

There is no fee associated with the cosmetic notification process. To submit additional documents related to your cosmetic after a notification has been sent, such as copies of the labels or inserts, use the Transport Form for Submitting Additional Documents to Health Canada.

You should review the Guide for Cosmetic Notifications to ensure your cosmetic notification form is competed correctly.[xii]

Labelling

Cosmetic labelling is subject to two Acts and their associated regulations:

- The *Food and Drugs Act* and the *Cosmetic Regulations*
- The *Consumer Packaging and Labelling Act and the Consumer Packaging and Labelling Regulations*

Labelling helps consumers make more informed decisions about the cosmetics they use, since they can easily identify ingredients to which they may be sensitive. Mandatory ingredient labelling using the **International Nomenclature of Cosmetic Ingredients (INCI)** system also lets doctors refer to one common name. This is useful for treatments and incident reporting purposes.

Many other countries also use the INCI system. This means that people from Canada who travel abroad will be able to recognize, and avoid ingredients, without needing to know other terminology.[xiii]

Resources

- Guide to Cosmetic Ingredient Labelling
- Guide to the Consumer Packaging and Labelling Act and Regulations
- Labelling of Cosmetics
- Labelling Requirements for Cosmetics in Pressurized Containers
- Guidelines for the non-prescription and cosmetic industry regarding non-therapeutic advertising and labelling claims

Marketing and Advertisement

Advertising Standards Canada (ASC) is the national, not-for-profit, advertising self-regulatory body that administers the Canadian Code of Advertising Standards. The ASC also administers the *Guidelines for the Nonprescription and Cosmetic Industry regarding Non-therapeutic Advertising and Labelling Claims* which help marketers differentiate non-therapeutic/cosmetic claims from therapeutic/health claims. Prior to broadcast, radio or television ads are previewed and cleared with ASC.

Advertising promotes the sale of a product. The advertisement should clearly communicate the intended use of the cosmetic in a manner that is consistent with the definition under the *Food and Drugs Act*. Claims on a label or in an ad for what a cosmetic can do must be accurate, so they do not mislead people.

Therapeutic claims are those that indicate or suggest modifying body functions or prevent or treat a disease or condition. These types of claims are only allowed on drugs or natural health products, not on cosmetic products and are required to carry a drug identification number (DIN) or natural product number (NPN). [xiv]

Common Marketing Terms

Marketing terms may be used on cosmetic product labels, packaging or in radio television or print ads. Health Canada does not regulate these as they are not related to health or safety. However, the Competition Bureau regulates marketing terms and can take action on those that are false or misleading as per the *Competition Act* and *Consumer Packaging and Labelling Act.*

Here are some commonly used marketing terms you may come across:

- Fragrance-free or unscented
- Hypoallergenic
  - "**Hypoallergenic**" is not a legal or a scientific term. It means the manufacturer has chosen ingredients that have the least chance of causing an allergy. This does not mean the product will not cause an allergic reaction in some people, as there are no non-allergenic cosmetics
- Preservative-free
- Ophthalmologist-tested/dermatologist-tested
  - A test was conducted to make sure that the product is not (or is less) irritating to eyes or skin and
  - A skin or eye doctor was involved in the test at some point during the study
- Not tested on animals
  - The cosmetic animal testing ban came into force on December 22, 2023. At this time, the cosmetics industry will be required to retain proof that their cosmetic is not tested on animals if their labels or advertisements make such claims
- Organic
  - "**Organic**" means that a plant or other natural material is certified to be produced without pesticides[xv]

Relevant Resources

- Good Manufacturing Practices (GMPs)
- Guidance Document: Classification of Products at the Cosmetic-Drug Interface
- Guide to Completing Cosmetic Notification Forms
- Cosmetic Ingredient Hotlist
- Product Assessment Against Criteria: Antiperspirants
- Product Assessment Against Criteria: Diaper Rash Products
- Heavy Metals in Cosmetics
- Advance notice of importation process for cosmetics and drugs
- Guidance document: Evidence of safety requirements for tooth whitening products containing peroxide and peroxide-generating compounds
- Determination of Flame Projection – Official Method D0-30

Natural Health Products

Regulations

The Natural and Non-prescription Health Products Directorate (NNHPD) is the regulating authority for **natural health products (NHPs)** in Canada. All NHPs are regulated under the *Natural Health Products Regulations*, which is a separate and distinct regulatory framework from prescription drugs. NHPs are regulated in a manner appropriate for the lower-risk nature of these products which include:

- herbal remedies
- some sunscreens
- vitamins and minerals

Under the regulations, companies that manufacture, package, label, or import NHPs must:

- hold valid product and site licences
- follow good manufacturing practices (GMP) requirements

In 2021, the Commissioner of the Environment and Sustainable Development completed an audit of Health Canada's NHP program, resulting in Health Canada identifying key initiatives for the program including improved labelling, inspections, cost recovery and extending the *Protecting Canadians from Unsafe Drugs Act (Vanessa's law)* to NHPs.

Licensing

All NHPs sold in Canada require a **product license** before being marketed. Obtaining a license requires submitting a Natural Health Product Licence Application Form to Health Canada which details information on the product, including:

- Medicinal ingredients
- Source
- Potency
- Non-medicinal ingredients
- Recommended use

Once a product licence application has been assessed and granted market authorization by Health Canada, the product label will bear an eight-digit **product licence number** preceded by the distinct letters NPN (Natural Product Number), or, in the case of a homeopathic medicine, by the letters DIN-HM.[xvi]

The Licenced Natural Health Database (LNHPD) contains information about natural health products that have been issued a product licence by Health Canada. These products have been assessed by Health Canada and found to be safe, effective and of high quality under their recommended conditions of use. Consumers 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.

Classes of Applications

When applying for a product licence, it is important to understand the concept of monographs as they partially determine which type of application to use. A **NNHPD monograph** is a written description of particular elements on an identified ingredient or product. NNHPD published a Compendium of Monographs that allows applicants to support the safety, efficacy, and quality of an NHP in their application. There are **three classes of applications** as described below. [xvii]

Class I applications are those that must comply with all of the parameters of an Individual Natural and Non-prescription Health Products Directorate (NNHPD) monograph (exactly as worded in the monograph with no modifications).

Class II applications are general and traditional applications supported entirely by a combination of two 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 maintain 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 dos of up to 10g (If crude material or quantity crude equivalent for non-standardized extracts.

Class III applications are comprised of general, traditional, and homeopathic application 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.
- Products with **ingredient combination issues** (including those covered by a monograph) that may require safety assessment. These combinations include but are not exclusive to the following lower certainty 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.

The following table outlines the various application requirements by class and application types.
Figure 5: Product Application Requirements[xviii]

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

Site Licensing

Section 27 of the *Natural Health Products Regulations* requires a manufacturer, packager, labeller, and/or importer of NHPs for sale to hold a valid site licence. A site licence issued by the NNHPD gives the licensee authorization to conduct the activities listed on the licence.

In order to maintain the validity of the site licence, a licensee must renew and amend (if applicable) their site licence and notify the NNHPD of changes to the information submitted in their site licence application.

To apply for a site licence, applicants must provide the NNHPD, a site license application which includes the following forms and documents:

1. **Site Licence Application (SLA) Form:** captures all of the information outlined in section 28 (a) to (e) of the *Natural Health Products Regulations*.
2. **Designated Party Authorization (DPA) Form (when applicable):** must submit when applicants/licensees have designated a third-party person to file a submission with the NNHPD on their behalf.
3. **Evidence of Good Manufacturing Practices compliance:** This may be demonstrated by providing a certificate from a qualified authority or a complete Quality Assurance Report (QAR) form. Good Manufacturing Practices guidelines can be found here.[xix]

The Site Licensing Guidance Document provides an overview of the requirements, rights and responsibility of the licensee and the NNHPD in regards to site licensing.

Labelling

Labelling and packaging requirements are set out by the *Natural Health Products Regulations* and are enforced by Health Canada. A supplementary guidance document has been created to provide information on label design specifications, required sections of the product facts table and labelling content to meet the regulatory requirements.

Information required on the principal display panel of the inner and outer labels:

- brand name
- product number
- dosage form
- "sterile" (if applicable)
- net amount in the immediate container in terms of weight, measure or number

Information required on the inner label:

- the name of the product licence holder or importer
- the contact information of the product licence holder or person who represents the product licence holder or importer (telephone number, email address or website address)
- medicinal ingredients, quantity of each ingredient per dosage unit, and potency of each ingredient (if applicable)
- at least one use or purpose
- recommended route of administration
- dose
- duration of use, if any
- source of food allergens, gluten, and added sulphites, if applicable
- contains aspartame disclosure
- risk information
- other information (for example, recommended storage conditions)
- lot number
- expiry date

Information required on the outer label:

- a product facts table (if required)
- the name of the licence holder or importer (as applicable - only one of the two is required)
- recommended route of administration (specifying an oral route of administration is not needed if it is implied by the dosage form)
- lot number
- expiry date

The *Regulations Amending the Natural Health Products Regulations* came into force on June 21, 2022. However, for provisions related to the labelling requirements (sections 17 to 22), these will come into force on June 21, 2025. Any natural health product for which a product licence is issued **before** June 21, 2025, has until June 22, 2028, before they are required to comply with the new labelling requirements. Any natural health product for which a product licence is issued **on or after** June 21, 2025, will have to meet the new labelling requirements.[xx]

For questions about NHP labelling, contact Health Canda's Natural and Non-prescription Health Products Directorate at nnhpd.consultation-dpsnso@hc-sc.gc.ca.

For more information refer to the NHP Labelling Guidance Document.

Advertising and Marketing

The **Terms of Market Authorization (TMA)** set out the intended use(s) as authorized by Health Canada through the product licence, product monograph or product label. Promotional claims must align with the product label, monograph, or the scope of the product licence to ensure compliance. When non-compliant claims are identified, Health Canada typically adopts a cooperative approach, issuing a compliance letter that requests corrective action or the cessation of the advertisement. This approach is effective in most cases. However, if compliance is not achieved, Health Canada is prepared to take additional compliance and enforcement measures if necessary.[xxi]

Advertising is for the purpose of promotion the sale of a health product; it is critical to determine whether the purpose of a message is to promote the sale of a health product or to provide information. Health Canada has created Guidance on distinction between advertising and other activities for health products to support this assessment.

The Advertising Standards Canada (ASC) also administers the Guidelines for Consumer Advertising of Health Products which help marketers understand the principles that govern health product advertising, and develop messages that comply with the advertising provisions of Canadian legislation, policies and guidance documents.

Export

Health Products and Food Branch Inspectorate (HPFBI) of Health Canada oversees the importation and exportation of health products under the *Food and Drugs Act* and its regulations, focusing on compliance, risk management, and safety. With globalization increasing the complexity of supply chains their import and export policy for health products ensures imported products meet Canadian standards, while exported products adhere to international agreements like **Mutual Recognition Agreements (MRAs).** MRAs validate the equivalency of good manufacturing practices between Canada and partner nations, supporting the safety and quality of exported health products.

A health product may be exported from Canada if it has been fabricated by a Canadian site licence holder and has received market authorization (NPN or DIN-HM). A health product fabricated in Canada for the sole purpose of export rather than Canadian consumption is not required to have Canadian-approved product labelling, though the label should indicate the product is for export only and that the product is not known to contravene any laws of the importing country. For more information on exporting health products for commercial use.


United States

American Classification

Similar to Canada, the way in which a product is manufactured and marketed affects the regulations that apply to it in the United States (U.S.). However, the categories available, their definitions, and the related regulations differ from those used in Canada.

In the U.S., a **"drug"** is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases and articles (other than food) intended to affect the structure or any function of the body. **Over the counter (OTC) drugs** are drugs that can be purchased without a doctor's prescription.

A **"cosmetic"** is an article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. Included in this definition are products such as skin moisturizers, perfumes, lipsticks, fingernail polishes, and eye and facial makeup preparations. It should be noted that "**soap**" is considered its own category with its own regulations. Cleansers may be regulated as soap, cosmetic or drug, depending on its ingredients and intended use. To learn more, see Cosmetic Product Categories and Codes.

Often cosmetic products that have a medicinal or drug-like benefit are referred to as "**cosmeceutical**" by the cosmetic industry, however, it is important to note this term has no meaning under law in the U.S.[xxii] Unlike in Canada, products can be considered both a drug and a cosmetic, depending on the intended use of a product. For example, shampoo would generally be considered a cosmetic, but an anti-dandruff shampoo would also be considered a drug. Other cosmetic/drug products include some toothpastes that contain fluoride or make anti-cavity or anti-gingivitis claims, deodorants that are also antiperspirants and moisturizers and makeup marketed with sun-protection claims.[xxiii]

The closest the U.S. has to the Canadian natural health product (NHP) category is "**complementary and alternative medicine**" (CAM). CAMs are defined by the National Center for Complementary and Integrative Health as a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine. It is important to note that CAM products are not considered a separate category by the FDA and are instead regulated as part of other FDA categories such as drugs and cosmetics.[xxiv]

A "**dietary supplement**" is regulated by the FDA as a food product but under a different set of rules than conventional food and drug products. Dietary supplements are ingested and intended to add to or supplement the diet. Common supplements can be defined as vitamins, minerals, herb or other botanicals (including compounds), amino acid, and live microbials. [xxv]

Intended Use

The most important factor in determining a product's classification in the U.S. is its "intended use". Products with more than one intended use may even fall under multiple classifications, such as a moisturizer marketed with sun-protection claims. Intended use can be established in many ways, including the claims stated on labeling or in advertising, the effect product reputation has on consumer perception, and the use of ingredients with well-known therapeutic effects.[xxvi]

Cosmetics

Regulations

In the U.S., cosmetics are regulated under the *Food, Drug, and Cosmetic Act (FD&C Act)* and the *Fair Packaging and Labelling Act (FPLA)*. The U.S. Food & Drug Administration (FDA) regulates cosmetics under the authority of these laws. Cosmetics do not require FDA approval before they go to market, unless they contain colour additives. Except for colour additives and prohibited/restricted ingredients, manufacturers may use any ingredients in cosmetics provided that they are safe under the labeled or customary conditions of use, the product is properly labelled, and the ingredient does not cause the cosmetic to be considered "adulterated" or "misbranded".[xxvii]

Additional laws that FDA enforces for cosmetics include:

- *Modernization of Cosmetics Regulation Act of 2022*
- *Microbead-Free Waters Act of 2015*

Registration

The *Modernization of Cosmetics Regulation Act of 2022* (MoCRA) provided new authorities to FDA including:

- **Facility Registration:** Cosmetic product manufacturers and processors must register their facilities with FDA, update content within 60 days of any changes, and renew their registration every two years.
- **Product Listing:** A responsible person must list each marketed cosmetic product with FDA, including product ingredients, and provide any updates annually.

A *responsible person* means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of the *FD&C Act* or section 4(a) of the *FPLA*. [xxviii]

Relevant Resources

- Registration & Listing Cosmetic Product Facilities and Products.
- FORM FDA 5066 Registration of Cosmetic Product Facility Document
- Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products

Labelling

Proper labelling is an important aspect of putting a cosmetic product on the market. FDA regulates cosmetic labelling under the authority of both the *FD&C Act* and the *FPLA*. These laws and their related regulations are intended to protect consumers from health hazards and deceptive practices and to help consumers make informed decisions regarding product purchase.

It is illegal to introduce a misbranded cosmetic into interstate commerce, and such products are subject to regulatory action. **Some of the ways a cosmetic can become misbranded are:**

- its labelling is false or misleading
- its label fails to provide required information
- its required label information is not properly displayed
- its labelling violates requirements of the *Poison Prevention Packaging Act of 1970*

The FDA does not have the resources or authority under the law for pre-market approval of cosmetic product labelling. It is the manufacturer's and/or distributor's responsibility to ensure that products are labelled properly. Failure to comply with labelling requirements may result in a misbranded product.

The following information must appear on the principal display panel:

- **An identity statement:** indicating the nature and use of a product, by means of either the common or usual name, a descriptive name, a fanciful name understood by the public, or an illustration.
- **An accurate statement of the net quality of contents:** in terms of weight, measure, numerical count or a combination of numerical count and weigh or measure.

The following information must appear on an information panel:

- **Name and place of business:** This may be the manufacturer, packer, or distributor. This includes the street address if it is listed in current phone directory or city directory.
- **Distributor statement:** If the name and address are not those of the manufacturer, the label must say "Manufactured for…," or "Distributed by…," or similar wording expressing the facts.
- **Material facts:** Failure to reveal material facts is one form of misleading labelling and therefore makes a product misbranded.
- **Warning and caution statements:** These must be prominent and conspicuous. The *FD&C Act* and related regulations specify warning and caution statements related to specific products. In addition, cosmetics that may be hazardous to consumers must bear appropriate label warnings. An example of such hazardous products is flammable cosmetics.
- **Ingredients:** If the product is sold on a retail basis to consumers, even if it is labelled "For professional use only" or words to that effect, the ingredients must appear on an information panel, in descending order of predominance. Remember, if the product is also a drug, its labelling must comply with the regulations for both OTC drug and cosmetic ingredient labelling, as stated above. To learn more, see "Ingredient Names," "Color Additives and Cosmetics," "Fragrances in Cosmetics," and "Trade Secret Ingredients."[xxix]

Relevant Resources

- Cosmetic Labelling Guide
- Summary of Regulatory Requirements for Cosmetic Labelling
- List of Labelling Regulations for Cosmetics in Title 21 of the Code of Federal Regulations
- Required Warning Statement for Tanning Products Without Sunscreen

Soaps

The FDA's regulatory definition of soap includes the following three conditions; all three conditions must be met to be defined as a soap:

1. **What it is made of:** the product must be composed mainly of the "alkali salts of fatty acids," that is, the material you get when you combine fats or oils with an alkali, such as lye.
2. **What ingredients cause its cleaning action:** those "alkali salts of fatty acids" must be the only material that results in the product's cleaning action. If the product contains synthetic detergents, it is a cosmetic, not a soap. You can still use the word "soap" on the label.
3. **How it's intended to be used:** it must be labelled and marketed only for use as soap. If it is intended for purposes such as moisturizing the skin, making the user smell nice, or deodorizing the user's body, it is a cosmetic. If the product is intended to treat or prevent disease, such as killing germs, or treating conditions, such as acne or eczema, it is a drug. You can still use the word "soap" on the label. The product may be both a cosmetic and a drug. Learn more at Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?).

If your product meets FDA's regulatory definition of soap, it is regulated by the Consumer Product Safety Commission (CPSC), not by FDA.

What if the ingredients are "natural" or "organic"? The laws and regulations that FDA enforces do not have definitions for "natural" or "organic." The same requirements apply to your product no matter whether the ingredients are plant, animal, mineral, or synthetic. It is important not to assume that using only ingredients from plants will make your products safe.

Advertising and Marketing

The law does not require cosmetic labelling to have FDA approval before cosmetic products go on the market, and FDA does not have a list of approved or accepted claims for cosmetics.

Under the law, information on cosmetic labelling, including claims, must be truthful and not misleading. In addition, if a product is marketed with claims for purposes such as treating or preventing disease, or affecting the structure or function of the body – including skin – it is a drug according to the law, and it must meet the requirement for drugs, even if it affects the appearance.

Because the FDA does not have the authority to approve claims before cosmetics go on the market, you may see cosmetics with claims that go beyond what the law permits. FDA monitors cosmetics on the market and can take action against companies that break the laws they enforce. For example, FDA has issued warning letters to cosmetic firms that have made unapproved drug claims for products marketed as cosmetics.

In addition, while FDA regulates cosmetic labelling claims, the Federal Trade Commission (FTC) regulates advertising claims. Under the law, claims in advertising must be truthful, cannot be deceptive or unfair, and must be evidence-based. [xxx]

Label Claims:

- Alcohol Free, Aromatherapy, "Cosmeceutical", Cruelty Free/Not Tested on Animals, Hypoallergenic Cosmetics, "Organic" Cosmetics, Thigh Creams (Cellulite Creams), Wrinkle Treatments and Other Anti-aging Products

Relevant Resources

- Shelf Life/Expiration Date
- Country of Origin Marking: From U.S. Customs and Border Protection
- "Made in U.S.A.": From the U.S. Federal Trade Commission
- Are your "all natural claims all accurate? From the U.S. Federal Trade Commission

Import Requirements

The FDA oversees the import of cosmetics into the U.S. to ensure compliance with safety and labelling standards. Imported products are inspected with U.S. Customs and Border Protection (CBP), and those found adulterated or misbranded may be refused entry. Importers are not required to register with the FDA but must meet the same standards as domestic products. Common violations include unsafe ingredients, improper labelling, or microbial contamination. **While FDA approval is not required for most cosmetics, adherence to U.S. regulations, including labelling and ingredient restrictions, is mandatory**. Import alerts focus on known issues like therapeutic claims or unapproved colour additives.[xxxi]

Everything imported to the United States has to be labelled with its country of origin.[xxxii]

Importers must also meet other general CBP import requirements. For more information on importing products to the United States, you can read the CBP webpage on Tips for New Importers and Exporters or look through their online information center.

Relevant Resources

- Import Program – Cosmetics Overview
- Cosmetics Importers FAQ
- Cosmetics Importers & Exporters Fact Sheet

OTC Drugs

Regulations

The FDA defines an OTC drug as medicine that you can buy without a prescription. They are safe and effective when you follow the directions on the label and as directed by your health care professional.

There are **two regulatory pathways** to bring a nonprescription drug to market in the U.S.:

1. The drug application process
2. Over-the-Counter (OTC) Drug Review (OTC Monograph) process

Under the drug application process, a sponsor of a nonprescription drug submits a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) to FDA for approval. The sponsor cannot market the nonprescription drug until FDA approves the NDA or ANDA.

OTC drugs may be marketed without an approved drug application under section 505 of the *FD&C Act* if they meet the requirements of section 505G of the *FD&C Act* and the OTC drug monograph. OCT monographs represent regulatory standards for the marketing of non-prescriptions drug products without an approved NDA. FDA has a list of all available OTC Monographs.

FDA encourages all potential drug sponsors or investigators of nonprescription drugs to initiate contact with the Office of Nonprescription Drugs (NDA products) or the Office of Generic Drugs (ANDA products) as early as possible, so that drug sponsors or investigators have the opportunity to consider FDA's recommendations in planning preclinical and clinical development programs. [xxxiii]

Relevant Resources

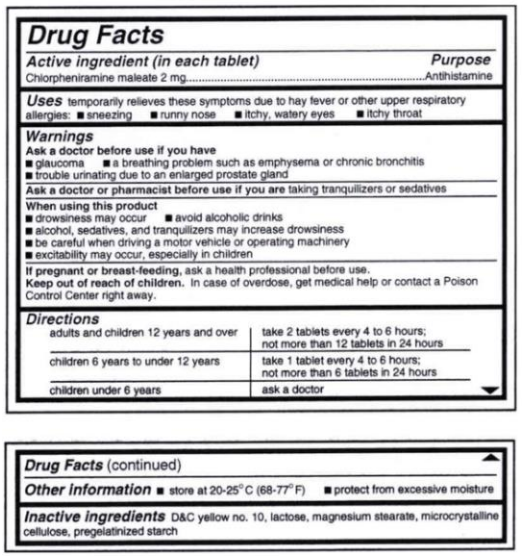
- New Drug Application (NDA)
- Investigational New Drug (IND) Application
- Abbreviated New Drug Application (ANDA)
- OTC Drug Review Process | OTC Drug Monographs
- Label Comprehension Studies for Nonprescription Drug Products guidance document
- Self-Selection Studies for Nonprescription Drug Products guidance document
- Small Business Assistance: Frequently Asked Questions on the Regulatory Process of Over-the-Counter (OTC) Drugs
- Innovative Approaches for Nonprescription Drug Products draft guidance document
- FDA Announces Proposed Rule: Nonprescription Drug Product with an Additional Condition for Nonprescription Use

Labelling

All nonprescription, OTC medicine labels have detailed usage and warning information so consumers can properly choose and use the products. The label tells a consumer what a medicine is supposed to do, who should or should not take it, and how to use it. The FDA requires a standard label of important drug information for all OTC drug products so that all labels have information listed in the same order; are arranged in a consistent style and contain easier to understand words. The Over-the-Counter Drug Facts Label.

The OTC label should tell you[xxxiv]**:**

- Active ingredient(s)
- Purpose(s)
- Use(s)
- Warning(s)
- Directions
- Inactive ingredients
- Expiration date
- Lot or batch code
- Name and address of manufacturer, packer, or distributor
- Net quantity of contents (how much of the product is in each package)
- Other information



Drug Facts

Active ingredient (in each tablet) — **Purpose**
Chlorpheniramine maleate 2 mg — Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings
Ask a doctor before use if you have
■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product
■ drowsiness may occur ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Drug Facts (continued)

Other information ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

Nondescription Drug Product with an Additional Condition for Nonprescription Use (ACNU)

FDA announced a new rule in December 2024 intended to increase options for consumer access to appropriate, safe, and effective drug products, which could improve public health. FDA recognizes the benefit of providing consumers with options for additional types of nonprescription drugs, such as some drugs that are currently available only by prescription and that treat chronic diseases or conditions. The rule is expected to broaden the types of nonprescription drugs available to consumers.[xxxv]

Currently, without the ACNU rule, the label of the nonprescription drug product must have enough information that consumers need to choose whether the drug is right for them (self-select) and to use the drug appropriately without the supervision of a healthcare provider. The ACNU rule provides a way for drug companies developing a drug product for nonprescription use to address the label limitations that otherwise exist for nonprescription drugs.

Specifically, under the new rule, a drug company may propose to have an ACNU for the drug when the label on its own cannot, by itself, provide all the information consumers need to appropriately select or use the drug on their own in the nonprescription setting.

For more information, see the webpage FDA Announces Final Rule: Nonprescription Drug Product with an Additional Condition for Nonprescription Use. [xxxvi]

Marketing and Advertising

Under the drug application process, a nonprescription drug may be marketed as either:

1. **Direct-to-nonprescription** (commonly referred to as direct-to-OTC)
2. **Prescription-to-nonprescription** switch (commonly referred to as Rx-to-OTC switch)

The Federal Trade Commission (FTC) handles most matters regarding claims in advertisements for OTC drugs while the FDA handles most matters regarding the labelling of OTC drugs. As with any other product, claims for OTC drugs must be truthful and non-deceptive. Given the health and safety issues that can arise in marketing these products, advertisers should take care in substantiating their claims. Depending on the claim, advertisers may be required to back up their representations with competent and reliable scientific evidence, including tests, studies, or other objective data. [xxxvii]

FTC's Advertising FAQ's: A Guide for Small Business.

For more information about labelling OTC drugs, visit the FDA website.

Import Requirements

All foreign drug establishments whose products are imported or offered for import into U.S. are required to register their establishment with FDA and list all their drug products in commercial distribution in the U.S. (See FAQ: If I am required to register my drug facility and list my drug product, how do I proceed? for more details).

Imported products regulated by the FDA are subject to inspection at the time of entry by the U.S. Bureau of Customs & Border Protection (CBP). Shipments not found to comply with the law are subject to detention and must be brought into compliance, destroyed or re-exported. Under the *FD&C Act,* FDA may refuse admission to any drug that "appears" to be unapproved, misbranded, or adulterated, placing the burden on the importer to prove the drug is not in violation of the Act.[xxxviii]

To ensure that FDA is notified of all regulated products imported into the U.S., the importer, or their representative, must file an entry notice and an entry bond with CBP pending a decision regarding the admissibility of the product. FDA inspection and enforcement procedures for imports rely on coordination with CBP. FDA is notified by CBP of the product's entry and makes a decision as to its admissibility.[xxxix]

Relevant Resources

- Small Business Assistance, Import and Export of Human Drugs and Biologics
- Customs procedures, requirements and forms are available on the U.S. Customs website

Dietary Supplements

Regulations

The *FD&C Act* was amended in 1994 by the *Dietary Supplement Health and Education Act (DSHEA)* to define '**dietary supplement'** and set out FDA's authority regarding such products and dietary ingredients.

There are two types of ingredients that may be used in dietary supplements:

- **dietary ingredients** include vitamins and minerals, herbs and botanicals, amino acids and probiotics (enzymes and live microbials);
- **other ingredients** which include substances such as fillers, binders, excipients, preservatives, sweeteners, and flavorings.

Under the *DSHEA*, manufacturers and distributors of dietary supplements and dietary ingredients are responsible for evaluating the safety and labeling of their products before marketing to ensure they meet all the requirements of the *FD&C Act* and *DSHEA*. The FDA's role in regulating supplements primarily begins after the product enters the marketplace.[xl]

FDA is responsible for enforcing the laws and regulations governing dietary supplements and dietary ingredients. To identify violations, the agency conducts inspections, monitors the marketplace, examines dietary supplements and dietary ingredients offered for import, and reviews **new dietary ingredient (NDI)** notifications and other regulatory submissions for dietary supplements. [xli]

The *DSHEA* requires that a manufacturer or distributor notify FDA at least 75 days before introducing a product with a new dietary ingredient (NDI) into interstate commerce. They must submit information detailing the conclusion that the NDI-containing dietary supplement will reasonable be expected to be safe.[xlii]

Relevant Resources

- Dietary Supplements
- Dietary Supplement Products & Ingredients
- Information for Industry on Dietary Supplements
- Dietary Supplements Guidance Documents & Regulatory Information
- Draft Guidance for Industry: New Dietary Ingredient Notifications and Related Issues
- FDA 101: Dietary Supplements

Labelling

FDA regulations require dietary supplement labels to:

- bear a **product name** and a **statement** that it is a "dietary supplement" or equivalent term replacing "dietary" with the name or type of dietary ingredient in the product (e.g., "iron supplement" or "herbal supplement")
- the **name** and **place of business of** the manufacturer, packer, or distributor
- nutrition labeling in the form of a "**supplement facts**" panel (except for some small volume products or those produced by eligible small businesses)
- a list of "**other ingredients**" not declared in the Supplement Facts panel
- **net quantity** of contents

The **supplement facts** panel must list

- the serving size and number of servings per container,
- declare each dietary ingredient in the product,
- except for dietary ingredients that are part of a proprietary blend, provide information on the amount of the dietary ingredient per serving.

Depending on the type of ingredient, the amount per serving must be declared as a quantitative amount by weight, as a percentage of the daily value, or both. Finally, dietary supplement labels must provide a domestic address or domestic phone number for reporting serious adverse events to the manufacturer, packer, or distributor whose name and place of business are listed on the label.

Ingredients not listed on the "**supplement facts**" panel must be listed in the "**other ingredients"** list beneath. The types of ingredients listed there could include the sources of dietary ingredients, if not listed in the "supplement facts" panel (e.g., rose hips as the source of vitamin C), other food ingredients (e.g., water and sugar), food additives, and color additives. Gelatin, starch, stabilizers, preservatives, and flavors are additional examples of ingredients commonly declared in the "other ingredients" list. [xliii]

Relevant Resources

- Dietary Supplement Labeling Guide
- Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Non-prescription Drug Consumer Protection Act
- Small Entity Compliance Guide: Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Small Entity Compliance Guide
- Label Claims for Conventional Foods and Dietary Supplements

Marketing and Advertising

There are three types of claims, each with different requirements, that manufacturers may make for their dietary supplement products: health claims, structure/function claims, and nutrient content claims.[xliv]

- **Health claims:** describe a relationship between a food substance (a food, food component, or dietary supplement), and reduced risk of a disease or health-related condition.
- **Structure/function claims:** describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body (i.e. calcium builds strong bones).
- **Nutrient content claims:** describe the level of a nutrient in the product, using terms such as *free*, *high*, and *low* or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced* and *lite*.

Similar to OTC drugs, the Federal Trade Commission (FTC) handles most matters regarding claims in advertisements for dietary supplements while the FDA handles most matters regarding the safety, quality and labelling.

For more information on these claims and the necessary requirements to be able to make them, please refer to the FDA webpage on Label Claims for Conventional Foods and Dietary Supplements.

Import Requirements

Under the *FD&C Act,* importers of dietary supplements intended for introduction into U.S. interstate commerce are responsible for ensuring that the products are safe, sanitary, and labeled according to U.S. requirements.

Similar to other imported food products are subject to FDA inspection when offered for import at U.S. ports of entry. FDA may detain shipments of products offered for import if the shipments are found not to follow U.S. requirements. Both imported and domestically produced products must meet the same legal requirements in the United States.[xlv]

Relevant Resources

- Manual of Compliance Policy Guides Chapter 5 - Food, Colors, and Cosmetics
- Prior Notice of Imported Food
- Hazard Analysis Critical Control Point (HACCP)
- Accredited Third-party Certification Program
- Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals
- Voluntary Qualified Importer Program (VQIP)
- Import & Export Guidance Documents & Regulatory Information

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