



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FILE COPY

June 13, 2000

M. Shashikant Shah R.Ph
Able Laboratories, Inc.
6 Hollywood Court, CN1013
South Plainfield, New Jersey 07080

Dear Mr. Shah:

Your petition requesting the Food and Drug Administration to determine whether ROWASA rectal suppository, 500 mg was withdrawn from the market due to safety or efficacy reasons, was received by this office on 06/13/00. It was assigned docket number 00P-1340/CP 1 and it was filed on 06/13/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script that reads "Jennie Butler".

Jennie Butler
Dockets Management Branch

00P-1340

ACK 1