DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 24 2001

6019 '01 MAY 29 A9:57

Mr. Shashikant Shah, R. Ph.
Able Laboratories, Inc.
6 Hollywood Court CN1013
South Plainfield, NJ 07080

Re: Docket No. 00P-1340/CP1

Dear Mr. Shah:

This formally responds to your Citizen Petition, dated June 12, 2000, requesting that the Food and Drug Administration (FDA) determine whether ROWASA® (mesalamine) Rectal Suppositories, 500-mg, were withdrawn from sale for reasons of safety or effectiveness.

The FDA has reviewed its records and determined that ROWASA Rectal Suppositories, 500 mg were not withdrawn for reasons of safety or effectiveness. Accordingly, FDA will continue to list ROWASA® (mesalamine) Rectal Suppositories, 500 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book").

Enclosed is a copy of the Federal Register notice that announces the FDA determination. If you need further information, do not hesitate to contact me at 301-594-5670.

Sincerely,

S Mitchell

S. Mitchell Weitzman
Regulatory Policy Staff
Center for Drug Evaluation and Research

Enclosure

00P-1340

LET 2

Notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DISPLAY DATE: 5-23-01 PUBLICATION DATE: 5-24-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–1340]

Determination That ROWASA (mesalamine) Rectal Suppositories, 500 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that ROWASA (mesalamine) Rectal Suppositories, 500 milligrams (mg) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for mesalamine rectal suppositories, 500 mg.

FOR FURTHER INFORMATION CONTACT: S. Mitchell Weitzman, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5670.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products approved under an ANDA. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

On June 12, 2000, Able Laboratories, Inc., under 21 CFR 10.30, submitted a citizen petition (Docket No. 00P–1340/CP1) to FDA. The petition requested that the agency determine whether mesalamine Rectal Suppositories, 500 mg, was withdrawn from sale for reasons of safety or effectiveness. Mesalamine rectal suppositories, 500 mg, is the subject of NDA 19–919. FDA approved NDA 19–919, held by Solvay Pharmaceuticals, Inc. (Solvay), on December 18, 1990. On July 1, 1999, Solvay informed FDA that ROWASA Rectal Suppositories had been voluntarily recalled after repeated, sporadic dissolution specification failures were observed.

FDA has reviewed its records and, under § 314.161, has determined that Solvay's decision to recall and terminate marketing mesalamine rectal suppositories, 500 mg, was not for reasons of safety or effectiveness. Accordingly, the agency will continue to list mesalamine rectal suppositories, 500 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to mesalamine rectal suppositories, 500 mg, may be approved by the agency.

Dated: May 17, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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