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CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

October 14, 2003

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

Re: Safety Reporting Requirements for Human Drug and Biological Products

Dear Sir or Madam:

The Food and Drug Administration (FDA) proposed rule on Safety Reporting Requirements for Human Drug and Biological Products, which was published in the *Federal Register* on March 14, 2003, has been reviewed in the context of safety reporting of medicines available directly to the consumer. The Consumer Healthcare Products Association (CHPA)[1] submits these comments on certain provisions of the proposed rule as they would affect over-the-counter (OTC) drug products approved under New Drug Applications (NDAs) or Abbreviated New Drug Applications (ANDAs).

Executive Summary

CHPA welcomes the underlying rationale for the proposed rule, including the move by the FDA towards global harmonization of safety reporting requirements in alignment with the European Union and Japan. This alignment process will save considerable valuable resources for both industry and the governmental agencies in the processing of safety reports and allow more effective pharmacovigilance and continued protection of public health.

CHPA member companies have reviewed the provisions in the proposed rule primarily in terms of the postmarketing safety reporting requirements for consumer healthcare products. OTC drugs have long marketing histories and are known to have favorable safety profiles, and so unexpected serious adverse events are unlikely with their use. While clinical trials are undertaken for OTC drug products, this activity is considerably less than that required for initial approval of a prescription medicine and would result in a relatively lower frequency of serious adverse events.

In this context, the content of the proposed rule, specifically Sections II through III.I, was reviewed with focus on the implications for post-marketing safety reporting for OTC drug products subject to NDA or ANDA requirements, and comments are given below.

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[1] CHPA, founded in 1881, is the national association representing manufacturers and distributors of over-the-counter (OTC) drug products and dietary supplements. CHPA members account for over 90 percent of OTC drugs marketed in the United States.

While the rationale behind FDA's proposals is clear, the practical implications may be problematic and in some cases extraordinarily resource-intensive; their contribution to continued public health in the context of OTC drug pharmacovigilance is debatable. To balance the real need for harmonized safety reporting and pro-active pharmacovigilance with not unlimited resource, one option is to adopt a targeted risk management approach to consumer healthcare products with perceived safety issues. This would, however, require further dialogue between the industry and the agency. It would incorporate elements of FDA's proposals but on a selective, mutually-agreed product-specific basis.

Introduction

On March 14th, 2003, the FDA published proposals to amend the safety reporting requirements for human drug and biological products (21 CFR Parts 310, 312 et al.: Safety Reporting Requirements for Human Drug and Biological Products; Proposed Rule).

These proposals have been reviewed by CHPA member companies from the consumer healthcare viewpoint. Because products marketed under the OTC drug monographs are not subject to reporting of post-marketing adverse events, these comments on post-marketing surveillance will be confined to OTC products approved under an NDA or ANDA and for which adverse event reporting is mandatory. Comments pertaining to clinical studies for OTC drug products will be confined to those circumstances for which they are subject to an IND.

Background

CHPA member companies market a diverse range of products for consumer use, including cosmetics and dietary supplements, as well as monograph and NDA OTC drug products. Some of the same companies also market prescription drugs. Safety reporting for this diverse range of products is covered by different regulations specific to the class of product. Reporting requirements for an OTC product approved under an NDA or ANDA are identical to those for a prescription product similarly approved.

Adverse event reporting is not required for OTC drug products subject to monographs. FDA has determined these products have well established active ingredients that are "generally recognized as safe." Similarly, dietary supplements are also not the subject of required safety reporting procedures. Some healthcare companies (including many CHPA member companies) do, however, voluntarily submit expedited reports to the FDA for serious adverse events on products in these classifications, although they are not required.

In addition to being marketed in the United States, this diverse range of consumer products is also available in many other countries where they are subject to regulations that may require expedited and/or periodic safety reporting.