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CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

October 23, 2000

Charles Ganley, M.D.
Director, Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research (HFD-560)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-1706

Re: Docket No. 78N-036L

Dear Dr. Ganley:

Some time ago FDA asked the Laxative Task Group of the Consumer Healthcare Products Association (CHPA, formerly the Nonprescription Drug Manufacturers Association) to comment on the agency's determination and comments pertaining to psyllium (see attached letter from William E. Gilbertson, Pharm.D., July 28, 1995, regarding Docket No. 78N-036L). The agency specifically sought comments on the following topics:

1. Methodology to more accurately assay the amount of hydrophilic mucilloid, for a possible revision of USP monograph standards for psyllium preparations;

2. Change in dosage ranges;

3. Assessment of need for name changes so names are appropriate and consistent; and

4. Review of compendial purity standards for *plantago*-seed, psyllium husk, and psyllium hydrophilic mucilloid for oral suspension to ensure consistent and reasonable standards.

This letter provides the CHPA Psyllium Subgroup's responses on each of these topics.

Assay of hydrophilic mucilloid

FDA is requesting that manufacturers of psyllium products work with the USP Convention to possibly revise the monograph standards for psyllium preparations to more accurately measure hydrophilic mucilloid content, i.e., to consider including measurements of mucilloid content in gram-weight (the compendial standards measure the mucilloid content using swell volume methodology) and/or converting the swell volume to gram-weight.

CHPA members who manufacture over-the-counter (OTC) psyllium products consider the current swell volume methodology sufficient for measuring the content of psyllium husk and fragmented psyllium husk for oral suspension. The swell volume test is well established with much historical data; it is a test that manufacturing plants can use very effectively. Company studies demonstrate that swell volume is precise (precision is 1.6% Relative Standard Deviation).

In addition, a CHPA member company is working to establish a USP monograph for a finished product, "Psyllium Hydrophilic Mucilloid Granules," a granular mixture of psyllium husk and seed. This proposed product monograph also relies on swell volume methodology as a measure of psyllium content. The swell volume assay contained in the proposed Psyllium Hydrophilic Mucilloid Granules monograph is similar to the swell volume test used in the current USP monograph for Psyllium Hydrophilic Mucilloid for Oral Suspension, but differs to accommodate differences in the product formulations. The swell volume assay for Psyllium Hydrophilic Mucilloid Granules was reviewed during a 1999 FDA inspection of the manufacture and was found to be acceptable.

We believe there is confusion around the term "psyllium hydrophilic mucilloid." FDA's July 28, 1995 letter to CHPA stated that "because the final (laxative) monograph will only contain active ingredients that have USP monographs, only *plantago* seed, psyllium husk and psyllium hydrophilic mucilloid for oral suspension would be included at this time." We would like to point out that the USP monograph defines Psyllium Hydrophilic Mucilloid for Oral Suspension as "a dry mixture of Psyllium Husk with suitable additives" (see attached USP monograph). This describes a finished product and thus would not be included in the OTC laxative monograph, which is specific to active ingredients. "*Plantago* Seed" and "Psyllium Husk" USP monographs refer to active ingredients.

CHPA members consider the active ingredient in "Psyllium Hydrophilic Mucilloid for Oral Suspension" to be "psyllium hydrophilic mucilloid" and would like the option of keeping this and "psyllium (hemicellulose)" as active ingredients in the final laxative monograph. Clarity is required around the names and active ingredient definitions (see Appendix).

Change in dosage ranges

FDA proposes dosages for psyllium-containing products be based on the levels of mucilloid that can be extracted from psyllium seeds. The FDA is proposing 2.5-14 g of psyllium hydrophilic mucilloid for a daily dosage for adults and children 12 years of age and over and 1.25-7 g for children 6 to under 12 years of age and a maximum daily dosage of 30 g of *plantago* seed (as opposed to 2.5-30 g and 1.25-15 g, for products containing any psyllium ingredient identified in 334.10 (f) in the Tentative Final Monograph [TFM]). The agency states that a daily dose of 2.5-14 g provides for a range that generally reflects dosages for mucilloid content that are suggested for use for occasional constipation.