The Current FDA Regulation around Foods for Special Dietary Uses

Jessica P. O'Connell, JD, MPH
Covington & Burling LLP
August 14, 2019

MEDICAL FOODS WORKSHOP:
Science, Regulation and Practical Aspects
AUGUST 13–14, 2019 WASHINGTON, DC

Brief Overview of “FSDU” as a Category

- **1938 FDCA**: established the regulatory framework that allows “foods” to be represented for “special dietary uses”
- Section 403(j) permits foods to be “represented for special dietary uses” provided that the “label bears such information concerning its vitamin, mineral, and other dietary properties [as FDA] determines to be, and by regulations prescribes as, necessary in order [to] fully inform purchasers as to its value for such uses”

Brief Overview of "FSDU" as a Category

- **November 1941**: FDA regulation stating that the term ''special dietary uses'' means particular (as distinguished from general) uses of food, including ''uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of disease, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight.''
- Until DSHEA, this category included dietary supplements

Brief Overview of "FSDU" as a Category

- **September 1972**: FDA concludes that Lofenalac (PKU product) would no longer be regulated as a drug but rather as a ‘‘food for special dietary use’’
- Effort on the part of the agency to "minimize barriers to innovative development of such products, which may be manufactured as a public service and not for profit, and to reduce consumer costs" (48 Fed. Reg. 31876)
- In addition, the agency began to follow a policy of regulating similar types of products as foods for special dietary use

Brief Overview of "FSDU" as a Category

- **January 1973**: FDA exempts certain foods for special dietary use from nutrition labeling requirements
- FDA: Nutrition labeling developed for foods intended for consumption by the general population was not well suited for some food products, including two types of foods for special dietary use: (1) Any food represented for use as the sole item of the diet; and (2) foods represented for use solely under medical supervision in the dietary management of specific diseases and disorders.

Current Regulatory Status

- Current FDCA Definition: The term “special dietary use,” as applied to food used by man, means a particular use for which a product purports or is represented to be used, including but not limited to the following uses:
  - Supplying 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.
  - Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.
  - Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

Current Regulatory Status

- 21 CFR Part 105
  - General requirements for “foods for special dietary use”
  - Specific labeling requirements for
    - Hypoallergenic foods
    - Infant foods
    - Usefulness in reducing or maintaining body weight
  - 1996 – FDA revoked specific labeling requirements for food for use in the diet of diabetics *as part of regulatory reform*
    - FDA: The weight of evidence and current recommendations by recognized authorities is that no specific food is, or is not, more useful than others in the diets of diabetics.
    - FDA: the provisions for diabetic labeling in Sec. 105.67 are outdated and misleading

Current Regulatory Status

"Regulation of Medical Foods" ANPRM (11/1996)

- FDA "re-evaluating" its approach to regulating medical foods
- Many products that purport to be medical foods fall outside statutory definition – FDA thinks more likely FSDU
- "Distinctive nutritional requirement" – 2 possible interpretations to help distinguish from FSDU
  - Physiological
  - Alternative

- FDA: The statutory definitions of ''medical food'' and food for special dietary use, and the differing treatment of these two categories of products under the NLEA (i.e., medical foods are exempt from nutrition and claim requirements, while there is no special treatment of FSDU), establish that Congress intended that medical foods and FSDU be viewed and regulated as separate and distinct categories of products.

Current Regulatory Status

"Regulation of Medical Foods" ANPRM (11/1996)

"Distinctive nutritional requirement"

- Physiological: Only for nutritional requirements *different from* the nutritional requirements of healthy people
  - *If food intended to meet typical nutritional requirements, it would be a FSDU
  - *FDA appears to be operating under this interpretation in recent WLs

- Alternative: Would also include limitations on ability to ingest/digest conventional foods, even if nutritional requirements are the same (e.g., liquid food; concentrated nutrition forms)

Current Regulatory Status

- *FDA considers the statutory definition of "medical food" to narrowly constrain the types of products that fit within this category of food. Medical foods are distinguished from the **broader category of foods for special dietary use** by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, and must be intended to be used under medical supervision.*