# FDA Issues Controversial Draft Guidance on New Dietary Ingredients

*By Ashish Talati and Abhishek Gurnani*

## Introduction

Dietary supplements are regulated by the Food and Drug Administration (FDA) pursuant to the Dietary Supplement Health and Education Act (DSHEA) of 1994. While DSHEA outlines specific criteria pertaining to the marketing of dietary supplements including labeling, good manufacturing practices (GMPs), and product statements and claims, it offers little guidance on new dietary ingredients and the new dietary ingredient notification process. As a result, submitters of NDI notifications have relied heavily on industry commentary, feedback from FDA, and basic regulatory guidelines listed in the Code of Federal Regulations[1], in both interpreting Section 8 of DSHEA and preparing NDI notifications for submission to FDA.

## Dietary Supplement Health and Education Act (DSHEA) of 1994

DSHEA amended the Food, Drug and Cosmetic Act (FD&C Act) to include a requirement that at least 75 days before introducing a new dietary ingredient into interstate commerce, information be submitted to FDA supporting the conclusion that the product will reasonable be expected to be safe.[2] A new dietary ingredient was first defined in DSHEA as "a dietary


**Ashish Talati** is a Partner and Chair of the Food and Drug Law Practice at Amin Talati, LLC

**Abhishek Gurnani** is an Associate Attorney who practices Food and Drug Law at Amin Talati, LLC

ingredient that was not marketed in the United States before October 15, 1994."[3] Ingredients that were present in the food supply as an article used for food in a form in which the food has not been chemically altered are not considered "new dietary ingredients" and thus are not subject to notification requirements.[4]

While DSHEA outlined the safety standard by which FDA would review new dietary ingredients, it did not specify what type of information could be supplied to FDA in order to support a conclusion that the dietary ingredient will reasonably be expected to be safe. Basic requirements for premarket notifications are also provided in the Code of Federal Regulations, Title 21, Section 190.6 which sets forth when a notification must be submitted, basic content requirements for a notification, and administrative information regarding FDA's review of submitted notifications. The industry, for nearly 20 years, simply relied on FDA feedback regarding previous notifications and 21 CFR 190.6 in drafting their NDI notifications.

## A Significant Development in Dietary Supplement Regulation

A significant development in dietary supplement regulation occurred in July of 2011 with the release of FDA's draft guidance on NDI notifications. Section 113(b) of the Food Safety Modernization Act (FSMA) required FDA to release detailed guidance on when and how a new dietary ingredient notification must be submitted to FDA.5 The draft guidance provides valuable insight for industry including when a dietary supplement ingredient is considered a NDI, when the manufacturer or distributor of a dietary ingredient or dietary supplement should submit a NDI notification to FDA, the evidence needed to document the safety of a NDI, and appropriate methods for establishing the identity of a NDI.

The issuance of this draft guidance on NDI notifications is a significant step forward in the advancement of food safety. However, an overwhelming majority of industry members have expressed concerns with FDA's draft guidance, noting that the guidance, if finalized as is, would not only detrimentally impact the industry, but also flood FDA with an insurmountable workflow.

## Implications of FDA's Draft Guidance on Industry

The industry believes that the draft guidance interprets the NDI notification requirement in DSHEA to be supplement-specific, while years of Agency feedback and actions in response to previously submitted notification reveals an ingredient-specific interpretation of the NDI notification requirement by FDA. A requirement that each new supplement be subject to notification would result in duplicate notifications to FDA where a company may use the same NDI in a number of its dietary supplement products. FDA would be forced to review safety data that it would have already assessed in a previous NDI notification submitted by the same company.

Other industry comments note that the draft guidance significantly heightens the safety standard by requiring safety studies and evidence that would be used to establish the safety of food additives, also in direct contradiction to DSHEA. DSHEA established a separate regulatory category for dietary supplements and specifically exempted dietary ingredients from being regulated as food additives.

Most importantly, the industry contends that with the draft guidance, FDA seeks to expand its definition of "new dietary ingredient" by redefining what constitutes "chemical alteration" without following rulemaking procedures outlined in the Administrative Procedures Act.[6] A number of manufacturing processes that were once thought to be minor by the industry are now considered by FDA to be processes that result in a new dietary ingredient subject to notification.[7]

The industry believes that the draft guidance, if finalized as is, would severely disrupt the dietary supplement market, with the imposition of unnecessary burdens, both on industry as well as FDA, which would stall innovation and inhibit economic growth and competitiveness. FDA's altered interpretation of DSHEA represented in its draft guidance would effectively designate thousands of dietary supplements that have been marketed for years as adulterated.

Members of the dietary supplement industry including ingredient manufacturers, trade associations, and various consultants, including attorneys for the industry, submitted comments to the draft guidance. It is the industry's hope that FDA will take all comments into serious consideration when finalizing the guidance. In the past, FDA has included systematic responses to public comments and clearly provided its reasoning for finalizing a certain regulation or regulatory requirement. Ultimately the goal for both FDA and industry is consumer safety, so industry-agency cooperation is imperative in finalizing the guidance.

## Conclusion

This year will prove to be significant in terms of the regulation of dietary supplements as FDA seeks to finalize guidance on new dietary ingredients notifications that will not only apprise the industry of key requirements of notification but also remain in line with established legislation as well as previous Agency interpretations of the regulations. With thou-

sands of comments filed being reviewed by FDA, there is no set timeframe for when the draft guidance will be finalized. However, 2012 will certainly be an important year for new dietary ingredients and dietary supplement regulation as industry awaits further clarification of the draft guidance and submits NDI notifications to FDA.

1. 21 CFR 190.6
2. Dietary Supplement Health and Education Act (DSHEA) of 1994, Pub. L. No. 103-417 (codified as amended at 21 U.S.C. §§ 21 USC §350b (1994)).
3. Dietary Supplement Health and Education Act (DSHEA) of 1994, Pub. L. No. 103-417 (codified as amended at 21 U.S.C. §§ 21 USC §350b (1994)).
4. Dietary Supplement Health and Education Act (DSHEA) of 1994, Pub. L. No. 103-417 (1994).
5. President Obama signed the Food Safety Modernization Act (FSMA) (Public Law 111-353) into law on January 4, 2011. It required FDA to publish guidance on NDI notifications within 180 days of enactment of FSMA.
6. 5 U.S.C. §553
7. *See* FDA, Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues, § IV(B)(4) (July 5, 2011), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm257563.htm (last visited Nov. 10, 2011) (i.e., *Use of solvents other than water or aqueous ethanol (tincture) to* make an extract or High temperature baking or cooking of an ingredient that has not previously been baked or cooked, unless the process causes only minor loss of volatile components with no other changes to the chemical composition of the ingredient).