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Food, Drug And Device Law Alert - FDA Revises 2011 Draft Guidance On New Dietary Ingredients For Supplements

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The Food and Drug Administration (FDA) recently issued a revised version of the draft guidance titled, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues." The draft guidance is a revised version of one issued in 2011 (summarized here) and, despite the passage of five years, many of the key provisions have not changed. The 2011 version received many industry comments, largely because of its broad view of what constitutes a new dietary ingredient (NDI) and narrow view of certain exceptions, discussed further below, which will likely require the industry to submit far more NDI notifications than it has historically.

Comments on the revised draft guidance are due on or before October 11, 2016.

By way of background, the 1994 Dietary Supplement Health and Education Act (DSHEA) requires dietary supplement manufacturers to notify the FDA in advance when they intend to add an NDI 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 be accompanied by evidence on its safety.

The FDA states that this draft guidance is intended to inform and assist manufacturers, distributors, and others in deciding when a pre-market safety notification for a dietary supplement containing a new dietary ingredient is necessary and in preparing the notifications.

As noted above, under DSHEA it is not necessary to submit an NDI notification to the FDA for ingredients that were in the food supply before Oct. 15, 1994. The draft guidance makes clear that "in the food supply" means the ingredient must have been on the market as a dietary supplement before that date and not "in the food supply"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NDI notifications on the theory that their ingredient was a component of conventional food before Oct. 15, 1994, the draft guidance rejects their premise.

The result could be that many notifications will 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 Also, according to the draft guidance, if there is a change to the manufacturing process of an ingredient that was marketed as a dietary supplement before Oct. 15, 1994, and the change "alter[s]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.

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The draft guidance further states that a dietary supplement that contains an NDI is adulterated under the Food, Drug and Cosmetic Act, even if the supplement contains only dietary ingredients that have been present in the food supply as articles used for food in a form in which the food has not been chemically altered.

The draft guidance also establishes 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 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 is included in the draft guidance, as follows:

	New Dietary Ingredient (NDI)	**NDI notification required?**	**NDI adulteration Standard applies?**
A dietary ingredient that was marketed in the U.S. before October 15, 1994	No	No	No
A dietary ingredient that was NOT marketed in the U.S. before October 15, 1994 AND was present in the food supply as an article used for food	Yes	See a) or b)	Yes

which has			
a) not been chemically altered	Yes	No	Yes
b) been chemically altered	Yes	Yes	Yes
A dietary ingredient that was NOT marketed in the U.S. before October 15, 1994 AND was NOT present in the food supply as an article used for food.	Yes	Yes	Yes

An appendix to the guidance, reproduced here, includes a somewhat complicated decision tree to assist manufacturers and others in deciding whether an NDI notification is necessary.

The 102-page draft guidance addresses 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 contains 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.

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