



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 12 2000

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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:

Pursuant to 21 CFR 10.30 (e)(2), this letter informs you that the we are still considering the issue raised in your petition as to whether ROWASA (mesalamine) Rectal Suppositories, 500 mg, was withdrawn from sale for reasons of safety or effectiveness.

We expect to conclude our evaluation shortly and will respond to your petition once that process is completed.

Sincerely yours,

Janet Woodcock, M.D.
Director

Center for Drug Evaluation and Research

00P-1340

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