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1. FDA Small Business REdi Fall 2015 Conference - Sept 29-30, 2015
2. Webinar on Electronic Common Technical Document (eCTD) – October 8, 2015 (To Be Announced)
3. FDA Small Business REdi Conference: Prescription Drug Labeling – Challenges and Issues – Nov 3-4, 2015 (To Be Announced)

Drug, Not a Drug, or More?

Determining whether a product is a drug, device, cosmetic, or biologic, or a combination of these components can often be tricky. The classification determination depends mainly on the intended use, mode of action, and ingredients. According to the [Federal Food, Drug, and Cosmetic Act](#) (FD&C Act):

A drug:

- Is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease
- Is intended to affect the structure or any function of the body of man or other animals

A medical device:

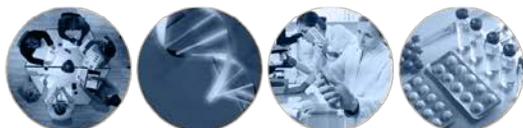
- Is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease
- Is intended to affect the structure or any function of the body of man or other animals
- Does not achieve its primary intended purposes through chemical action within or on the body of man or other animals
- Is not dependent upon being metabolized for the achievement of any of its primary intended purposes

A **cosmetic** is 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.

A **dietary supplement** (as defined in the Dietary Supplement Health and Education Act (DSHEA) of 1994) is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet.

- The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites.
- Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gels, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet.

A **biological product**, as defined in section [351\(i\) of the Public Health Service Act](#), is a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsenamine or derivative of arsenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.



Determining Whether a Product is a Drug

Intended Use of a product affects how it will be regulated and whether it will be classified as a drug. “Intended use” is defined in [21 CFR 201.128](#) as the “objective intent” of the persons legally responsible for the labeling of drugs. The intent is determined by such persons’ expressions or may be shown by the circumstances surrounding the distribution of the article.

This “objective intent” can be determined by such things as labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. Note that even representations and claims on a product’s or a firm’s website can and are used by FDA in determining an article’s “intended use.”

Intended use may also be established by **consumer perception** of a product’s reputation. In other words, why is the consumer buying the product and what does the consumer expect it to do?

Similarly, **ingredients** can cause a product to be considered a drug because they have a well-known therapeutic use. For example, fluoride in toothpaste is considered a drug.

Determining Whether a Product is More than a Drug (Combination Products)

In some cases, the product may be a combination product. In other words, it may be composed of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device, and a biological product. Under [21 CFR 3.2\(e\)](#), a combination product includes:

1. A product comprised of two or more regulated components (i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity

Ex: Device coated or impregnated with a drug or biologic.

2. Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products

Ex: Drug or biological product packaged with a delivery device.

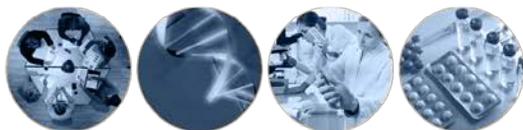
3. A drug, device, or biological product packaged separately that, according to its investigational plan or proposed labeling, is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where, upon approval of the proposed product, the labeling of the approved product would need to be changed

Ex: Photosensitizing drug and activating laser/light source.

4. Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect

Ex: Photosensitizing drug and activating laser/light source, if the drug and the activating light source are being investigated for a new indication and both components are required to achieve the investigational use, indication, or effect.

Note that drug-drug combinations and drug-cosmetic combinations are NOT combination products as defined by 21 CFR 3.2(e). Such products may have to meet the requirements of both CDER and the Center for Food Safety and Applied Nutrition (CFSAN).



Center Lead: A combination product is assigned to an Agency Center that will have primary jurisdiction for its premarket review and regulation. This assignment is based on a determination of the primary mode of action of the combination product. Because combination products are comprised of more than one type of regulated article (biological product, device, or drug), and each constituent part contributes a biological product, device, or drug mode of action, combination products will have more than one identifiable mode of action.

Mode of Action is the means by which a product achieves an intended therapeutic effect or action and is defined in [21 CFR 3.2\(k\)](#). For purposes of this definition, "therapeutic" action or effect includes any effect or action of the product intended to diagnose, cure, mitigate, treat, or prevent disease, or affect the structure or any function of the body. A constituent part of a combination product is said to have a drug, device, or biological product mode of action if that constituent part meets the definition of a drug, device, or biological product. The final rule in the August 25, 2005 [Federal Register](#) defines primary mode of action as "the single mode of action of a combination product that provides the most important therapeutic action of the combination product."

The formal jurisdiction process for both combination and non-combination products is accomplished through the Request for Designation (RFD) process, described in [21 CFR Part 3](#). When the classification of a product as a drug, device or biological product is unclear or in dispute, or when the jurisdiction of a combination or non-combination product is unclear or in dispute, the sponsor should submit a formal request for designation to the Office of Combination Products as soon as they have sufficient information for FDA to make a decision regarding assignment of a product. Check out the [Combination Products webpage](#) for additional information.

Determining the regulatory status of an article can be a complex process. We hope that we were able to shed some light on this issue!

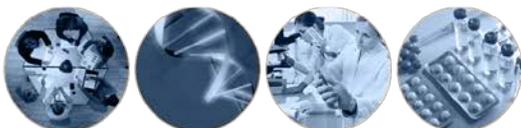
Cheers,

Renu Lal, Pharm.D.

CDER Small Business and Industry Assistance

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This communication is consistent with 21CFR10.85(k) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.



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