CHPA

founded 1881

November 10, 2009

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

Re: Docket No. FDA-2008-N-0334; RIN 0910-AF96: Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements; 74 *Fed. Reg.* 42184-42203 (August 21, 2009)

Dear Sir or Madam:

On August 21, 2009, the Food and Drug Administration (FDA) issued a proposed rule on electronic submission requirements for postmarketing safety reports for human drug and biological products (74 *Fed. Reg*. 42184 – 42203). The Consumer Healthcare Products Association (CHPA) welcomes the opportunity to comment on the proposed rule[1]. Founded in 1881, CHPA is a national trade association representing manufacturers and distributors of over-the-counter (OTC) products and dietary supplements. Our membership represents approximately 90% of the OTC medicines sold in the United States.

The notice indicated that nonprescription drugs marketed under approved applications (*i.e.,* NDAs and ANDAs) would be subject to the mandatory electronic format requirements as outlined in the proposed rule. Furthermore, the *Federal Register* notice inquired whether the final rule should require the use of electronic format for postmarketing safety reports for nonprescription human drug products marketed without an approved application (*i.e.,* nonprescription or OTC monograph drugs). Interested members of CHPA members have reviewed the proposed rule and wish to express their support for extending the final rule to

[1] 74 *Fed. Reg.* 48184 – 42202; Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements.
Retrieved October 27, 2009, from http://edocket.access.gpo.gov/2009/pdf/E9-19682.pdf.

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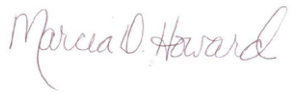
nonprescription human drug products marketed without an approved application (or OTC monograph drug products).

We thank the agency for the opportunity to provide comments on this matter. Please contact Mr. David Spangler, senior vice president, policy & international affairs (DSpangler@chpa-info.org) or me if you have any questions or if CHPA can be of assistance.

Sincerely,



Marcia D. Howard, Ph.D.
Director, Regulatory & Scientific Affairs

MDH/11-09-09

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