

Item	United States	Canada
Product categories	Foods (including dietary supplements) Food additives Color additives Scents (fragrances) Cosmetics Nonprescription drugs (including homeopathic drugs) Prescription drugs Biologics Medical devices	Foods Food-like NHPs (fortified foods, energy drinks, bars etc.) Food additives Cosmetics Natural Health Products (including Homeopathic drugs) Nonprescription drugs Prescription drugs Biologics Medical devices Disinfectants and sanitizers with disinfectant claims
Allowed claims for products categories	Depends on “intended use: Food: no claims; health claims; nutrient content, etc.  Dietary supplements: nutrient content; claims of “wellbeing”; structure or function claims; health claims  Drugs/Biologics: disease claims (to “diagnose, treat, prevent, mitigate of cure”) and/or affect the structure or function of the body;  Devices: no claims or disease claims (devices primarily exert effects through a physical- not chemical- means)	Depends on “recommended conditions of use”:  Food: no claims, health claims; nutrient content  NHPs: Health claims including structure-function, risk- reduction, and therapeutic or treatment claims; claims may be traditional and/or modern  Drugs/Biologics - disease claims and/or affect the structure or function of the body; “diagnose, treat, prevent, mitigate of cure”  Devices: disease claims
Level of evidence for botanical drugs and NHPs	Botanical drugs: strong evidence of safety and efficacy obtained through a series of “adequate and well-controlled” studies; requires both nonclinical studies and clinical studies.	NHPs: level of evidence to support safety and efficacy varies for each claim; ranges from traditional references, and observational studies, to randomized clinical trials  Data to support a health claim should be appropriate to support the strength of the claim
Require pre-market approval	“New” drugs and biologics, some (Class III) medical devices	All NHPs, new drugs and biologics, some medical devices
Clinical trials for safety	or GRAS applications, new drug and biologics approval; some medical devices (Class III)	May be requested to help characterize the risk
Clinical trials for efficacy	“New” drugs and biologics	All products, except foods.
Regulatory filings	Medical devices, based on claims Foods: No pre-market approval for conventional foods  “GRAS” determinations: for ingredients “generally recognized as safe” intended to be used for foods, or drugs  Health Claims: petition  Structure-Function Claims: 75 day notice  “New” drugs: IND: Investigational New Drug application – to initiate clinical studies; allowance to proceed  NDA: New Drug Application – request to market “new” drug; pre- market approval	NHPs, depending if the claims are traditional or modern health claims  CTA: Clinical Trial Application - to initiate clinical studies  NHPs: Product License Application (PLA), Terms of Market Authorization (TMA)  OTC: Market Authorization: Drug Identification Number (DIN)  Drugs: IND and NDS (New Drug Submission) - similar to US. Market Authorization: DIN, Natural Product Number (NPN)
Regulation of advertising/promotion	Direct to consumer: Federal Trade Commission Prescription: Food and Drug Administration	Health Products and Food Branch (HPFB) Inspectorate Health Canada
Intellectual property protections	Market Exclusivity (FDA) Patent-term restoration (under Hatch-Waxman Act) (USPTO) Other: Copyright, trademarks, trade secrets	Market exclusivity for drugs  Other: trademarks, trade dress, trade secrets, patents, brand promotion and protection

<p><b>Approval time</b></p>	<p>Foods, dietary supplements: no premarket product approval; some claims, (e.g., health claims, structure-function) are subject to specific processes, such as promulgation of a regulation, or pre-market 75-day notification</p> <p>Same as other drugs, depending on whether the NDA receives Standard or Priority review (generally 6–18 months)</p>	<p>For simple products that mirror existing NHPD monographs 10 days</p> <p>NPN: within 60 days of filing an application</p> <p>For products with unique ingredients and health claims: NPN in 180 days</p>
<p><b>Path to market</b></p>	<p>Depends on the market channel (foods, dietary supplements, drugs, etc.)</p>	<p>Differs for NHP and similar OTC products or prescription drugs</p>

Tamayo and Huang <sup>2(4-5)</sup>