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E-ALERT | Food & Drug

August 16, 2013

FDA UPDATES DRAFT GUIDANCE ON MEDICAL FOODS

On August 13, FDA published a new version of its draft guidance on medical foods, entitled "Frequently Asked Questions about Medical Foods; Second Edition."[1] A previous version of the guidance was released in May 2007.[2] The revisions in the new draft guidance reflect FDA's consideration of this expanding category and articulate the agency's position on some, but not all, of the common issues involving medical foods. In particular, the draft guidance provides specific guidance on the scope of medical foods by addressing diseases and conditions that medical foods can – and cannot – be marketed to target.

Background on Medical Foods

The Orphan Drug Act defines a medical food 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nutritional requirements, based on recognized scientific principles, are established by medical evaluation."[3] The new draft guidance, like its previous version, advises that FDA considers this statutory definition to "narrowly constrain" the scope of this category. The agency distinguishes medical foods from foods that are consumed for special dietary use or that make health claims. FDA has established regulatory criteria clarifying the statutory definition of medical foods:[4]

- It is a 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;
- It is 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;
- It provides 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;
- It is intended to be used under medical supervision; and

[1] The recently released draft guidance is available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/ucm054048.htm .

[2] Covington released a client alert discussing the May 2007 guidance that is available at http://www.cov.com/files/Publication/df3fa74d-b25a-46f8-95e2-4fac084bce11/Presentation/PublicationAttachment/af342ac6-f808-449f-8595-5b4f928a6c7e/814.pdf.

[3] 21 U.S.C. 360ee(b)(3)

[4] 21 C.F.R. 101.9.

- It is 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 medical food.

Products that satisfy these criteria qualify as medical foods and are exempt from nutrition labeling requirements and the requirement for health claims and nutrient content claims under the Nutrition Labeling and Education Act of 1990. Accordingly, medical foods may bear claims about the dietary management of disease or about meeting the distinctive nutritional requirements of disease patients. FDA has also interpreted the definition of "medical food" to require at least as much substantiation for claims made for medical food as required for health claims on conventional foods, i.e. "significant scientific agreement."

FDA emphasizes that medical foods are still foods, so the other labeling requirements that apply to conventional foods also apply to medical foods. The agency reiterates that medical foods must also comply with all other applicable FDA requirements for foods, including the Current Good Manufacturing Practice regulations, Registration of Food Facilities regulations, the Food Allergen Labeling and Consumer Protection Act of 2004, and regulations specific to the product's formulation and processing.

Key Aspects of Revised Draft Guidance

The newly released draft guidance includes considerably more substantive material than its previous version. The most notable additions address the scope of the medical foods category by clarifying some of the diseases and conditions that a medical food can be used to manage. FDA has struggled over the past several years to define the scope of this expanding category. In 1996, the agency published an Advance Notice of Proposed Rulemaking for the regulation of medical foods[5] but withdrew it in 2004 as not viable for final action.[6]

According to the draft guidance, FDA considers inborn errors of metabolism (IEMs) to be diseases or conditions that a medical food can be used to manage. The agency notes in the draft guidance, however, that this view applies only to IEMs that cannot be managed solely with a diet modification. The IEM must require medical food in addition to a specific dietary modification in order for the patient to obtain adequate levels of essential nutrients.

FDA states that type 1 and type 2 Diabetes Mellitus (DM), diseases resulting from essential nutrient deficiencies, such as scurvy and pellagra, and pregnancy generally are not diseases or conditions that a medical food can be used to manage. For each of these conditions, the patient typically does not satisfy the criteria set out in 21 CR 101.9(j)(8)(ii) of having either (1) a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or (2) a special medically determined nutrient requirement that cannot be managed through the modification of the normal diet alone. FDA previously raised this latter argument in warning letters for purported medical foods for diabetics and pregnant women. Although the agency recognizes that patients in the three situations it identifies – type 1 or type 2 DM, diseases resulting from essential nutrient deficiencies, and pregnancy – should meet certain nutrient requirements, FDA explains that the management of each condition can typically be achieved through the modification of the normal diet alone.[7]

The draft guidance also explains that FDA does not require medical foods to be made available only by written or oral prescription. Moreover, a medical food's labeling may not bear the symbol "Rx only"

[5] 61 Fed. Reg. 60661 (Nov. 29, 1996).
[6] 69 Fed. Reg. 68831 (Nov. 26, 2004).
[7] FDA indicates in the draft guidance that it does not consider pregnancy to be a disease.

– indeed, the use of this symbol would cause the medical food to be misbranded. The agency does emphasize, however, that a medical food should be used under "active and ongoing" supervision of a healthcare practitioner who has determined that the medical food is necessary for the patient's overall medical care. FDA also indicates that the patient should generally see the physician on a recurring basis for, among other things, instructions on the use of the medical food. Foods that are merely recommended by a physician or other healthcare professional as part of an overall diet designed to reduce the risk of a disease or medical condition, or as a weight loss product, are not considered to be medical foods. In line with this analysis, FDA states that it "would not object" to labeling that communicates the requirement that the medical food be consumed or administered enterally under medical supervision. The agency provides the example, "must be used under the supervision of a physician."

Consistent with FDA's position regarding the symbol "Rx only," FDA states that the labeling of medical foods should not include National Drug Code numbers. Including such a number on a medical food, which are not drugs, would also cause the product to be misbranded. FDA's position in this regard could have significant implications with respect to reimbursement for medical foods.

Covington & Burling LLP is experienced in legal matters concerning the regulation of medical and conventional foods and is available to provide individualized compliance counseling concerning food labeling and marketing issues.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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