



December 2, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane,
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-D-0376; Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Availability; Extension of Comment Period

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit comments pertaining to the Food and Drug Administration's (FDA) draft guidance on new dietary ingredient notifications and related issues as published on July 5, 2011.¹ For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. They work with physicians, nurses, and other health-care professionals to ensure that medicines are used safely and effectively.

On October 25, 1994, the Dietary Supplement Health and Education Act of 1994 (DSHEA) was signed into law. DSHEA amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding definitions of "dietary supplement" and "new dietary ingredient" (NDI) and requires the manufacturer or distributor of a NDI, or of the dietary supplement that contains the NDI, to submit a premarket notification to FDA at least 75 days before introduction unless the NDI and any other dietary ingredients in the dietary supplement "have been present in the food supply as an article used for food in a form in which the food has not been chemically altered". If the required premarket notification is not submitted to FDA, the dietary supplement containing the NDI is deemed to be adulterated.

On January 4, 2011, the President signed into law the FDA Food Safety Modernization Act (FSMA) requiring the FDA to publish, not later than 180 days after the date of

enactment, guidance that clarifies when a dietary supplement ingredient is a NDI, when the manufacturer or distributor of a dietary ingredient or dietary supplement should submit a NDI notification to FDA.

DSHEA does not specify the type or amount of evidence that must be included in a NDI notification and this guidance is necessary to more clearly define situations in which manufacturers and distributors should submit a NDI notification. ASHP supports the Agency's guidance as the Society has been concerned with the increasing prevalence of unlabeled active drug ingredients (e.g., sibutramine, sildenafil and related analogues, anabolic steroids) in these products. It has been estimated that more than 40 million people in the United States use at least one dietary supplement, which range from vitamins and minerals to therapies marketed as weight-loss therapies or athletic and sexual performance aids. Further, approximately 25% of supplement users have a serious medical condition. As the FDA notes, there are an estimated 55,600 dietary supplement products on the market, with another 1,000 new products introduced annually. However, since the Agency began reviewing NDI notifications as a result of DSHEA, the FDA has only received 700 NDI notifications. Given these statistics, the ASHP is concerned that only a small percentage of these products are sold in establishments where a pharmacist or other health care professional is available for consultation and we are particularly concerned with the rise in adulterated products. This guidance is an important step in a process to ensure that patients are not subject to unnecessary public health risks in the form of new ingredients with unknown safety profiles. Further, ASHP supports this draft guidance as it may address circumstances when an established dietary ingredient may be considered a new ingredient if the concentration or formulation is different from what has been previously introduced.

Even when products are not adulterated, they often have pharmacologic actions. This is especially true of products derived from botanicals. The significant effects of botanicals are illustrated by the fact that 100 FDA-approved drug products are derived from or based on chemicals from plants. This may prevent the introduction of unnecessary health risks into the market. ASHP instructs its members to submit information on suspected or actual adverse events to dietary supplements via MedWatch.

ASHP's official policy is one which calls for expanded FDA authority in regulating these products:

To advocate that Congress grant authority to the Food and Drug Administration (FDA) to

- (1) require that dietary supplements undergo FDA approval for evidence of safety and efficacy;

- (2) mandate FDA-approved dietary supplement labeling that includes disclosure of excipients;
- (3) mandate FDA-approved patient information materials that describe safe use in a clear, standardized format, including the potential for interaction with medications and cautions for special populations; and
- (4) establish and maintain an adverse-event reporting system specifically for dietary supplements, and require dietary supplement manufacturers to report suspected adverse reactions to the FDA; further,

To oppose direct-to-consumer advertising of dietary supplements unless the following criteria are met

- (1) federal laws are amended to include all the requirements described above to ensure that dietary supplements are safe and effective;
- (2) evidence-based information regarding safety and efficacy is provided in a format that allows for informed decision-making by the consumer;
- (3) the advertising includes a recommendation to consult with a health care professional before initiating use;
- (4) any known warnings or precautions regarding dietary supplement–medication interactions or dietary supplement–disease interactions are provided as part of the advertising; and
- (5) the advertising is educational in nature and includes pharmacists as a source of information.

The Society appreciates the opportunity to comment on the FDA's proposed guidance on New Dietary Ingredient notifications. Please contact me if you have any questions or wish to discuss our comments further. I can be reached by telephone at 301-664-8806, or by e-mail at ctopoleski@ashp.org.

Sincerely,



Christopher J. Topoleski
Director, Federal Regulatory Affairs

¹ Federal Register, Volume 76, No. 128. Pages 39111