DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 71-795

Danbury Pharmacal, Inc.
Attention: Mr. Nessim Maleh
131 West Street
P.O. Box 296
Danbury, Connecticut 06810

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Dear Sir:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Sulindac Tablets USP, 200 mg.

Reference is also made to our communications dated February 25 and 26, 1988.

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; however the effective date of approval is delayed until April 3, 1990 pursuant to 21 U.S.C. 355(j)(4)(B) relating to patent rights. This Division should be advised of any change in the marketing status of this drug. Thus, if circumstances arise which may have impact upon the effective date of approval (e.g. a license agreement between you and the patent holder), you are requested to supplement your application with documentation from the patent holder that a licensing agreement exists and include any relevant conditions or restrictions.

Any significant change in the conditions outlined in this abbreviated application including a change in the effective date of approval requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.70 of the new drug regulations.

Postmarketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80 and 314.81 of the Regulations.

For Initial Campaigns: We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your immediate 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 Advertising and Labeling (HFN-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

For Subsequent Campaigns: We call your attention to Section 314.81(b)(3) of the Regulations which requires that materials for any subsequent advertising or promotional campaign, at the time of their initial use, be submitted to our Division of Drug Advertising and Labeling (HFN-240) with a completed Form FD-2253.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 331(d).

Sincerely yours,

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drug Evaluation and Research