FDA updates draft guidance on premarket safety notifications for dietary supplement industry

For Immediate Release

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The U.S. Food and Drug Administration today issued a revised draft guidance to improve dietary supplement companies' new dietary ingredient (NDI) premarket safety notifications to the agency. These notifications help the agency identify safety concerns before products reach consumers.

Under the Dietary Supplement Health and Education Act (DSHEA), the manufacturer or distributor must notify the FDA at least 75 days before beginning to market a dietary supplement that contains a new dietary ingredient (one that was not marketed in the United States before Oct. 15, 1994), unless the NDI is used in the food supply without chemical alteration. Dietary supplements are considered adulterated if they contain an NDI not used in the food supply and the required notification has not been submitted to the FDA 75 days before marketing.

The FDA estimates that there are more than 55,600 dietary supplements on the market, and that 5,560 new dietary supplement products come on the market each year. However, the agency has received fewer than 1,000 NDI notifications since DSHEA was passed in 1994. An initial draft guidance, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," was released in 2011. After considering the feedback received on that draft, the FDA revised the draft guidance to clarify several important points that were misunderstood or not fully explained, to describe the public health significance of the recommendations, and to request additional comment before publishing a final guidance.

"This revised draft guidance is an important step forward in the agency's work to protect public health from potentially dangerous new dietary ingredients," said Steven Tave, acting director of the FDA's Office of Dietary Supplement Programs. "Notification of new dietary ingredients is the only pre-market opportunity the agency has to identify unsafe supplements before they are available to consumers. The revised draft guidance is intended to improve the quality of industry's new dietary ingredient reporting so the FDA can more effectively monitor the safety of dietary supplements."

Over the past three years, the FDA has taken numerous actions on dietary supplements, including action on several products containing new dietary ingredients that pose safety concerns and should have been the subject of an NDI notification but were not, such as Acacia rigidula.

In December 2015, the agency announced the creation of the Office of Dietary Supplement Programs, elevating the program from its previous status as a division under the former Office of

Nutrition, Labeling and Dietary Supplements (now Office of Nutrition and Food Labeling). As part of that action, the agency reaffirmed its commitment to remove from the market products that contain potentially harmful pharmaceutical agents, are otherwise dangerous to consumers, or are falsely labeled as dietary supplements; enforce the dietary supplement good manufacturing practices regulation; and take action against claims that present a risk of harm to consumers (such as egregious claims of benefit in treating serious diseases) or economic fraud.

A manufacturer may choose to implement the recommendations in a draft guidance before the guidance becomes final.

The FDA encourages public comments on the revised draft guidance during the 60-day comment period.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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