



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

## CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

October 15, 2003

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

Re: Docket No. 78N-0301: External Analgesic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record and Amendment of Tentative Final Monograph

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) External Analgesics Task Group submits these comments in response to FDA's reopening of the administrative record for the over-the-counter (OTC) external analgesics rulemaking and the agency's proposal to amend the tentative final monograph (TFM) for external analgesics (68 FR 42324-42327, July 17, 2003). The proposed amendment would classify any OTC external analgesic active ingredient in a patch, plaster, or poultice dosage form as Category III (more data needed), although the active ingredients are Category I (generally recognized as safe and effective). FDA has reopened the administrative record for comments on the existing data in the docket and on the agency's proposed TFM amendment, and for new data and information relevant to inclusion of patch, plaster, and poultice products in the final monograph.

CHPA, founded in 1881, is the national association representing manufacturers and distributors of OTC drug products and dietary supplements. CHPA members account for over 90 percent of OTC drugs marketed in the United States, including many external analgesic products. Accordingly, the association has important interest in this matter, and the CHPA External Analgesics Task Group welcomes the opportunity to comment on the proposed rule. These comments are not meant to supersede comments submitted by individual members of CHPA.

**Action Requested:**

The CHPA task group requests that dosage forms different from those of creams, lotions, and ointments be permitted under the monograph for OTC external analgesic drug products. FDA's long-standing policy in the OTC Review is to determine the limits of active ingredient safety and effectiveness and to allow the marketing of many different types of products

within those limits. The overwhelming safety and effectiveness of the OTC medications marketed today under the monograph system show that this is a wise policy.

It is also requested that FDA and industry work together to develop principles for a guidance for industry to use when developing alternate dosage forms, including patches, poultices, and plasters. This guidance would include specific recommended protocols and test methods that could be used in a product-qualification program, but it would not preclude the use of alternate methods that provide scientifically valid results. The guidance would be referenced in the final monograph for OTC external analgesics as the recommended standard for all alternate dosage forms.

Finally, the CHPA task group requests that the record be kept open for receipt of additional data. Manufacturers may need to submit data to support the development of a guidance. The task group would appreciate being able to submit these data to support alternative dosage forms.

The remainder of this submission is organized in the following sections:

- I. Executive Summary
- II. Regulatory Background
- III. Data Regarding Topical Counterirritant Patch, Plaster, and Poultice Products
- IV. Properties of Patches, Plasters, and Poultices as Vehicles for Application of Counterirritant External Analgesics
- V. Safety of Currently Marketed Products
- VI. Proposal for Testing and Development of a Guidance Document
- VII. Comments on Labeling
- VIII. Request for FDA to Work with Industry to Develop Guidance and to Keep Docket Open for Submission of Relevant Data
- IX. Summary of Requested Action

Attachment 1: Literature Search Strategy

Attachment 2: Data Regarding Topical Counterirritant Patches, Plasters, and Poultices,  
Docket 78N-0301 and Published Scientific Literature