May 31, 2007

FDA Releases Guidance for Industry on Medical Foods

The Federal Food and Drug Administration ("FDA") recently released a Guidance for Industry – Frequently Asked Questions About Medical Foods ("Medical Foods Guidance" or "Guidance").[1] The Guidance reiterates the statutory and regulatory provisions addressing medical foods, as well as FDA's longstanding interpretations of those authorities. While the Medical Foods Guidance includes no new statements of policy, FDA states that the Guidance is intended to be a convenient place for industry to find answers to common questions about medical foods. This Client Alert summarizes the key features of the Medical Foods Guidance and provides historical context for FDA's approach to medical foods.

I. Definition and Criteria for Medical Foods

The term "medical food" is defined in section 5(b) of 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.

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

Medical foods are exempted from nutrition labeling requirements, and in FDA's regulation codifying that exemption, the agency set forth the following criteria to clarify the definition a "medical food":

i. 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;

ii. 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;

iii. 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;

iv. It is intended to be used under medical supervision; and

[1] *Available at* http://www.cfsan.fda.gov/~dms/medfguid.html.

v. 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.

21 C.F.R. 101.9(j)(8). Medical foods are also exempted from the labeling requirements for health claims and nutrient content claims, but are subject to other labeling requirements applicable to foods generally, including ingredient labeling and the requirements of the Food Allergen Labeling and Consumer Protection Act of 2004 ("FALCPA").

Medical foods must also comply with all applicable requirements governing the manufacture of foods, including Current Good Manufacturing Practices ("cGMPs") and Registration of Food Facilities requirements. Ingredients used in medical foods must be either generally recognized as safe ("GRAS"), approved food additives, or food additives that are the subject of an exemption for investigational use. FDA also implements a Compliance Program specifically for medical foods.[2]

II. FDA's Historical Approach to Medical Foods

In light of the hazy contours of the statutory definition of medical foods, FDA has periodically considered providing more specific criteria or guidance as to which products properly fall within this product category. In 1996, FDA published an Advance Notice of Proposed Rulemaking ("ANPRM") for the regulation of medical foods.[3] Recognizing that a broad group of heterogeneous products were being marketed as medical foods, FDA articulated the essential features of medical foods, contrasted them with foods for special dietary use,[4] and invited comment on possible interpretations of the "distinctive nutritional requirements" aspect of the medical foods definition. In 2004, however, FDA withdrew the ANPRM as not viable for final action, but the agency advised that when evaluating medical foods, FDA would continue to refer to the basic principles described in the ANPRM and in FDA's Medical Foods Compliance Program.[5]

FDA's release of its new Medical Foods Guidance may have been sparked by the continuing proliferation of a broad range of medical food products, and appears to suggest a renewed agency interest in this product category. FDA advises in the guidance that it considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food, but the agency is apparently not prepared at this time to provide more clarity as to the bounds of that definition. While FDA warning letters for purported medical foods have focused primarily on the absence of distinctive nutritional requirements for the disease or condition for which the product is marketed, the agency has also recently addressed unlawful marketing practices and illegal drug claims for purported medical foods.

Covington & Burling has extensive experience and expertise with the regulation of medical foods, and would be pleased to provide counsel for clients interested in this product category.

[2] CP 7321.002, *available at* http://www.cfsan.fda.gov/~acrobat/cp21002.pdf.

[3] 61 Fed. Reg. 60661 (November 29, 1996).

[4] *See* 21 U.S.C. 350(c)(3).

[5] 69 Fed. Reg. 68831, 68834 (November 26, 2004).

This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

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

Eugene Lambert	202.662.5422	elambert@cov.com
Richard Kingham	202.662.5268	rkingham@cov.com
Jeannie Perron	202.662.5687	jperron@cov.com
Sarah Taylor Roller	202.662.5563	sroller@cov.com
Miriam Guggenheim	202.662.5235	mguggenheim@cov.com
Heather Banuelos	202.662.5161	hbanuelos@cov.com