



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

ANDA 75-927

Food and Drug Administration  
Rockville MD 20857

Scientific and Regulatory Affairs Consulting [L 18 111]  
Agent for: Interpharm, Inc.  
Attention: C. Jeanne Taborsky  
6333 Summercrest Drive  
Columbia, MD 21045

Dear Madam:

This is in reference to your abbreviated new drug application dated July 18, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Naproxen Tablets USP, 250 mg, 375 mg and 500 mg.

Reference is also made to your amendments dated December 4 and December 28, 2000; November 26 and December 7, 2001.

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 Naproxen Tablets USP, 250 mg, 375 mg and 500 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Naprosyn® Tablets, 250 mg, 375 mg and 500 mg, respectively, of Syntex (USA) Inc. LLC). 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 which 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 proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-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 FD-2253 at the time of their initial use.

Sincerely yours,



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