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Determining regulatory categories for products

There are several categories of pharmaceutical products that are regulated differently. They include Cosmetics, Dietary Supplements, Homeopathics, Medical Foods, Prescription drugs, and Over the Counter (OTC) drugs. All of these categories have regulations set forth by the FDA, and are subject to a variety of content and labeling regulations. The determination of regulatory class depends on the product's ingredients and the claims made on the label.

A product is regulated as a Cosmetic if its intended use is 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, with the exception of soaps. A product whose intended use is as a cosmetic, but also contains an active ingredient (i.e. toothpaste, etc) is regulated as an OTC drug product.

A product is regulated as a Dietary Supplement if it contains a dietary ingredient intended to supplement the diet. The Dietary Supplement Health and Education Act of 1994 (DSHEA) places dietary supplements in a special category under the general umbrella of foods, not drugs, and requires that every supplement be labeled a dietary supplement.

A product is regulated as a Homeopathic product if it is labeled as being homeopathic which is listed in the Homeopathic Pharmacopeia of the United States (HPUS), an addendum to it, or its supplements. Homeopathic drug products must contain diluents commonly used in homeopathic pharmaceutics. Drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not homeopathic drug products.

A product is regulated as a Medical Food if it is a food which is formulated to be consumed or administered enterally (through the digestive tract) under the supervision of a physician and which is intended for the specific dietary management of a disease or condition

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for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. The term “medical food” does not indicate any food fed to a sick person; medical foods are specially formulated and processed, as opposed to a naturally occurring food item that is used in its natural state.

A product is regulated as a drug if it is a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. There are two main classes of drugs; those that require a prescription from a healthcare professional, and those that are sold over the counter without prescriptions. If it contains an active pharmaceutical ingredient, requires a prescription from a doctor or another healthcare professional with the authority to prescribe medication, and is prescribed for one person’s use, it is regulated as a Prescription Drug (Rx). A product is regulated as an Over The Counter (OTC) drug if it contains an active pharmaceutical ingredient and is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. OTCs do not require prescriptions, therefore are required to be safe enough for the consumer to use without a doctor’s supervision.

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