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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

May 25, 2000

XC: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 36

Terrance O. Noble
Chief Executive Officer
Apothecary Products, Inc.
11750 12th Avenue South
Burnsville, Minnesota 55337

Dear Mr. Noble:

During our inspection of your over-the-counter (OTC) drug repackaging facility located in Burnsville, Minnesota, our investigators found serious violations of the current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 [21 CFR 211]. Your OTC drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The violations observed during our inspection include but are not limited to the following:

1. Failure to use stability testing results in the determination of appropriate expiration dates for drug products [21 CFR 211.166(a)]. For example, you have no stability testing data to support expiration dates on several of your repackaged OTC drugs.
2. Failure to conduct stability testing in the container-closure system in which the drug product is marketed [21 CFR 211.166(a)(4)]. For example, your stability testing data for several OTC drug products does not evaluate the stability in the repackaged containers used at your firm.
3. Failure to conduct at least one specific identity test on incoming raw materials and failure to validate the supplier's test results when a supplier's report of analysis is accepted in lieu of the required purity, strength, and quality testing [21 CFR 211.84(d)(2)]. For example, you have conducted no such testing or validation for your oral solid dosage OTC drugs.

Page Two

Terrance O. Noble
May 25, 2000

4. Failure to provide training in current good manufacturing practices to employees engaged in the repackaging and holding of drug products [21 CFR 211.25(a)].
5. Failure to maintain records of returned drug products including the reason for return, date of disposition, and ultimate disposition of the returned drug product [21 CFR 211.204].
6. Failure to prevent unauthorized personnel from accessing the label storage area [21 CFR 211.122(d)]. For example, labeling for OTC drugs was stored in an uncontrolled, unlocked area of your warehouse.
7. Failure to maintain master control records for each repackaged drug product [21 CFR 211.186(a)].

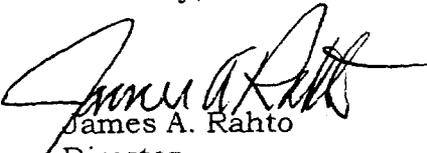
The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

We have previously notified you of serious violations at your facility. We are very concerned that deviations continue to occur.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that the Food and Drug Administration expects all your locations to be in compliance.

You should notify this office in writing within 15 working days of receipt of this letter of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to Acting Compliance Officer Michael W. Roosevelt at the address on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

MWR/ccl
Enclosure: FDA-483, 4/13/00