TRADE MARKET INTELLIGENCE

SPECIAL REPORT:

Natural Health and Personal Care Product Regulations in Canada and the US

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NATURAL HEALTH AND PERSONAL CARE PRODUCT REGULATIONS IN CANADA AND THE US

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Report Overview

The beauty and personal health industries are deeply affected by the global mega-trend towards health & wellness. Consumers are increasingly seeking out natural solutions to help improve their wellbeing and personal appearance.[1] Rising heath-consciousness, an aging population, growing willingness to practice self-care, and high healthcare costs in North America have led to an increase in the use of products such as supplements and herbal solutions.[2] [3]

With growing demand, there are broad opportunities for nutraceutical, supplement, and personal care product manufactures 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 United States must also understand the differences between American and Canadian regulatory compliance.

This report is meant to provide an introduction and overview of how Canada and the United States 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.

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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 being represented for sale, and its intended purpose determines how a product is classified.[4]

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.[5]

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.[6] Products claiming therapeutic effects or that contain certain active ingredients are not considered cosmetics.[7]

A "**natural health product**", sometimes referred to as 'complementary' or 'alternative' medicine, includes:

- vitamins and minerals;
- herbal remedies;
- homeopathic medicines;
- traditional medicines like traditional Chinese and Ayurvedic (East Indian) medicines;
- probiotics; and,
- other products like amino acids and essential fatty acids.[8]

Natural health products are defined as a substance set out in Schedule 1: Included Natural Health Product Substances of the *Natural Health Products Regulations* or 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 for use in:

- the diagnosis, treatment, mitigation or prevention of 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 natural health product does not include a substance set out in in Schedule 2: Excluded Natural Health Product Substances.[9]

It should be noted that Health Canada is currently in the process of updating its approach to regulating self-care products. As part of this process, Health Canada is looking to introduce a risk-based approach to regulatory oversight for non-prescription drugs and expedite pathways for lower risk products. This would make the regulation of non-prescription drugs more similar to natural health products.[10] Health Canada is looking to introduce new amendments to the Food and Drug Regulations regarding this in Spring of 2020.[11]

Representation for 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 includes both explicit and implied representation through words, symbols, and pictures.

Classification decisions are made primarily on the composition of a product, the effect it has on the body, and the representation for sale of a given product. Consumer perceptions about the therapeutic uses of a product may also be taken into account. Generally, products with therapeutic claims are evaluated as drugs or natural health products and require additional proof of efficacy in order to legally make those claims.[12]

Cosmetics

Regulations

Cosmetics sold in Canada must meet the requirements set out by the Food and Drugs Act and the Cosmetic Regulations. These regulations include requirements around manufacturing, preparation, preservation, packing, and storage. Manufacturers and importers are also required to notify Health Canada that they are selling the product and provide a list of the product's ingredients. Chemicals in cosmetics may also be subject to the Canadian Environmental Protection Act.[13]

Resources

- Classification of Products at the Cosmetic-Drug Interface
- Product Assessment Against Criteria: Antiperspirants
- Product Assessment Against Criteria: Diaper Rash Products
- Good Manufacturing Practices (GMPs)
- Guidelines for Volatile Organic Compounds in Consumer Products
- Heavy Metals in Cosmetics
- Determination of Flame Projection - Official Method D0-30

Registration

All cosmetics manufacturers and importers are required to complete a Cosmetic Notification Form (CNF) for products intended to be sold in Canada. A CNF must be submitted for new products, amendments to existing products, and the discontinuation of sale. Multiple products may be covered under one CNF under certain circumstances. The CNF has nine sections and can be completed using an online form. Health Canada offers a Guide to Completing Cosmetic Notification Forms which gives detailed instructions on the process.

The notifier for the CNF may be the manufacturer, an importer, or a person responsible on their behalf. All correspondence regarding the CNF will be sent to the notifier.

After a CNF has been submitted, Health Canada may request additional information or clarification. Failure to respond to an information request within the specified time may result in compliance and enforcement action, depending on the nature of the request. If Health Canada finds that a product has been misclassified due to ingredient content or therapeutic claims, the notifier may be redirected to another program or be subject to compliance action.[14]

Labelling

Cosmetic labelling is subject to three 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; and
- The Hazardous Products Act and the Consumer Chemicals and Containers Regulations.

The Food and Drugs Act and Cosmetic Regulation address labelling with regards to: the expression of the product's identity, the indication of the name and address of the principal place of business of the manufacturer, the listing of ingredients, and presentation of avoidable hazards.

The Consumer Packaging and Labelling Act and Regulations regulate the mandatory label information that must appear on prepackaged products for consumers. This includes English and French requirements, product identification information, net quantity in metric units, and the identity and principal place of business of the dealer. The Act also covers misleading representation and standardization of container sizes.

The Consumer Chemicals and Containers Regulations, as they read on September 30, 2001, of the Hazardous Products Act, define the symbols and warning statements used on pressurized containers as prescribed by the Cosmetic Regulations.[15]

Resources

- Labelling of Cosmetics
- Guide to the Consumer Packaging and Labelling Act and Regulations
- Guide to Cosmetic Ingredient Labelling
- Labelling Requirements for Cosmetics in Pressurized Containers

Marketing and Advertising

Advertising Standards Canada (ASC) is the national, not-for-profit, advertising self-regulatory body that administers the *Canadian Code of Advertising Standards*. Prior to broadcast, radio or television ads are previewed and cleared with ASC.[16] ASC administers the *Advertising Code for Standards for Cosmetics, Toiletries and Fragrances*, which can be obtained by contacting ASC.[17] The 2016 version of ASC's guidelines for non-therapeutic advertising and labelling claims is available online.

Print advertising issues are investigated by the Competition Bureau of Industry Canada under the authority of the Competition Act. Health Canada may also become involved if a print advertisement poses a safety concern.[18]

The use of certain marketing terms is regulated under the Consumer Packaging and Labelling Act and the Competition Act. Marketing terms include things like "hypoallergenic", "fragrance free", "dermatologist tested", and "not tested on animals".[19]

In Canada, cosmetics cannot be regulated "organic" by the Canadian Food Inspection Agency and therefore cannot bear the Canada Organic Logo.[20] Canadian companies wishing to display credible organic claims on their labels or in their advertising may want to consider doing further research on obtaining organic certification from an international body instead. Other options may be suitable, depending on the product, target market, and recognizability of the certifying body.

Natural Health Products

Regulations

Natural health products (NHPs) are regulated under the Natural Health Products Regulations and their subsequent amendments. For an NHP to be sold legally in Canada, the product itself must have a licence and the sites involved in the manufacturing, packaging, labelling, or importation of the product must have site licences. Products/sites must also meet labelling standards and good manufacturing practice (GMP) standards to obtain these licences.[21] Product licence holders are required to monitor all adverse reactions related to their product and report serious adverse reactions of Health Canada.[22]

The Regulations are administered by Health Canada's Natural Health Products Program. There are three directorates under this program:

The Natural and Non-prescription Health Products Directorate (NNHPD) – The regulating authority for commercial sales of NHPs. NNHPD makes assessments and issues product and site licences.

The Marketed Health Products Directorate (MHPD) – Provides post-approval safety surveillance and risk communications regarding regulated health products. MHPD also handles the management of adverse reactions reported by individuals.

The Health Products and Food Branch Inspectorate (HPFBI) – Responsible for the enforcement of the Regulations and compliance actions such as product recalls and investigations. Consumer complaints are handled by HPFBI. [23]

NHPs that make health claims must be supported by appropriate evidence towards their safety and efficacy. The type and amount of supporting evidence depends on the claim made and overall risks. Evidence types required and accepted ranges from clinical trial data to traditional resources.[24]

Resources

- About Natural Health Product Regulation in Canada
- Information Kit - Regulation of Natural Health Products
- General Questions – Regulation of Natural Health Products
- Classification of products at the food-natural health product interface: products in food formats
- Quality of Natural Health Products Guide
- Finished Product Specifications Form User Guide
- Good Manufacturing Practices Guidance Document
- Clinical Trials for Natural Health Products
- Overview of the Reporting Adverse Reactions to Marketed Health Products - Guidance Document for Industry
- Health Products and Food Branch Inspectorate - Natural Health Products Compliance and Enforcement Policy (POL-0044)
- Guidance for Industry on Third-Party Issuance of International Trade Certificates

Product Licensing

All NHPs require a product licence prior to sale in Canada. NHPs that have been approved by Health Canada are issued a product licence and an eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM), which must appear on the label.[25] All licenced products appear in Health Canada's Licensed Natural Health Products Database. The database is publicly available and includes information such as ingredients, dosage form, and risk information.[26]

There are several different types of application, which have varying service standard times, as outlined below:

NNHPD Product License Application Service Standards[27]

Application Type		Type of Notice Issued	Assessment	Regulatory Decision Issued	Service Standards
Class I	Compendial	Notice of Refusal - no Acknowledgement notice applies for this class	N/A	Product Licence or Notice of Refusal	60 Calendar Days
	Class I Amendment				
Class II	General	Application Acknowledgement or Notice of Refusal	N/A	Product Licence or Notice of Refusal	90 Calendar Days
	Traditional				
	Class II Amendment				
Class III	General		180 Calendar Days	Product Licence or Notice of Refusal	210 Calendar Days
	Traditional				
	Homeopathic				
	Class III Amendment				

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. An 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.[28]

Class I applications must comply with all of the parameters of a single NNHPD monograph with no modifications.

Class II applications (both general and traditional) may be supported entirely by a combination of two or more NNHPD monographs (with or without deviation to one or more of the monograph statements that maintains the intent of the statements), supported entirely by a single NNHPD monograph with a deviation in one or more monograph statements that maintains the intent of the statements, or products supported by a combination of monographs with the addition of common fruits vegetables listed in the Canadian Nutrient File (some exclusions apply).

Class III applications (general, traditional, and homeopathic) require a full assessment. This may apply to products with a novel preparation, products with ingredient combination issues that may require a safety assessment, applications referencing monograph information but going beyond the original monograph's parameters, any homeopathic applications with specific claims, and more.[29]

As noted, there is also some variation in the assessment of applications for general, traditional, and homeopathic NHPs. Health Canada provides guidance on the process for each category, links to which have been included in the guidance documents section below.

Resources

- Management of Product Licence Applications for Natural Health Products
- Pathway for licensing natural health products used as traditional medicines
- Pathway for licensing natural health products making modern health claims
- Data requirements for switching medicinal ingredients from prescription to non-prescription status
- Guidance Document: Schedule A and Section 3 to the Food and Drugs Act
- Evidence for Homeopathic Medicines
- Natural Health Products Ingredients Database

Site Licensing

Canadian manufacturers, packagers, labellers, and importers of NHPs must hold a valid site licence, which gives the licensee authorization to conduct the activities listed on the licence according to Good Manufacturing Practice (GMP) standards.[30] To obtain 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 GMP requirements.[31]

It should be noted that businesses and individuals who manufacture NHPs for the sole purpose of exporting finished products outside of Canada may not require site licensing.[32]

Resources

- Site Licensing Guidance Document
- Good Manufacturing Practices Guidance Document

Labelling

Labelling and packaging requirements are set out by the *Natural Health Products Regulations* and enforced by Health Canada.

Information currently 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; and,
- any special storage conditions.[33]

As part of Health Canada's update to the regulation of self-care products, Health Canada is looking to introduce targeted amendments to the *Natural Health Products*

Regulations to improve labelling of natural health products in the spring of 2020. This may affect plain language requirements, font sizing and contrast, standardized formatting, and the presentation of risk information.[34]

Currently, there is a labelling guidance document available, but it has been archived and will not be updated going forward. Until further guidance is released on the upcoming changes, companies may want to contact the Natural and Non-Prescription Health Product Directorate of Health Canada directly for resources and information regarding labelling requirements.

Marketing and Advertising

Promotional claims must be consistent with an NHP's product licence, monograph, and label. Product licences, monographs, and labels include "Terms of Market Authorization" which set out the intended use or uses of a product as authorized by Health Canada. Promotional claims must not be directly or indirectly inconsistent with the Terms of Market Authorization.[35]

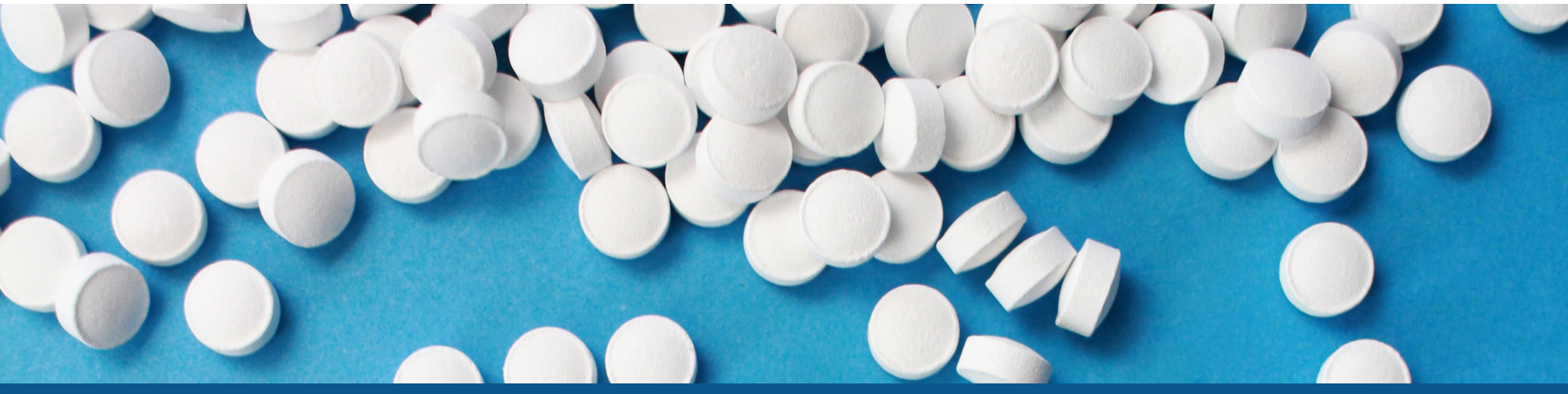
Additionally, since all health products have some degree of risk it is unacceptable to state or suggest that a product is "safe", "side effect free", or "has no known side effects". It is also impermissible to market natural/naturally sourced products as being safer than synthetic or man-made pharmaceuticals.[36]

Like with cosmetics, NHPs cannot be regulated as "organic" by the Canadian Food Inspection Agency.[37]

Export

The export of natural health products is regulated under the Food and Drugs Act.[38] Companies intending to export health products should notify Health Canada using the export certificate form.[39] Further information on obtaining an export certificate is available online.

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 that the product is for export only and that the product is not known to contravene any laws of the importing country.[40]



American Classification

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

In the United States, a "**drug**" is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or an article (other than food) intended to affect the structure or any function of the body of man or other animals. "**Over-the-counter (OTC) drugs**" are drugs that can be purchased without a doctor's prescription.[41]

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.[42] It should be noted that traditional "**soap**" is considered its own category with its own regulations. Cleansers may be regulated as a soap, cosmetic, or drug, depending on its ingredients and intended use.[43]

Unlike in Canada, products can be considered both a drug and a cosmetic, depending on the intended use of the product. For example, shampoo would generally be considered a cosmetic, but an anti-dandruff shampoo would also be considered a drug.[44]

The closest the United States has to the Canadian Natural Health Product 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.[45]

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 defined as vitamins, minerals, herb or other botanical, amino acid, dietary substances for use by man to supplement the diet by increasing total dietary intake. Dietary supplements cannot be intended to treat, diagnose, prevent, or cure diseases the way drugs do.[46]

Intended Use

The most important factor in determining a product's classification in the United States 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.[47]

Cosmetics

Regulations

Cosmetics sold in the US must meet the requirements in the *Federal Food, Drug, and Cosmetic Act*, *Microbead-Free Waters Act of 2015*, and the *Regulations Related to Cosmetics from Title 21 of the Code of Federal Regulations (21 CFR)*.[48] Cosmetics do not require FDA approval before they go to market, unless they contain colour additives. However, the FDA can pursue enforcement measures against products or firms that are found to violate or are noncompliant with the law. With the exception of colour additives and prohibited/restricted ingredients, manufactures 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".[49]

Manufacturing companies are legally responsible for ensuring the safety of their products. Companies are not required to share their safety information with the FDA, and no specific tests are required to ensure safety, however the FDA advises that manufacturers use whatever testing is necessary to ensure the safety of their products and ingredients. Additionally, the FDA can and does perform inspections on cosmetic manufacturing facilities.[50]

If a product is found to be unsafe, the FDA may request the company perform a voluntary product recall or pursue action through the federal court to remove the product from the market. Noncompliant products may be seized by the government. The FDA may also initiate criminal action against a person in violation of the law.[51]

Resources

- Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)
- "Cosmeceutical"
- FDA Authority Over Cosmetics
- Cosmetic Products & Ingredients
- Prohibited & Restricted Ingredients in Cosmetics
- Color Additives and Cosmetics
- Color Additives Permitted for Use in Cosmetics (Table)
- Guidance for Industry: Safety of Nanomaterials in Cosmetic Products
- Fragrances in Cosmetics
- Key Legal Concepts: "Interstate Commerce," "Adulterated," and "Misbranded"
- Inspection of Cosmetics
- Draft Guidance for Industry: Cosmetic Good Manufacturing Practices
- GMP Guidelines/Inspection Checklist
- Product Testing of Cosmetics
- Recall Policy for Cosmetics
- Shelf Life-Expiration Dating of Cosmetics
- Small Businesses & Homemade Cosmetics: Fact Sheet

Soaps

Soap is regulated by the Consumer Product Safety Commission under *21 CFR 701.20* rather than by the FDA. However, very few cleansing products on the market are actually considered "soap". To be considered "soap" a product must meet three conditions:

- Composed mainly of alkali salts of fatty acids;
- Those alkali salts of fatty acids must be the only material that produces a cleansing action. Products that contain a synthetic detergent are considered a cosmetic not a soap, though the word soap is still permitted on the label; and,
- Marketed for use as a soap. If it the product marketed for purposes such as moisturizing, making the user smell nice, or deodorizing the user's body, it is considered a cosmetic. If the product is intended to treat or prevent disease, such as by killing germs or treating skin conditions, it is considered a drug. The word soap is still permitted on the label.[52]

Registration

It may be beneficial to manufacturers to participate in the Voluntary Cosmetic Registration Program (VCRP). Cosmetic manufacturers, distributors, and packers can file information on their products that are currently being marketed to consumers in the United States and register their manufacturing and/or packaging facility locations in the VCRP database. This allows the FDA to keep up to date on product ingredients being used across the industry and issue warnings to those companies on the VCRP mailing list if any ingredients are found to cause adverse reactions.[53]

Labelling

Cosmetic labelling is regulated under the *Federal Food, Drug, and Cosmetic Act* and the related *Labelling Regulations* and the *Fair Packaging and Labeling Act* in the United States.[54]

All label information must be in English. However, if a label includes any representation in another language then all of the required label information must also appear in the other language.

The basic information that must appear on cosmetic labelling includes:

- An identity statement which indicates the nature and use of the product;
- An accurate statement of the net quantity of contents;
- The name and place of business of the manufacturer, packer, or distributor;
- A distributor statement. If the name and address are not those of the manufacturer, the label must include some form of "Manufactured for..." or "Distributed by...";
- Material facts. Directions for safe use would be an example of material facts;
- The appropriate warning and caution statements; and,
- Ingredients, in descending order of predominance.

Making therapeutic claims on a cosmetic label may cause the product to be classified as a drug.

If a product is an OTC drug as well as a cosmetic, its labeling must comply with the regulations for both OTC drug and cosmetic ingredient labeling, with the ingredients for the drug and cosmetic effects listed separately.[55]

Resources

- Cosmetics Labeling Regulations Overview
- Summary of Cosmetics Labeling Requirements
- Cosmetics Labeling Guide
- "Trade Secret" Ingredients in Labelling

Marketing and Advertising

The FDA regulates labelling claims while the Federal Trade Commission regulates advertising claims.

Labelling and advertising for cosmetics does not need to have FDA approval, and the FDA does not have a list of approved or accepted claims that can be used in marketing material. However, there are restrictions to what can be claimed. Legally, claims must be truthful and not misleading. Additionally, products marketed with therapeutic claims may be classified as drugs and are regulated accordingly.[56]

Similar to Canada, the FDA does not regulate the terms "natural" or "organic" for cosmetics and personal care products.[57] However, if cosmetics and personal care products contain agricultural ingredients and can meet the U.S. Department of Agriculture (USDA)'s organic standards it may be eligible to be certified under the National Organic Program regulations.[58] Cosmetics labelled with organic claims must meet both USDA and FDA labelling and safety requirements.[59]

Resources

- Alcohol Free
- Aromatherapy
- Consumer Update: Are Some Cosmetics Promising Too Much?
- "Cosmeceutical"
- Cruelty Free/Not Tested on Animals
- Hypoallergenic Cosmetics
- "Organic" Cosmetics
- Super (un)natural product claims: From the U.S. Federal Trade Commission
- Are your "all natural" claims all accurate? From the U.S. Federal Trade Commission
- National Organic Program - Cosmetics, Body Care Products, and Personal Care Products
- USDA Organic Certification and Accreditation

TIP: Companies looking for help creating labelling and advertising material may want to consider hiring a consultant. NSBI's* Small Business Development Program *supports the acquisition of a private sector consultant to provide professional expertise, contributing up to 50% of eligible project costs to a maximum incentive of $15,000 CAD.

You can* contact *your Regional Business Development Advisor to find out more about the program.

Import Requirements

Imported cosmetics must comply with the same laws and regulations as products produced in the United States. So long as they meet requirements, products that are purely cosmetics do not need FDA approval prior to import.

The FDA works with United States Customs and Border Protection (CBP) to monitor imported cosmetics. CBP has the authority to examine imported cosmetics at the time of entry. Products not in compliance with FDA laws and regulations are subject to refusal of admission and must either be brought into compliance, destroyed, or re-exported. Not all cosmetics are sampled/inspected upon entry, however the FDA does issue Import Alerts on certain products or ingredients which will be subject to closer scrutiny. Cosmetics may also be randomly sampled. Cosmetics that are also considered drugs are subject to drug import regulations.[60]

Everything imported to the United States also has to be labelled with its country of origin.[61]

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.

Resources

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

OTC Drugs

Regulations

Over-the-counter (OTC) drugs are defined, in the United States, as drugs that are safe and effective for use by the general public without seeking treatment by a health professional.[62] Natural health and personal care products with therapeutic benefits may be classified as OTCs.

OTC drugs are regulated by the FDA and may gain approval under either the OTC Monograph Process or through the New Drug Application (NDA) Process. These are both reviewed by the Center for Drug Evaluation's Office of Drug Evaluation IV – The Division of Non-prescription Drugs.[63]

OTC monographs are regulatory standards, based upon an established OTC drug review of the safety and effectiveness of an OTC therapeutic drug category. They cover the marketing conditions for some OTC drug products including the active ingredients, labeling, and other general requirements. OTC products that meet the standards of an applicable monograph do not require marketing pre-clearance by the FDA, though some additional requirements for the marketing of human drug products may apply.[64]

An NDA can be used to request approval of an OTC drug that deviates in any respect from a finalized monograph.[65] An NDA application is a formal proposal that the FDA approve a new drug for sale and marketing in the United States. NDAs are meant to allow the FDA to make an informed decision on the safety and effectiveness of a product, whether the benefits outweigh the risks, whether the proposed labelling is appropriate and contains all necessary information, and whether the manufacturing methods and controls are sufficient to maintain consistent quality.[66]

After a product has been cleared by the Monograph or NDA process, firms that manufacture, prepare, propagate, compound, or process drugs in the U.S. or that are offered for import into the U.S must register with the FDA.[67]

Registering with the FDA requires three steps:

- Establishment Registration
- Labeler Code Form
- Product Listing

Each step requires a submission, as well as periodic updates and renewals. For more information on completing these steps, please refer to the guidance documents.

Resources

- CDERLearn Course: Bringing an Over-the-Counter (OTC) Drug to Market
- OTC (Nonprescription) Drugs
- Small Business Assistance: FAQ on the Regulatory Process of Over-the-Counter (OTC) Drugs
- Drug Applications for Over-the-Counter (OTC) Drugs
- Over-the-Counter (OTC) Drug Monograph Process
- New Drug Application (NDA)
- Status of OTC Rulemakings
- Drug Registration and Listing System (DRLS and eDRLS)
- Electronic Drug Registration and Listing Instructions

Labelling

OTC Drug product labelling is subject to regulations set out under *21 CFR 201.66*. Generally, all OTC labels should contain basic information such as the title, active ingredients, inactive ingredients, purpose, uses, warnings, directions. Other requirements apply, which are summarized in the FDA's Labeling OTC Human Drug Products guide.

Marketing and Advertising

The Federal Trade Commission is the body that handles matters regarding claims in advertisements of OTCs. Like other products OTCs must follow the basic rules of being truthful and non-deceptive. Given that OTCs carry health and safety risk, advertisers must take care in substantiating their claims and may be required to back up their representations with suitable scientific evidence.[68]

In addition to the FTC, the National Advertising Division (NAD) of the Council of Better Business Bureaus reviews advertising complaints and may refer cases to the FTC or other appropriate authorities if necessary.[69]

Import Requirements

All foreign drug establishments are required to register their establishment with the FDA prior to import into the United States. Establishments must also provide a list of all the drug products for commercial distribution in the United States. Importers or their representatives must file an entry notice and an entry bond with United States Customs and Border Protection (CBP). CBP notifies the FDA of a product's entry and makes a decision as to the product's admissibility. An OTC drug can be imported into the United States under a New Drug Application (NDA), Abbreviated New Drug Application (ANDA) or in compliance with an OTC monograph.[70]

Resources

- What must I do to import a human drug product that has been approved by the FDA into the US?
- If I am required to register my drug facility and list my drug product, how do I proceed?

Dietary Supplements

Regulations

The FDA regulates dietary supplement products and dietary ingredients as a category of food, with a different set of regulations than those covering conventional food and drug products, as set out by the Dietary Supplement Health and Education Act (DSHEA) of 1994.[71]

Dietary supplements must be orally ingested and must contain a dietary ingredient intended to supplement the diet. The DSHEA considers a 'dietary ingredient' to be one or a combination of: a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by man to supplement the diet by increasing the total dietary intake (e.g., enzymes or tissues from organs or glands), or a concentrate, metabolite, constituent or extract. The DSHEA also defines the term "new dietary ingredient" as an ingredient that meets the dietary ingredient definition, but which was not sold in the United States in a dietary supplement before October 15, 1994. Manufacturers and distributors are responsible for determining whether a dietary ingredient is "new" and documenting that it was marketed before the cut off date if it is not.[72]

With the exception of supplements containing 'new dietary ingredients', businesses do not have to receive FDA approval prior to marketing a dietary supplement in the United States. Manufacturers and distributors are, however, responsible for ensuring the safety of their products and truthfulness of their claims according to DSHEA regulations.[73] The FDA has published regulations for Current Good Manufacturing Practices for those who manufacture, package or hold dietary supplement products.[74] The FDA is empowered to remove products from the market if it has been established that a product is adulterated or misbranded.[75]

For "new dietary ingredients", firms must submit a premarket safety notification to FDA at least 75 days prior to introducing the product to the market.[76] Further information on this process is included in the guidance documents.

While approval of specific products is not necessarily required, manufacturers are required to register themselves with the FDA, pursuant to the Bioterrorism Act, prior to producing and selling supplements.[77]

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

Labelling

The DSHEA includes specific regulations for supplement labelling. There are five required statements, with additional regulations around placement and stylization:

- the statement of identity (name of the dietary supplement);
- the net quantity of contents statement (amount of the dietary supplement;
- the nutrition labeling;
- the ingredient list;
- the name and place of business of the manufacturer, packer, or distributor.[78]

Label approval is not required prior to bringing a product to market.[79] However, as previously mentioned, businesses are responsible for making sure they meet regulations as failure to do so may lead to a product being considered 'mislabelled' and removed from the market by the FDA.[80]

Like with cosmetics, imported dietary supplement products also require county of origin labelling.[81]

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

TIP: If you're looking to develop an export plan, NSBI's ***Trade Market Intelligence Service*** *may be able to provide your company with research to help target your efforts. The Service can address many types of questions and provide reports on topics such as market trends and demand.*

You can ***contact*** *your Regional Business Development Advisor to find out more about the program.*

Marketing and Advertising

As with other product categories in the United States, the FDA is primarily responsible for regulating product labelling while the FTC is primarily responsible for claims in advertising.[82]

Dietary supplements cannot be intended to treat, diagnose, prevent, or cure diseases and legally cannot make claims to that effect. Doing so could cause the product to be considered 'misbranded', allowing the FDA to remove the product from the market. [83]

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.[84] 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

Food products, including dietary supplements, can be imported into the United States without pre-approval so long as prior notice is sent to the FDA and the facilities that produce, store, or handle the products are registered with the FDA.

Imported products are subject to inspection at the port of entry and may be detained if they are not in compliance with United States legal requirements. [85]

Resources

- Prior Notice of Imported Food
- Reportable Food Registry for Industry
- Registration of Food Facilities
- Foreign Food Facility Inspection Program
- Voluntary Qualified Importer Program (VQIP)

Companies that are unclear on their responsibilities and requirements should contact the organization responsible for the implementation of revelant regulations or seek the advice of legal counsel. While guidance documents are helpful, they do not constitute legal advice and may not reflect the most current iteration of regulatory practices.

YOU'RE READY. WE'RE HERE TO HELP.

NSBI is dedicated to helping Nova Scotia companies enter and grow in markets around the world. Our team of sector and market specialists bring the intelligence and insights companies need to make informed export decisions.

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