HealthTech Activator

Regulatory Touchpoint Map Nutraceuticals/High-value foods/ Functional foods – US FD

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NUTRACEUTICALS/HIGH-VALUE FOODS/FUNCTIONAL FOODS – FDA TERMS: DIETARY SUPPLEMENTS, FOODS OR FOOD ADDITIVES

PERSPECTIVE OF PERSON/ROLE	KNOWLEDGE REQUIRED TO OPERATE EFFECTIVELY	RELEVANT REGULATORY FRAMEWORKS	NOTES
DECIDING WHICH CATEGORY YOUR PRODUCT IS REGULATED IN			
R&D team Scientist/ inventor/ grower/ manufacturer/ exporter	Is product regulated? Specific to any 'claim' the company wants to make about the product or the intended use for the product. All marketing claims made must comply with the intended use.	• Generally all foods and food components have some form of regulatory control in the US market. • Important to identify the FDA category for the product. • The basic categories1 include: • Foods • Food ingredients/ additives • Dietary supplements • Complementary and Alternative medicine • Pharmaceuticals	• Further regulation can also apply for any specific attributes of the product or relating to import controls and biosecurity. • E.g. Genetically engineered foods; phytosanitary requirements etc.
	Which regulations apply?	• Highly variable depending on product and the intended product claims. • Company strategy can impact regulatory category – develop the marketing claims to suit the regulatory category.	• E.g. Does A2 milk make a claim to treat a health condition? • If company strategy is to claim impact on a health condition then higher level of evidence is required.
	Timing of regulatory requirements	• Early regulatory awareness guides R&D, commercial and marketing plans.	• Once regulatory category identified then R&D can proceed to develop right level of evidence.
	Additional guidance provided by FDA	• Current Good Manufacturing Practices (CGMPs) • Food Facility Registration • Hazard Analysis & Critical Control Points (HACCP) • Imports & Exports	• https://www.fda.gov/food/guidanceregulation/default.htm

1 Note that Nutraceuticals is a marketing term, it is not a regulatory category. Depending on the ingredients and marketing claim, the product will generally be regulated under one of the FDA categories described.

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FOODS			
R&D team	Where to seek expert advice.	• Develop product according to guidance on: › Food quality controls and standards › Ingredients	• Local associations and CRIs including: › New Zealand Food Safety (e.g. Verified Risk Management Programmes) › Plant and Food › Beef and Lamb New Zealand. › Local and international food safety and regulatory consulting groups.
Marketing team/ commercial lead	What marketing claims and labels are acceptable within this category?	• Avoid making claims about any therapeutic benefit to humans or animals.	• Products or ingredients that claim to have a use in the diagnosis, cure, mitigation, treatment or prevention of disease are defined as medicines and regulated as such.
FOOD INGREDIENTS			
R&D team	What constitutes a food ingredient?	• Any component that is added to a food is deemed to be an ingredient. • Any ingredient that has a technical effect in the food (e.g. preservative or colourant) needs to be approved.	• Any substance that is reasonably expected to become a component of food is a food additive. • See FDA food ingredient decision tree here: • https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm228269.htm • See list of food ingredients and their status here: • https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm091048.htm • See searchable GRAS database here: • https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices
		• Ingredients that are generally recognised as safe (GRAS) are exempt from the need to apply for approval and use a notification process.	• The FDA strongly encourages you to submit a GRAS notice to it if you intend to market a food substance on the basis of a GRAS conclusion even though neither the FD&C Act nor their regulations in 21 CFR require you to do so. Submitting a GRAS notice to the FDA represents prudent practice for those who claim an exclusion from a statutory requirement.

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DIETARY SUPPLEMENTS			
R&D team	Definition of dietary supplement and the evidence for health claims	• FDA law defines dietary supplements in part as products taken by mouth that contain a 'dietary ingredient'. • Dietary ingredients include vitamins, minerals, amino acids, and herbs or botanicals, as well as other substances that can be used to supplement the diet. • The definition can be challenging to interpret and is mainly based on the type of ingredient and level of claim that a company intends to make about the product's effects. • FDA provides guidance on how labelling should be developed, including acceptable claims.	• Companies may only make 'health claims' or 'qualified health claims' where there is 'Significant Scientific Agreement' (SSA) that the ingredient has such an effect. • SSA is decided by the FDA using the following criteria: › (1) Identifying studies that evaluate the substance/disease relationship › (2) Identifying surrogate endpoints for disease risk › (3) Evaluating the human studies to determine whether scientific conclusions can be drawn from them about the substance/disease relationship › (4) Assessing the methodological quality of each human study from which scientific conclusions about the substance/disease relationship can be drawn › (5) Evaluating the totality of scientific evidence › (6) Assessing significant scientific agreement › (7) Specificity of claim language for qualified health claims, and › (8) Re-evaluation of existing SSA or qualified health claims. • Guidance on how to collect evidence for health claims here: › https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm#system
	Need for evidence of safety	• Dietary supplements may also rely on GRAS status (as for food ingredients above).	
	Timing of regulation	• FDA focus on compliance around adulteration and 'misbranding' once product is on the market.	

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DIETARY SUPPLEMENTS			
Manufacturers		• Requirement for Current Good Manufacturing Practice (CGMP)	• FDA requires any entity that manufactures, packages, labels or stores a dietary supplement to establish and follow Current Good Manufacturing Practice (CGMP). • CGMP aims to ensure the quality of the dietary supplement and to ensure that the dietary supplement is packaged and labelled as specified in the master manufacturing record.
COMPLEMENTARY AND ALTERNATIVE MEDICINE (CLOSEST FDA CATEGORY TO NUTRACEUTICALS)			
Inventor, founder, CEO		• Defining Complementary and Alternative Medicines (CAM)	• Complementary and alternative medicines consist of four categories of health treatments: • 'Biologically Based Practices' includes, but is not limited to, botanicals, animal-derived extracts, vitamins, minerals, fatty acids, amino acids, proteins, prebiotics and probiotics, whole diets and 'functional foods'. • 'Energy Medicine' considered to be energy fields, either measureable or putative. • 'Manipulative and Body-Based Practices' includes any form of manipulation or massage and similar practices. • 'Mind-Body Medicine' that involves interactions among the brain, mind, body and behaviour that affect health.

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		• CAMs are not exempt from other regulation.	• Where products are considered complementary and alternative medicines (CAM), this does not exempt them from standard regulation, e.g. food, food ingredient, cosmetic, pharmaceutical or device. Regulation depends on the product ingredients/mechanism and the claims made about the product. • E.g. Any nutraceutical claiming to supplement a person's dietary intake for general health reasons would still be regulated as a dietary supplement, and any nutraceutical such as a berry extract claiming to be beneficial in treating diabetes would be regulated as a drug. • Companies should clearly define the therapeutic claim about their product that they can support with evidence through the R&D programme and identify the regulatory pathway to follow based on this claim.
CTO (CSO, CMO)		• Levels of evidence required	• Where CAMs are sold with a claim of having any therapeutic effect on a disease (see definition below«) they are regulated as drugs and require the standard level of evidence to support the claim being made.
		• Use of entries in Pharmacopeia, official Homeopathic Pharmacopeia, or official National Formulary	• Where established data of safety and efficacy and reference standards exists on a drug (including nutraceuticals) this is captured in pharmacopoeia and these may be referenced in support of registering new products: http://www.usp.org/products
	Where to seek expert advice.	• Get certainty about the regulatory category and requirements from an expert.	• Early clarity of the regulatory category, FDA guidance and reference standards will help streamline the R&D path and reduce R&D risk. • See Medsafe list of regulatory consultants (for local services): http://www.medsafe.govt.nz/regulatory/consultants.asp • Companies can approach the FDA directly for advice, but this should be done in partnership with an experienced Regulatory Affairs professional (either from NZ or in-country).
CFO	Likely costs and skills for regulatory administrative support	Clear regulatory strategy helps define likely costs of R&D and market entry paths.	

Notes of Complementary and (CAM) products

Relevant to all stages of company from seed to mature.

Extract of FDA guidance:

> *According to NCCAM (US National Center for Complementary and Alternative Medicine), the domain called 'biologically based practices' includes, but is not limited to, botanicals, animal-derived extracts, vitamins, minerals, fatty acids, amino acids, proteins, prebiotics and probiotics, whole diets and 'functional foods'.*
>
> *Many biologically based products within this domain are subject to statutory and regulatory requirements under the Federal Food, Drug and Cosmetic Act or the Public Health Service Act. The intended use of a product plays a central role in how it is regulated.*
>
> https://www.fda.gov/RegulatoryInformation/Guidances/ucm144657.htm

Extract of Food ingredient decision tree: https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm228269.htm

FDA resources:

Food guidance and regulation overview: https://www.fda.gov/Food/GuidanceRegulation/default.htm

Regulatory info on food export from NZ to the US see: https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/default.htm

Complementary and alternative medicines: https://www.fda.gov/RegulatoryInformation/Guidances/ucm144657.htm

* Definition of a drug (including those that are CAMs)

(A) articles recognised in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; **and**

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; **and**

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; **and**

(D) articles intended for use as a component of any articles specified in clause (A), (B), or (C).