DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 71-523

Sidmak Laboratories, Inc.
Attention: Mr. Edward J. Hiross
17 West Street, P.O. Box 371
East Hanover, New Jersey 07936

Dear Sir:

Reference is made to your abbreviated new drug application dated September 12, 1986, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Trazone-50 (trazodone hydrochloride) Tablets, 50 mg.

Also refer to your amendments dated December 12, 1986, July 9, 1987 and August 12, 1987.

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.

Any significant change in the conditions outlined in this abbreviated application 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.

This Administration should be advised of any change in the marketing status of this drug.

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.

Sincerely yours,

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

RECEIVED
12/15/87

Attachment

ADDENDUM

Please be advised that you are required to submit, ~~every eight weeks~~, all adverse drug experience reports received on Trazodone Hydrochloride Tablets pertaining to the side effect priapism. This special reporting requirement will remain in effect until you are notified and is in addition to those reporting requirements found in 21 CFR 314.80. These reports should be sent in duplicate to:

Food and Drug Administration
Central Document Room
Park Building, Room 214
12420 Parklawn Drive
Rockville, Maryland 20857

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[illegible], M.D.
Director
Division of Generic Drugs
Office of Drug Standards
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