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ALERTS

Food, Drug And Device Law Alert - FDA To Hold Public Meeting To Discuss Developing A List Of Pre-DSHEA Dietary Ingredients

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The U.S. Food and Drug Administration (FDA) will hold a public meeting to discuss its efforts to develop a list of dietary ingredients that pre-date the Dietary Supplement Health and Education Act (DSHEA) of 1994. The public meeting will be held on October 3 from 8 a.m. to 5 p.m. at the Center for Food Safety and Applied Nutrition's Wiley Auditorium in College Park, Maryland.

The FDA states the meeting will give interested stakeholders an opportunity to discuss what evidence is necessary to show that an ingredient was marketed before October 15, 1994, making a new dietary ingredient (NDI) notification unnecessary. The public meeting also will focus on what process should be used to develop the list.

The meeting is related to a revised draft guidance from August 2016 titled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues." By way of background, DSHEA requires dietary supplement manufacturers to notify the FDA in advance when they intend to add a new dietary ingredient to their products, except when the ingredient has been part of the food supply and has not been chemically altered for use in supplements. The notifications must identify the new dietary ingredient and provide evidence of its safety.

The draft guidance made clear that "in the food supply" means the ingredient must have been on the market as a dietary supplement before October 15, 1994 and not "in the food supply" as an ingredient of conventional foods. If dietary supplement manufacturers have not been filing NDI notifications on the theory that their ingredient was a component of conventional food before October 15, 1994, the draft guidance rejected their premise. As a result, many notifications may have to be filed.

Also, according to the draft guidance, if there is a change to the manufacturing process of an ingredient that was marketed as a dietary supplement before Oct. 15, 1994, and the change "alter[s] the physicochemical structure or properties, purity and impurities, or biological properties (such as bioavailability or toxicity) of the ingredient," an NDI notification is required.
The draft guidance also established requirements – among them specific business record documentation – to prove that an ingredient was marketed as a dietary supplement in the U.S. before Oct. 15, 1994, and therefore is not an NDI. According to the draft guidance:

Documentation to show that a dietary ingredient is not an NDI should consist of written business records, promotional materials, or press reports with a contemporaneous date prior to Oct. 15, 1994. Examples

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include sales records, manufacturing records, commercial invoices, magazine advertisements, mail order catalogues, or sales brochures. Documentation should include adequate information to establish that marketing took place in the U.S., the identity (e.g., chemical or botanical name) and form (e.g., ground herb, water extract, oil) of the marketed ingredient, and whether the ingredient was marketed as a dietary ingredient or for some other purpose.

The draft guidance expressly states that affidavits alone, i.e., unaccompanied by such records, are insufficient to show that an ingredient is not an NDI.

A summary chart showing when an NDI notification is required and when the adulteration standard applies was included in the draft guidance, as follows:

The 102-page draft guidance addressed many other questions about when an NDI may be marketed, such as in relation to the timing of its testing or approval, if any, as a drug. The guidance also contained detailed instructions on the contents of an NDI notification when one is required and of the evidence of safety that will be required depending on the evidence of historical use and proposed use of the ingredient.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or the chair of the firm's Food, Drug & Device Group, Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com.

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