

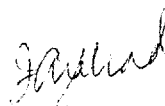



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: June 21, 2000

FROM: Jane A. Axelrad and Lana Ogram  
Co-Chairs of the Pharmacy Compounding Steering Committee

SUBJECT: Background Material for FDA Advisory Committee Meeting on July 13-14, 2000

TO: Committee Members

Enclosed are 4 volumes of materials relating to the July 13-14, 2000, meeting of the Pharmacy Compounding Advisory Committee.

Volume 1 contains documentation supporting the January 4, 2000 proposed rule (65 FR 256) that would amend FDA regulations to add two drug products (aminopyrine and astemizole) to the list of drug products that cannot be compounded because they have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective. There were no comments received on this proposed rule. In addition to these 2 drug products, documentation is included to support the inclusion of 3 additional drug products (cisapride, grepafloxacin and troglitazone) to the list in a future proposed rule. These products were recently withdrawn from the market by the sponsors for safety reasons.

Volume 2 contains a concept paper on drug products that present demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of those drug products, and Volumes 3 and 4 contain references used in preparing the concept paper. We are interested in discussing this paper with the Committee in preparation for developing a proposed rule on difficult to compound drugs.

Proposed Drug Products for the Withdrawn or Removed Drug Product List

