These Flakes Can't Fake it – FDA Says They're Not Medical Foods

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FDA recently issued a warning letter to a medical food manufacturer for several violations of the Federal Food, Drug, and Cosmetic Act (FDCA).[1] The violations were discovered during FDA's inspection of the facility. FDA said that four of the manufacturer's products did not meet the definition of a medical food and were instead unapproved new drugs, misbranded conventional foods, and misbranded dietary supplements.

Background

A medical food is defined under the Orphan Drug Act as:

> a food which is formulated to be consumed or administered enterally 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[2]

FDA's regulations also provide criteria that a product must meet in order to be considered a medical food.[3] FDA considers the medical food definition to be very narrow. The product must be:

1. Specially formulated and processed, rather than a naturally occurring food;
2. Consumed by oral intake or via feeding tube; and,
3. Intended to be used under medical supervision (note: this does not mean medical foods can only be dispensed under a prescription, although many are)

Most importantly, a medical food must be intended for the dietary management of a specific disease or condition, the dietary management of which cannot be achieved by the modification of the normal diet alone. In order to meet this requirement, the product must:[4]

1. Be 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; and
2. Provide nutritional support specifically modified for management of the unique dietary needs of a particular disease or condition.

The Warning Letter

The products at issue are nutritional flakes, liquid protein, and liquid fiber that are promoted as medical foods for use by persons with numerous conditions, including combinations of: pressure ulcers, hypoalbuminemia, protein calorie malnutrition, poor appetite, trauma, muscle wasting associated with cancer and AIDS, immune dysfunction, dialysis, bariatric surgery, chronic

1 https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm575113.htm
2 21 U.S.C. § 360ee(b)(3)
3 21 C.F.R. 101.9(j)(8)
4 *Id.*

constipation, bowel irregularity, irritable bowel syndrome, diverticulitis, and diarrhea. FDA stated it was "not aware of any distinctive nutritional requirements" for individuals suffering from these conditions, meaning the products as promoted did not meet the definition of a medical food.

FDA also stated that the four products included claims that the products were intended for use in the cure, mitigation, treatment, or prevention of disease, which are drug claims, and because the products are not generally recognized as safe and effective for treating these conditions, they are considered unapproved new drugs under the FDCA. Additionally, FDA said they are misbranded because they do not bear adequate direction for use.
The claims FDA pointed to as drug claims include:

- "Helps to relieve chronic constipation, bowel irregularity, irritable bowel syndrome, and diverticulitis"
- "Helps against Hemorrhoids, Diverticulitis, IBS, and lowers Cholesterol"
- "Shorten and Control Diarrhea from the Start"

FDA goes further and states that even if three of the four products were not unapproved new drugs, they would still be misbranded conventional foods. Those three products were labeled with inaccurate nutrition facts, including inaccurately calculated calorie information and an improper use of the "Sugar Free" nutrient claim. FDA went on to provide numerous comments outlining what the manufacturer should change in order to market these products as conventional foods. The fourth product, FDA stated, is a misbranded dietary supplement because it fails to comply with numerous Supplement Facts labeling requirements.

AGG Observations

1. FDA has made it clear in this warning letter that it intends to enforce a narrow reading of the definition of medical food. Manufacturers should keep in mind that general nutrition or health claims will not fulfill the requirement that there be a specific dietary need of a particular disease or condition that the medical food is intended to meet. Similarly, foods that are recommended as part of an overall diet to manage symptoms or reduce the risk of disease would not meet the definition of a medical food.
2. Medical foods fall under FDA's food regulations, rather than the drug regulations. However, medical food manufacturers should be aware that if there is an insufficient connection between their product and the specific nutritional requirements of a specific disease, the claims may lead to the product being considered an unapproved new drug that is also misbranded.

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