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March 20, 2012

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 061
Rockville, MD 20852
(*Electronic submission to Docket FDA-2011-N-0842*)

Dear Sir or Madam,

Enclosed herein are comments on “Gluten in Drug Products: Request for Information and Comments”, published in the U.S. Federal Register on December 21, 2011. The Consumer Healthcare Products Association (CHPA) is the national trade association representing the leading manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements in the U.S. CHPA offers the following comments:

CHPA encourages FDA to work with industry and other stakeholders to develop and discuss alternatives to an ingredient ban. Given the extremely low levels of gluten in OTC drugs today, a ban on gluten-containing source ingredients would unnecessarily disrupt the supply chain and may limit the availability of important healthcare products relied on by millions of U.S. consumers.

Certain ingredients used in OTC medicines and dietary supplements, the majority as excipients, may be derived from wheat, barley or rye. These include starch, pregelatinized starch, dextrimaltose, malt, dextrin, cyclodextrins, maltodextrin, sodium starch glycolate (carboxymethyl starch), citric acid, caramel color, and various alcohols. The grain source material for these ingredients can vary. Manufacturers often rely on global supply chains and multiple ingredient suppliers. While corn or potato may be commonly used in the U.S., wheat is commonly used in Europe.

Many ingredients derived from wheat, barley or rye can be processed in a way that removes or reduces gluten to an insignificant level. Processes such as distillation (for alcohol), hydrolysis and extraction may significantly reduce or eliminate gluten in the final raw material. It is unclear if these derived materials present risk to individuals who have celiac disease.

The amount of gluten in finished OTC drug products where gluten is not intentionally added is minute, especially when compared to intake via the food supply. Banning use of ingredients derived from specific grains would disrupt the supply chain, resulting in major reformulation of products. Reformulation to ensure elimination of gluten would have significant consequences to manufacturing

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cost and resources. Such an effort would involve changes to labeling, analytical testing, stability testing, cleaning procedures and other aspects of processing. A complete ban on certain source materials may not guarantee lack of gluten due to cross- contamination. Qualification of new ingredients or different grades of ingredients could result in cost implications for consumers.

As noted above, alternatives to an ingredient ban, such as labeling (as has been done for allergies) and allowable limits for gluten-free drug or dietary supplement products should be discussed with industry and other stakeholders prior to considering a ban on source ingredients. Analytical methods and reasonable protocols to support “gluten-free” labeling (for example, less than 20 ppm) should be discussed and agreed upon. As an example, testing for gluten in every batch of finished product, vs. verification of lack of gluten in starting materials may be cost-prohibitive and unnecessary, thus depriving patients of useful information. Commercial gliadin ELISA test kits are widely available and could possibly be applied to pharmaceutical ingredients and products with proper validation. It is especially important to use a manufacturer’s knowledge of a manufacturing process to ascertain whether or not ingredients derived from wheat, barley or rye are free of gluten or will contribute only very dilute and insignificant quantities of gluten to a drug product.

We appreciate the opportunity to provide comments and would welcome further dialogue with FDA on this issue.

Sincerely,



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