CHPA

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October 24, 2013

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

Re: Docket No. FDA-2013-N-0878, Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification for a New Dietary Ingredient; 78 Fed. Reg. 52773-4 (August 26, 2013)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) welcomes the opportunity to comment on the above captioned request published in the August 26, 2013 Federal Register. CHPA is the 132-year old trade association representing U.S. manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements. As such, CHPA has an interest in the subject matter of the request for comments.

As stated in the Federal Food, Drug, and Cosmetic Act, Section 413(a), at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a New Dietary Ingredient (NDI), a manufacturer or distributor must submit to FDA information upon which it has determined that a dietary supplement containing an NDI will reasonably be expected to be safe. FDA notes in the August 26, 2013 Federal Register notice that they are developing an electronic means for submitting this information and has invited comments on the process by which this is to be submitted.

Echoing earlier comments submitted to the agency on the July 2011 Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notification and Related Issues[1], CHPA and its member companies marketing dietary supplement products support the presumption of safety for dietary ingredients outlined in the Dietary Supplement Health and Education Act (DSHEA) of 1994 and believe that an NDI notification should not be required for any ingredient marketed prior to the passage of DSHEA unless the safety of that ingredient has been altered. For NDIs that do require notification, the notifying party must simply show that these ingredients "will reasonably be expected to be safe."

[1] Docket No. FDA-2011-D-0376; 76 Fed. Reg. 39111, July 5, 2011

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We also take this opportunity to suggest a number of potential ways to enhance the electronic submission of information concerning the safety of an NDI. Whenever possible, the agency should provide drop down menus on the electronic submission site to facilitate information entry. This could include allowing the user/submitter to select from among multiple fields for such items as: whether a reference NDI exists, who is submitting the information (and who they are submitting for), whether or not the submission is for an ingredient or a final product and choices for declaring whether or not, and on what basis the submitter believes the ingredient (or a component of the product) is new. Selection of the included fields would be based upon finalization of the new Draft Guidance for Industry. CHPA would be happy to work with the Agency to develop these criteria.

CHPA member companies thank the Agency for the opportunity to provide comments concerning the procedures by which information supporting the safety of a dietary supplement containing an NDI will reasonably be expected to be safe.

On behalf of the CHPA Dietary Supplements Committee,

Jay E. Sirois
Director, Regulatory & Scientific Affairs