CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

Submitted electronically via www.regulations.gov

March 23, 2015

Division of Dockets Management (HFA 305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2011–N–0915; Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application. 80 *Federal Register* 3608-3609 (January 23, 2015)

Dear Sir or Madam:

On January 23, 2015, a *Federal Register* notice was released pertaining to a proposed collection of information regarding an FDA guidance to industry on postmarketing adverse event reporting for nonprescription human drug products marketed without an approved application (80 *Federal Register* 3608-3609)[1]. The Consumer Healthcare Products Association (CHPA[2]) appreciates the opportunity to respond to this request for comment. In the *Federal Register* notice[1], FDA estimates that it should take a sponsor approximately 2 hours to prepare and submit a report for a serious adverse event, and approximately 5 hours to comply with requirements to maintain records of efforts to obtain minimum data elements for a report of a serious adverse drug event and any follow-up reports.

There may be circumstances when the number of hours indicated as the average burden for reporting and recordkeeping may be accurate. However, in other instances these approximations may be underestimated. For example, CHPA members have suggested that up to 6 hours may be required to complete a single serious adverse event report, especially when the sponsor's medical and quality review teams are involved. Furthermore, it is estimated that as many as 8 hours may be required to maintain all relevant records for a single adverse event report as stipulated by statute[3].

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[1] *Federal Register* notice published 23 January 2015 (80 *Federal Register* 3608-3609). Accessed at http://www.gpo.gov/fdsys/pkg/FR-2015-01-23/pdf/2015-01111.pdf on 6 March 2015.
[2] CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of over-the-counter medicines and dietary supplements (www.chpa.org).
[3] Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109-462). Accessed at

Therefore, CHPA members recommend that FDA increase the average burdens estimated for reporting and recordkeeping to 6 hours and 8 hours, respectively.

Thank you in advanced for your time and attention to this matter. We hope FDA finds this information useful. If questions arise, please feel free to contact me.

Sincerely,

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http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm148035.htm on 6 March 2015.