



Consumer Healthcare
Products Association

October 18, 2004

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

Re: Applications for Approval to Market a New Drug; Complete Response Letter;
Amendments to Unapproved Applications; Proposed Rule [Docket No. 2004N-0267]

Dear Sir or Madam:

The Consumer Healthcare Products Association appreciates the opportunity to comment on the proposed rule referenced above. CHPA is the 123-year-old trade association representing manufacturers of nonprescription, or over-the-counter medicines and dietary supplements. CHPA members manufacture and distribute OTC medicines under new drug applications or on the basis of general recognition of safety and effectiveness. OTC medicines using new drug applications would be affected under the proposed rule.

CHPA supports FDA's proposal to discontinue the use of approvable letters and not approvable letters when taking action on NDAs, instead using complete response letters when the review cycle is complete but an application is not ready for approval (or, conversely, moving directly to an approval letter when the application is ready for approval). We concur with the agency's view that complete response letters should be a neutral mechanism to convey that the agency cannot approve an application in its current form. We note and concur with the agency's view that the complete response letter approach will ensure consistency in how sponsors are informed of changes needed if an application is to be approved, without implying anything as to the ultimate approvability of the application.

We believe the proposed rule would benefit from one clarification. Absent unusual circumstances, the agency should clearly define specific deficiencies in an application in a complete response letter. This would avoid presentation of new issues at a later date after a complete response letter has been issued, and minimize the potential for cycles of complete response letters.

We appreciate the opportunity to submit these comments, and thank you for considering our views.

Sincerely,

/s/

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& Assistant General Counsel

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