DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 70-033

Sidmak Laboratories, Inc.
Attention: Dr. Satish P. Patel
17 West Street
P. O. Box 371
East Hanover, New Jersey 07936

DEC - 6 1984

Gentlemen:

Please refer to your abbreviated new drug application dated April 25, 1984, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Metronidazole Tablets, USP 500 mg.

Reference is also made to your communication dated September 17, 1984 and November 29, 1984.

We have completed the review of this abbreviated new drug 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 new drug application requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.8 of the new drug 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). Also, please do not use Form FD-2253 for this submission.

For Subsequent Campaigns: We call your attention to Regulation 21 CFR 310.300(b)(3) which requires that all material for any subsequent advertising or promotional campaigns 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. A copy of Form FD-2253 is enclosed for your convenience.

RECEIVED
DEC 10 1984

The enclosures summarize the conditions relating to the approval of this application.

Sincerely yours,

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

Enclosures:
Conditions of Approval of a New Drug Application
Records & Reports Requirements
Form FD 2253

TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS FOR HUMAN USE

1. DATE SUBMITTED	*Form Approved: OMB No. 0910-0018* *Expiration Date: May 31, 1985*

2. NDA NO.	1	2	3	4	5	6
	N					

NOTE: This form is required by law (21 CFR 310.300(b)(3) and 431.60(b)(3). Penalty for failure to comply with any provision of Section 301, shall be imprisonment for not more than one year or fine of not more than $1,000, or both.

INSTRUCTIONS

1. Submit a separate form *(parts 1 through 3)* for each NDA or Antibiotic Application for which advertisement or promotional labeling material is submitted.
2. Attach two copies of each piece of material to the form.
3. Enter in Column C the total number of types *(not copies)* of material submitted.
4. Forward form and attachments to Department of Health and Human Services, Food and Drug Administration(HFN–240), 5600 Fishers Lane, Rockville, Maryland 20857.
5. Acknowledgement of receipt of the submission does not constitute approval of the materials listed below.

3. APPLICANT	4. DRUG NAME

5. ADVERTISEMENT/PROMOTIONAL LABELING MATERIAL

TYPE a.	DATE OF ISSUANCE b.	NO. c.	IDENTIFICATION *(Use code or other designation. If necessary, continue on 8½ x 11.)* d.
JOURNAL ADVERTISEMENT(S)			
PROMOTIONAL LABELING			
BROCHURE(S) LEAFLET(S)			
FILE CARD(S)			
HOUSE ORGAN(S)			
PRICE LIST(S)			
PHYSICIANS SAMPLE(S)			
PROMOTIONAL LETTER(S)			
LITERATURE REPRINT(S)			
OTHER *(Audio-Visual material (films, tapes, etc.) or typed scripts of such material).*			
LABELING ON WHICH THE ABOVE IS BASED *(Include currently approved labeling with each submission)*			
PACKAGE INSERT(S)			
OTHER LABELING *(If no package insert(s) exists)*			

6. TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT	7. SIGNATURE

8. APPLICANTS RETURN ADDRESS *(Begin typing address directly below window dot)*	9. FDA ACKNOWLEDGEMENT
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RECORDS AND REPORTS REQUIREMENT
(21 CFR 310.300)

310.300 Records and reports concerning experience on drugs for which an approval is in effect.

(a) On receiving notification that an application for a new drug is approved, the applicant shall establish and maintain records and make reports that are necessary to facilitate a determination whether there may be grounds for invoking section 505(e) of the Act to suspend or withdraw approval of the application, including adequately organized and indexed files containing full reports or any of the following kinds of information, pertinent to the safety or effectiveness of the drug or the adequacy of the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug to assure and preserve its identity, strength, quality, and purity, that has not previously been submitted as part of his application for the drug and which is received or otherwise obtained by him from any source:

(1) Unpublished reports of clinical experience, studies, investigations, and tests conducted by the applicant or reported to him by any person involving the drug that is the subject of the application and related drugs, and reports in the scientific literature involving the drug that is the subject of the application. An adequate summary and bibliography of reports in the scientific literature will ordinarily suffice. (The applicant must identify at the time of each report submission each drug he considers related to the subject drug.)

(2) Unpublished reports of animal experience, studies, investigations, and tests conducted by the applicant or reported to him by any person involving the drug that is the subject of the application and related drugs, and reports in the scientific literature involving the drug that is the subject of the application. An adequate summary and bibliography of reports in the scientific literature will ordinarily suffice. (The applicant must identify at the time of each report submission each drug he considers related to the subject drug.)

(3) Experience, investigation, studies, or test involving the chemical or physical properties or any other properties of the drug; such as, its behavior or properties in relation to microorganisms, including both the effects of the drug on microorganisms and the effects of microorganisms on the drug.

(4) The information required by this section shall include, when known, adequate identification of its source, including the name and post office address of the person who furnished such information.

(i) Information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical uses, studies, investigations, or tests, whether or not determined to be attributable to the drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. "Unexpected" as used in this subdivision refers to conditions or developments not previously submitted as part of the new-drug application or not encountered during clinical trials of the drug, or conditions or developments occurring at a rate higher than shown by information previously submitted as part of the new-drug application, or than encountered during such clinical trials.

(ii) Information concerning any unusual failure of the drug to exhibit its expected pharmacological activity.

(3) When mailing pieces, any other labeling, and advertising are devised for promotion of the drug, specimens shall be submitted at the time of initial dissemination of such labeling and at the time of initial publication of any advertisement for a prescription drug. Mailing pieces and labeling that are designed to contain samples of a drug shall be complete except for omission of the drug.

(4) All the kinds of information described in paragraph (a) of this section, other than that submitted under the provisions of subparagraph (1), (2), and (3) of this paragraph, shall be submitted at the following intervals, unless otherwise ordered in a written communication from the Commissioner:

(i) If the drug is intended for administration to man, within intervals of 3 months beginning with the date of approval of the application during the first year following such date; within intervals of 6 months during the second year following such date; and at yearly intervals thereafter.

(ii) If the drug is intended solely for administration to animals, at intervals within 6-months beginning with the date of approval of the application during the first year following such date, and at yearly intervals thereafter: Provided, however, that such reports are not required from applicants to the extent that the reporting obligation is based on their manufacture of complete medicated feed.

(iii) Whenever an applicant is required to submit reports under the provisions of subdivision (i) or (ii) of this subparagraph with respect to more than one approved application for preparations containing the same drug so that the same item(s) of information is (are) required to be reported for more than one application, he may elect to submit as part of the report for one such application all the information common to such applications in lieu of reporting separately and repetitively on each. The applicant shall state when this is done and identify all the applications for which the reports are submitted.

Conditions of Approval of a New Drug Application

The signing of the new drug application form is regarded as a commitment on your part that:

> All representations in the application apply to the drug produced until an approved supplement to the application provides for a change or a change is made in conformance with other provisions of § 314.8 of the new-drug regulations.
>
> The labeling and advertising for the drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling which is part of this application; and if the article is a prescription drug, it is understood that any labeling which furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for use of the drug will contain the same information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, any relevant warnings, hazards, contra-indications, side effects, and precautions, as that contained in the labeling which is part of this application in accord with § 1,106(b) (21 CFR 1,106(b)).

Section 505(e) of the Federal Food, Drug, and Cosmetic Act provides for approval of the application to be withdrawn if: clinical or other experience, tests, or other scientific data show that the drug is unsafe or not shown to be safe for use; further information indicates there is a lack of substantial evidence that the drug will have the effect it is represented to have; the application contains an untrue statement of material fact; the applicant fails to establish or maintain required records or make required reports; new information shows that the methods, facilities, or controls used in the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity; or the labeling of the drug is false and misleading.

The drug may not be labeled with another distributor's name, or repacked, or relabeled by another person unless provided for in the approved application or in conformance with § 314.8 of the new drug regulations.

Section 301(l) of the Act prohibits the use in the labeling, or in any advertising, ofany representation or suggestion that an application with respect to the drug is approved under section 505, or that the drug complies with the provisions of that section.

The approval of this application under section 505 in no way relieves you of the responsibility for complying with all other provisions of the Act.

NDA 70-033

Condition of Approval

At time of next printing, make the following revisions for the package insert:

Insert still contains numerous spelling errors:

CLINICAL PHARMACOLOGY - cerebrospinal (rather than cerebral spinal).

INDICATIONS AND USAGE:

endocervicitis, cervicitis, Consorts, Amebiasis.

CONTRAINDICATIONS - metronidazole

ADVERSE REACTIONS - occasionally