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Advancing Quality Healthcare
Through Over-the-Counter Medicines
and Nutritional Supplements

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

March 31, 2004

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

Re: Docket No. 2004D-0027; Draft Guidance for Industry on Time and Extent Applications

Dear Sir or Madam:

In the February 10, 2004 Federal Register, FDA invited comments on the above-referenced draft guidance, which is intended to provide the agency's current thinking on how and what information an applicant should include in a time and extent application (TEA) for consideration in the OTC Drug Review.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of OTC drugs and dietary supplements in the U.S. CHPA members account for over 90 percent of the retail sales of OTC drugs in the U.S. CHPA has been a major participant in every aspect of the OTC Review process since its inception in 1972.

We are encouraged that the agency is seeking to provide guidance on how to utilize the TEA process. We are also encouraged by the fact that the agency has acted on TEAs and has published notices of eligibility for ingredients and conditions based on TEA submissions.

However, we take this opportunity to again note our disappointment that the agency's TEA approaches requires completion of several lengthy, difficult, and unnecessary steps before even reaching the OTC Review process itself. A less complicated, less unwieldy approach to TEAs would allow a more vibrant and more readily used mechanism to incorporate new conditions into the OTC Review. A threshold review of eligibility for foreign-marketed OTC drugs, as CHPA suggested in its comments to the agency's advance notice of proposed rulemaking in 1996, and the proposed rule in 2000, would have provided such a mechanism. An in-depth review of the relevance of foreign data for establishing "material time" and "material extent" can be accomplished as an integral part of the required examination to establish a condition's status as generally recognized as safe and effective. There is no need for FDA to make a material time/extent determination separately from its consideration of safety and effectiveness.

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If there is interest in re-visiting in more depth ways in which the TEA rule could be amended to make it more useful, we are available to discuss our thoughts with the agency.

Sincerely,

/s/

David C. Spangler
Vice President – International &
Assistant General Counsel

cc: Matthew R. Holman, Center for Drug Evaluation and Research (HFD-560), FDA
Charles J. Ganley, Center for Drug Evaluation and Research (HFD-560), FDA
Curtis J. Rosebraugh, Center for Drug Evaluation and Research (HFD-550), FDA

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