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Via electronic submission
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January 20, 2004

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

Re: Docket No. 1978N-036L, RIN 0910-AA01
Laxative Drug Products for Over-the-Counter Human
Use; Reopening of the Administrative Record

Dear Sir or Madam:

On October 22, 2003, the Food and Drug Administration (FDA) announced a reopening of the administrative record for the rulemaking for over-the-counter (OTC) laxative drug products. The Consumer Healthcare Products Association (CHPA) sees this as an appropriate time to get clarification on an allowable statement of identity for OTC laxative drug products that contain fiber and on an indication under the OTC laxative monograph.

CHPA, founded in 1881, is the national association representing manufacturers and distributors of OTC drug products and dietary supplements. Members of the Association account for more than 90 percent of OTC drugs marketed in the United States, including many laxative products. Accordingly, CHPA has important interest in the monograph for OTC laxative drug products.

CHPA specifically asks for clarification about allowable statements of identity (SOI) for OTC laxative drug products containing fiber as were discussed in a letter from FDA to the Association (Gilbertson to Soller, June 10, 1993, attached). The Association, then named the Nonprescription Drug Manufacturers Association (NDMA), had submitted research protocols designed to obtain information about how various terms for SOI would be understood. The Agency turned down the NDMA request that the SOI for bulk-forming laxatives be changed to "Fiber therapy for irregularity." The Agency did, however, say that "[t]erms such as 'Bulk-forming laxative' or 'Fiber laxative' when used as statements of identity would not require such clinical proof" (that is, would not require clinical trials, as the Agency said would be required to

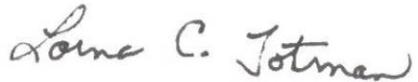
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support “Fiber therapy for irregularity.”) This seems to imply that “fiber laxative” may be used as an alternative to “bulk-forming laxative,” which is listed as the SOI in proposed 21 CFR §334.52 (a) in the Tentative Final Monograph for OTC laxatives (*Federal Register* 50:2153, January 15, 1985).

CHPA also would like a clarification of the last substantive paragraph of FDA’s 1993 letter which apparently contains an error. It says “. . . However, we might consider including the term ‘fiber laxative’ as an optional (allowable) indication for bulk-forming laxatives in the final monograph as follows: ‘Fiber therapy for relief of occasional constipation’ [which may be followed by ‘(irregularity).’]” Evidently the term “fiber laxative” was used where the term “fiber therapy” was intended.

CHPA is now requesting that FDA clarify these two points and include the SOI “fiber laxative” and the indication “Fiber therapy for relief of occasional constipation” [which may be followed by ‘(irregularity).’]” in the final laxative monograph. Please contact me if you need other information regarding these clarifications.

Sincerely,



Lorna C. Totman, Ph.D., DABT
Senior Director of Scientific Affairs
and Toxicology

LT/mm

Attachment: Letter from William E. Gilbertson, FDA, to R. William Soller, NDMA,
June 10, 1993

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