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New FDA guidance sheds more light on formulation, marketing of medical foods

By Hank Schultz, 15-Aug-2013

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The Food and Drug Administration has given additional clarification to a ill-defined subcategory of foods by issuing a revised draft guidance on medical foods. The new version clarifies some issues surrounding branding and marketing, and in so doing, raises a few issues of its own, according to an observer.

The new draft guidance expands upon one that had been in place for several years by adding 13 questions to the question and answer portion. It should help bring some more certainty to a little-known subset of foods, a market niche that has been underutilized, according to Denver-based attorney Justin Prochnow with the firm Greenberg Traurig who has done work on medical foods in the past.

"I think that companies don't know the law that well on (medical foods) There aren't many specific regulations on medical foods," Prochnow told NutraIngredients-USA.

"There is not a lot of clear regulation on the topic of medical foods so that is why companies have shied away from it. Unless you have got counsel who is familiar with it, you might be taking a risk," he said.

Aimed at specific nutrient requirements

First some basics: A medical food is defined in 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."*

So in this sense, medical foods are adjuncts of drug or other therapies, and are specifically aimed at addressing dietary issues resulting from the underlying disease itself or arising from those treatment interventions.

And that word "formulated" is important; if a given condition or treatment resulted in a potassium deficiency, for example, a marketer of bananas couldn't trump up his wares as a medical food for this purpose. Similarly, in cases such as liver disease where patients would need a low protein diet, foods that are normally low in protein would not meet the specification of a medical food.

In the additional questions, FDA focuses on labeling queries, formulation issues, marketing of medical foods and questions around specific conditions.

Conditions excluded

As far as specific conditions go, in the draft guidance FDA excludes pregnancy, diabetes and deficiency diseases such as scurvy and pellagra as being candidate populations for the formulation and marketing of a medical food. Deficiency conditions, whether they result from famine, eating disorders, alcoholism or other factors generally resolve themselves once a normal diet is reestablished, FDA said. *"A medical food must be intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements,"* FDA said in the draft guidance.

But the agency did say inborn errors of metabolism, or IEMs, are conditions that can be treated with a medical food. Examples of these given in the guidance involve amino acid/protein, organic acid, or fatty acid metabolism.

Several new questions that bear on the labeling and marketing of a medical food were of particular interest to Prochnow. One asks if "Rx only" can or should be used on the labels of medical foods. Answer: No, as such a label is meant for drugs only.

Sold only through practitioners?

Another asks if such foods should be made available by prescription. Answer: no again. But the answer goes on to describe FDA's thinking on how these foods should be used. The consumer or patient should use them under

the supervision of a physician and agency foresees these foods as part of an overall treatment scenario that would involve visits to the doctor and instructions from the physician on the use of the food. That answer raised a question for Prochnow, as a number of foods that currently fall within the penumbra of medical foods, such as products that serve the needs of elderly consumers experiencing sarcopenia, are available in outlets such as supermarkets, far from the supervision of a physician.

"It seems as if they are saying that these should only be offered through health care practitioners," Prochnow said. *"There was some suggestion of that in the Q&A.*

"There is nothing in the Orphan Drug Act that says it has to be done that way. The guidance doesn't come right out and say that, but if you read between the lines they certainly seem to indicate that it would be a problem to sell these products in a way in which you couldn't guarantee medical supervision," he said.

Click here to read the next of the new draft guidance.