

FDA Finalizes Guidance for Industry about Medical Foods

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Food & Drug

Last week, FDA finalized its guidance for industry about medical foods, which it issued in draft form in August 2013.¹ This guidance incorporates most of the principles that FDA articulated in the 2013 draft guidance regarding the agency's position on the definition of medical foods, the scope of lawful uses of medical foods, and other labeling and safety requirements.

This alert provides a brief background about the legal framework for medical foods and a high-level summary of the guidance, and highlights key differences between the draft guidance and final guidance.

What is a Medical Food?

A "medical food" is "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

In the guidance, FDA indicates that it considers this definition to "narrowly constrain" this category of products, and distinguishes medical foods from what FDA considers to be a broader category of specially formulated food products, foods for special dietary use (FSDU).³ Specifically, FDA states that the primary distinguishing aspect of a medical food is the requirement that a medical food be intended to meet the distinctive nutritional requirements of a disease or condition. FDA explains that "[m]edical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or

¹ The guidance, "Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition," is available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/ucm054048.htm>.

² 21 U.S.C. 360ee(b)(3).

³ A "special dietary use" is defined, in part, to mean "a particular use for which a food purports or is represented to be used, including . . . [s]upplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium." 21 U.S.C. 350(c)(3).

condition,” but, instead, are a specially formulated food product for patients who require that product as part of a disease or condition’s dietary management.

FDA has also established regulatory criteria to clarify the statutory definition of medical food. Medical foods that satisfy the following criteria are exempt from food nutrition labeling requirements, including specific requirements regarding health claims and nutrient content claims:

- 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 (meaning a tube or catheter that delivers nutrients beyond the oral cavity directly into the stomach or small intestine);
- 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
- 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.⁴

While exempt from certain nutrition labeling requirements, the guidance explains that the labeling of medical foods still must include other required information, such as a statement of identity, an ingredient list, a net quantity of contents statement, and the name and place of business of the manufacturer or distributor. The guidance also reiterates that medical foods must be manufactured and distributed in compliance with all applicable food safety requirements, including FDA’s current good manufacturing practice regulation and food facility registration requirements. Though the guidance doesn’t specifically mention new food safety requirements recently established under the FDA Food Safety Modernization Act (FSMA), medical food facilities will also be subject to any applicable FSMA-based requirements, including those for preventive controls for human food.

Key Aspects of the Final Guidance

As it did in the draft guidance, in the final guidance FDA identifies certain diseases or conditions that a medical food could be used to manage and other diseases or conditions that FDA has concluded a medical food should not be intended to manage.

⁴ 21 C.F.R. 101.9(j)(8).

Specifically, the guidance indicates that, generally, inborn errors of metabolism (IEM) are diseases or conditions that a medical food could be used to manage, so long as the specific IEM cannot be managed with modification of the normal diet alone. For those IEMs that cannot be managed with dietary modification alone, FDA indicates that a medical food could be used, for example, to help provide essential nutrients that are restricted by necessary changes to the diet. Some examples of specific IEMs that the guidance indicates medical foods could be used to manage are phenylketonuria, which requires dietary restriction of a specific amino acid, and ornithine transcarbamylase deficiency, which requires dietary restriction of nonessential amino acids. By contrast, FDA explains that the IEM galactosemia can be managed through dietary modification alone by reducing consumption of galactose and lactose.

The guidance also addresses the potential use of medical foods for the dietary management of pregnancy and diabetes and, like the draft guidance, concludes that these are generally conditions for which a medical food should not be marketed. However, the reasoning for this conclusion in the final guidance differs somewhat from FDA's reasoning in the draft guidance.

- **Pregnancy:** In the draft guidance, FDA acknowledged that there are nutrient requirements associated with pregnancy, but concluded that, because those nutrient requirements could be met through dietary modification, medical foods generally should not be marketed for the dietary management of pregnancy. FDA reaches the same conclusion in the final guidance, but based on FDA's determination that there are no distinctive nutritional requirements associated with pregnancy *because* any nutrient requirements can be met through dietary modification.
- **Diabetes:** In the draft guidance, FDA similarly acknowledged that there are nutrient requirements associated with both Type 1 and Type 2 diabetes, but that those requirements could be met through dietary modification alone. In the final guidance, however, FDA concludes that there are no distinctive nutritional requirements associated with the management of diabetes because essential nutrient requirements for individuals affected by diabetes *are no different* than those for unaffected (generally healthy) persons. This is a change from the position that FDA took in the draft guidance. The final guidance also recognizes, though, that diet therapy is a mainstay of diabetes management and that nutritional recommendations for those with diabetes are well-established.

FDA's partial shift in reasoning ties FDA's conclusions more closely to the statutory definition of medical food, because, in the final guidance, FDA concludes that neither diabetes nor pregnancy have "distinctive nutritional requirements" primarily because any nutritional needs resulting from these conditions can be met through dietary modification alone. While FDA's ultimate conclusions in the final guidance regarding pregnancy and diabetes are the same as those in the draft guidance, FDA appears to have based those conclusions more on statutory language requiring a distinctive nutritional requirement rather than FDA's own regulatory criteria (perhaps because the regulatory criterion that the condition cannot be managed through dietary modification alone has been criticized as not grounded in the statutory definition). It is possible that FDA could apply similar logic going forward with regard to other diseases or conditions that could be potentially managed by medical foods and conclude that a given disease does not have a distinctive nutritional requirement because the disease can be managed through dietary modification alone.

In addition, the final guidance reiterates FDA's conclusion in the draft guidance that medical foods cannot bear the term "Rx only" because that term can only be used in the labeling of

prescription drugs, and that medical foods should not bear an NDC number, which could cause the product's labeling to be misleading. FDA would not object, however, to the use of other nonmisleading language in the labeling of medical foods to communicate that the product must be used under a physician's supervision (e.g., "must be used under the supervision of a physician").

Covington & Burling LLP advises on legal issues concerning the regulation of medical foods and other specially formulated food products, including FSDU. If you have any questions concerning the issues discussed in this alert or other food regulatory matters, please contact any of the following attorneys of our Food & Drug Practice Group or visit our [food, drugs and device practice website](#):

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