DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

ANDA 89-763

Food and Drug Administration
Rockville MD 20857

APR 30 1990

Sidmak Laboratories, Inc.
Attention: Satish P. Patel, Ph.D.
17 West Street
P.O. Box 371
East Hanover, New Jersey 07963

Dear Sir:

Reference is made to your abbreviated new drug application dated July 1, 1987, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Theophylline (anhydrous) Controlled-release Tablets, 300 mg.

We acknowledge receipt of your amendments dated May 17, 1989 and June 12, 1989.

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 (HFD-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 (HFD-240) with a completed Form FD-2253.

Sincerely yours,

D.B. Bly

Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

SIDMAK LABORATORIES, INC.
EAST HANOVER, NJ 07936
DRUG REGULATORY AFFAIRS
RECEIVED Addendum 5-1-90

Addendum

In accordance with 21 CFR 314.70(b)(2)(v) and (x) you will be required to file supplemental application(s) for the following changes, if needed post approval of this ANDA.

a) Reprocessing of non-conforming batch(es). Supplemental application should accompany batch ticket, summary of process validation data (in-process controls), finished drug product report of analysis, dissolution data on 12 individual tablets and proposed expiration date from the date of initial date of manufacture of the drug product, and three month challenge condition stability data.

b) Batch scale-up beyond the proposed manufacturing batch size of 500,000, as stipulated in the application. Supplemental application should accompany batch ticket, summary of process validation data (in-process controls), the finished drug product report of analysis, and commitment to place first scale-up batch for stability testing.