DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-346

MAY 30 2003

Sidmak Laboratories
Attention: Deborah Pakay
U.S. Agent for: Pliva Pharmaceutical Industry, Inc.
72 Eagle Rock Avenue
P.O. Box 371
East Hanover, NJ 07936

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 31,, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Torsemide Tablets, 5 mg, 10 mg, and 20 mg.

Reference is also made to your amendments dated February 19, March 31, April 24, May 7, and May 27, 2003. We also refer to your correspondence dated June 10, and July 22, 2002 addressing the patent issues noted below.

The listed drug product (RLD) referenced in your application, Demadex® Tablets of Hoffmann LaRoche, Inc. (Roche) is subject to a period of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. patent RE34,672 (the '672 patent) is scheduled to expire on August 11, 2006. Your application contains a paragraph IV certification to the '672 patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, sale, or offer to sell Torsemide Tablets, 5 mg, 10 mg, and 20 mg will not infringe on this patent. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Pliva Pharmaceutical Industry, Inc. (Pliva) for infringement of the '672 patent which was the subject of the paragraph IV certifications. This action must be brought against Pliva prior to the expiration of forty-five days from the date the notice you provided under paragraph (2)(B)(i) was received by the NDA/patent holder. You notified the agency that Pliva complied with the requirements of Section

505(j)(2)(B) of the Act and that no legal action was brought against Pliva within the statutory forty-five day period.`

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Torsemide Tablets, 5 mg, 10 mg, and 20 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Demadex® Tablets, 5 mg, 10 mg, and 20 mg, respectively, of Hoffmann La Roche, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Robert Lumpkin for

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research