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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 13, 2003

W/L. 27 - 03

Mr. James L. McDaniel, President
U.S. Apothecary Labs, Inc.
11100 Greenstone Ave
Santa Fe Springs, CA 90670

Dear Mr. McDaniel:

This letter concerns the manufacturing and marketing of "RAD BLOCK KI" (Potassium Iodide, 65 mg). During an inspection of your pharmaceutical manufacturing facility conducted on July 1 - July 8, 2002, an investigator from the Food and Drug Administration (FDA) determined that your firm manufactures, promotes, and distributes this product.

The RAD BLOCK KI product label includes the words "Radiation Blocking Tablets" and "THE FDA RECOMMENDS TAKING POTASSIUM IODIDE (KI) IMMEDIATELY IF EXPOSURE TO DANGEROUS RADIATION IS POSSIBLE (FOR EXAMPLE, IF DOWNWIND OF A NUCLEAR REACTOR DISASTER OR NUCLEAR EXPLOSION OR RADIATION HAZARD)." Further, the label includes two vignettes, a "mushroom" cloud and a radiation blocking symbol. These items and the text noted on the label indicate that the product is intended to be utilized as a "radiation-blocking" agent. Therefore, your product is intended to be used in the cure, mitigation, treatment or prevention of disease. Such claims cause "RAD BLOCK KI" to be a "drug" under Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). We are unaware of any evidence that establishes that this drug is generally recognized as safe and effective for the intended use. Therefore, this product is also a "new drug" as described in Section 201(p) of the act and may not be legally marketed in the United States for these indications without an approved NDA under Section 505(a) of the Act or an abbreviated new drug application (ANDA) pursuant to Section 505(j) of the Act.

During the inspection, our investigator also found significant deviations from the Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals Regulations [Title 21,

Code of Federal Regulations (CFR), Parts 210 and 211]. These deviations cause your drug product to be adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for its manufacturing, processing, packing, or holding do not conform or are not operated or administered in conformity with the cGMP. The following deviations were identified during the inspection:

1. Failure to perform laboratory testing on each batch of drug product prior to release, to determine satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient [21 CFR 211.165 (a)]. Specifically, you are not conducting finished product testing before release of the product RAD BLOCK KI (Potassium Iodide, 65 mg).

2. Failure to assure that the quality control unit has authority to review production records of drug products to assure that no errors have occurred [21 CFR 211.22 (a)]. Specifically, the finished drug product RAD BLOCK distributed on February 25 and 26, 2002, was not released by the quality control unit until March 12, 2002.

3. Failure to describe sampling and testing plans for drug products in written procedures which include the method of sampling and number of units per batch to be tested [21CFR 211.165(c)]. Specifically, for your product RAD BLOCK KI your firm has not established a written plan to define the test methods and number of samples for final product testing. In addition, your firm failed to follow your own procedure for stability testing by submitting five samples for each lot to be tested when the procedure calls for [redacted] samples for each lot to be tested.

4. Failure to implement a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates [21 CFR 211.166 (a)]. Specifically you are placing a three-year expiration date on the label of your product RAD BLOCK KI and there is no test data available to support the validity of this expiration date.

5. Failure to retain an appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient, consisting of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications (21CFR 211.170). Specifically, your firm has not defined required reserve sample sizes and in practice retains whatever amount of tablets are left over after the finished drug products RAD BLOCK KI have been bottled. In addition, your firm has not defined or implemented adequate testing of reserve products. Specifically, your firm is not performing any exams for deterioration on reserve samples of the RAD BLOCK KI.

6. Failure to establish control procedures which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product [21 CFR 211.110(a)].

7. Specifically, your firm has failed to validate the processes associated with the manufacturing of the drug product RAD BLOCK KI.

8. Failure to establish and implement a procedure to assure that drug product component testing is performed with at least one specific test to verify the identity of each component [21 CFR 211.84(d)(1)]. Specifically, your firm has failed to test any of the raw materials of Potassium Iodide USP used to manufacture the drug product RAD BLOCK KI.

9. Failure to conduct GMP training with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them [21 CFR 211.25(a)]. Specifically, the training records reviewed by the investigator showed that the last cGMP training for employees involved in manufacturing was in 1999.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. A list of observations (form FDA-483) was issued and discussed with you at the conclusion of the inspection. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice regulations and other applicable regulations. Federal agencies are advised of the issuance of all warning letters about drugs and medical devices so that they may take this information into account when considering the award of contracts.

We acknowledge receipt of your July 9, 2002 letter in which you addressed the observations from the form FDA-483 issued July 8, 2002. Your responses in that letter are inadequate to demonstrate effective corrective actions. You failed to describe the corrective actions in sufficient detail to address the root causes of the deficiencies, and to describe quality system improvement.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, including product seizure and/or a permanent injunction requiring you to cease the manufacturing of drug products.

You should notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step 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.

If you have any questions about the contents of this letter, please contact Larry Stevens, Compliance Officer, at 949-798-7732

Your reply should be addressed to:

Director of Compliance
U. S. Food and Drug Administration
19900 MacArthur Blvd, Suite 300
Irvine, CA 92612

Sincerely,

for Alonza E. Cruse
District Director