Overview of Product Categories and the Pros and Cons

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Food Regulations in the United States

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Introduction:

Some food types are easily definable. Milk, bread, cheese, eggs, all have a very defined way of product review and compliance. What about products that are not so easily defined and could possibly fit in a couple of different categories? An example of this type of product would be a protein shake or a hydration drink. This paper will explore the different product categories in the US. It will also present the pros and cons of each category from a marketing and regulatory perspective.

Why is defining the product category important?

Before we explore the different food categories, it is important to have an understanding on why we are asking this question. The food category for the product helps to guide us to what regulations we must consider in developing the formulation, labeling and claims for the product. It can also impact the way a company can promote and distribute the product to the end user. The food category is also important so we have an understanding of what process must be followed before placing the product onto the market. Without having the knowledge of what category the product will be classified under, it is very hard to make assessments for product compliance and timing for launching new products onto the market.

Overview of Different Product Categories

The four product categories that will be reviewed are: Medical Food, Conventional Food, Food for Special Dietary Uses and Dietary Supplements. Each section will highlight how

the ingredients, labeling and claims are regulated and if the product has to have pre-market approval.

Medical Food

The statutory definition of a medical food is "a food which is formulated to be consumed or administered under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."[1] The definition can be a bit confusing so below are some questions to ask when deciding if the product can be a medical food[2]:

- Is the product specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube?
- Is the product intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone?
- Does it provide nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation?
- Will the product be used under medical supervision?

[1] 21 CFR 101.9 (j) (8)
[2] 21 CFR 101.9 (j) (8) (i-v)

- Is the product intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the product?

If the answer were yes to all the questions, then the product would be a medical food. If any of the answers are no, then the product would not be classified in this category.

Medical foods must follow many of the same labeling requirements of conventional foods with one major exemption. They are exempt from the nutritional and health claims labeling of food. Since products in this category are designed for a particular disease population many of the definitions are not applicable to this type of food. For example, what is "low fat" for the general population may not be "low fat" for a malnourished population. Also, medical foods are being used under medical supervision, so the doctor would advise the patient on how much to take and therefore the dietary intake can be significantly different from the general population. A medical food "is permitted to make a claim to address a patient's special dietary needs that exist because of a disease or medical condition. An example of this type of claim would be "For the dietary management of X disease or medical condition." [3]

The ingredients and additives used in medical foods follow the same regulations as conventional foods. All ingredients and additives must be FDA approved or GRAS. Medical foods do not need to obtain pre-approval from the FDA before being placed on the market. They can be sold in pharmacies and food stores.

[3] Institute of Food Technologist, Current US Legal Standards for Health-Related Claims. p. 19 also available on line at members.ift.org/NR/rdonlyres/69E560C7-9AEB-4DBF-8409-F5921FFEA4E2/0/HealthClaims.pdf (accessed April 2008)

Conventional Foods

The term conventional food falls into the same definition as food. Food is defined as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[4] Foods in this category are used by the general population for everyday use (examples would be bread, milk, cereals, soups, etc). They must comply with all food labeling regulations. Before making a nutrient or health claim on the label, the manufacturer must ensure that the formula complies too the requirements to make the claim. The manufacturer must also be aware of any standards established for the product.

All ingredients and additives used in conventional foods must be either pre-approved by the FDA or GRAS. All nutrient and health claims must be approved and meet the general provisions in 21 CFR Subpart A 101.13 and 101.14 along with the specific requirements for the claims in 21 CFR subpart D (Specific Requirements for Nutrient Content Claims) and subpart E (Specific Requirements for Health Claims). Conventional foods do not need to be pre-approved before being placed on the market.

Food for Special Dietary Use

The definition for Food for Special Dietary Use is defined as a food in which is:

"(i) Used for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions

[4] FDAC section 201 (f)

of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(ii) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(iii) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use."[5]

The main difference between a Medical Food and a Food for Special Dietary Use is that a Medical Food must be used under medical supervision. Also, medical foods fall outside the scope for nutrient and health claims. Food for Special Dietary Use must comply with those claims that have been approved for conventional foods or those specifically apply for this group of products: hypoallergenic foods and diet foods.

Ingredients and additives used in this type of product must be GRAS or pre-approved by the FDA. Products do not need to be pre-approved by the FDA with the exception of Infant Formulas, which falls outside of the scope of this paper.

Dietary Supplement

Dietary Supplements are under the food category but are regulated by a separate set of regulations that amends the Food, Drug and Cosmetic Act. The Dietary Supplement

[5] 21 CFR section 105.3

Health and Education Act (DSHEA) of 1994 establish the standards in which dietary supplements must follow. In general, a dietary supplement 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, gelcaps, 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."[6] The labeling must comply with the requirements in 21 CFR subpart C section 101.36, "Nutrition Labeling of dietary supplements." It is important to note some of the items that must be on the label when making certain type of claims. If a dietary supplements makes a claim that relates the nutrient to a function of the body (also known as structure function claims), it must have a disclaimer on the label. This disclaimer must state the following, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[7] The manufacturer must also notify the FDA of the claim within 30 days of placing the product on the market.

The manufacturer is responsible for the safety of the product and must either show evidence that the ingredient was in use before 1994 or that it is accepted and used in food.

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[6] US Food and Drug Administration, Center for Food Safety and Applied Nutrition, Overview of Dietary Supplements, January 3, 2001. available at http://www.cfsan.fda.gov/~dms/ds-oview.html (last visited April 2007).

[7] US Food and Drug Administration, Center for Food Safety and Applied Nutrition, Overview of Dietary Supplements, January 3, 2001. available at http://www.cfsan.fda.gov/~dms/ds-oview.html (last visited April 2007).

If the ingredient in the dietary supplement does not meet either one of the items above, then the manufacture must notify before marketing the product. CFR 21 section 190.6 outlines the requirements for the notification procedure. Once the manufacturer notifies the FDA, they must wait 75 days before placing the product on the market. It should be noted that no response from the FDA does not mean that the ingredient is safe for use and that they FDA approves it. Also, other manufacturers may not use the ingredient unless they notify it as well. In general, if the dietary supplement does not contain a new ingredient, it does not need any approval before marketing.

Impact to Marketing the Product

Now that we have reviewed the different product categories, we can start to see the impact it may have on marketing the product. We will use a hydration drink as an example to make this analysis for each product category.

Medical food- The advantages in marketing the product in this category is that we will be able to make health claims to the product as long as we link it to the type of patient population that we are trying to benefit. We can state that the product is for the dietary management for people at risk of dehydration. We can show the benefits of the nutrients in the product and how they help this population. The formula will not be restrictive to meet certain criteria before making the nutrient and health claims. Another benefit to this category is that we can still market the product in supermarkets and pharmacies. The disadvantage is that you may limit the exposure of the product and that it must be used under medical supervision.

Conventional Food and Food for Special Dietary Use- If we market the product in this category, we will be limited to the types of claims that can be made since we will have to comply with the nutrient and health claim regulations. In developing the formula, we will have to consider the claims we want to make and then formulate the product. The advantage is that you will have more exposure to a wider population of people.

Dietary Supplement- If we market the product under this category, we would need to ensure that the ingredients used are allowed and that the claims are approved. We will not be able to make structure function claims without a post market notification. We will also have to have disclaimers on the label. The advantage is the exposure to wider population of people.

Conclusion

The food category of the product can impact the product development and marketing in many ways. It is important for the scientist, business development and marketing personnel to work closely with the regulatory department to obtain an understanding of each type and its impact. The answer to "which product category" is vital to moving forward to bringing a product to market.