



DEPARTMENT OF HEALTH & HUMAN SERVICES

M345511

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

January 21, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Samuel T. Poxon
President and Owner
Calvin Scott & Company, Inc.
209 Eubank Blvd., NE
Albuquerque, NM 87123

Ref. # : DEN-00-17

PURGED

Dear Mr. Poxon:

During an inspection of your firm on November 10 - 18, 1999, Investigator Michael J. Kuchta determined that your firm repackages and relabels prescription and non-prescription drugs, including Schedule III and IV drugs. The products you repackage and relabel are drug products as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The above stated inspection revealed that your products are adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the controls used for the manufacturing, processing, packing, or holding of these products are not in conformance with current Good Manufacturing Practice regulations under Title 21, Code of Federal Regulations (21 CFR), parts 210 and 211. Deviations noted during the inspection include, but are not limited to the following:

1. Failure to establish a written testing program designed to assess the stability characteristics of repackaged drug products and to develop stability test results used in determining appropriate storage conditions and expiration dates. For example, your firm has a written stability testing program, [X X X X X X X X X X], Effective date: April 2, 1999, but it fails to define sample selection criteria, i.e., what products, in what kinds of containers, how many lots, sample size, method of collection to assure the sample is representative; controlled conditions for storage of samples; test intervals; and the kinds of analysis required.

2. Failure of repackaged drug products to bear expiration dates determined by appropriate stability studies to assure drug products meet appropriate standards of identity, strength, quality, and purity at time of use. For example, no stability studies were observed to support expiration dates on repackaged drug products beyond the expiration date of the bulk drug manufacturer's original expiration date. For example, in February and in September 1999, the expiration dates of two lots of Product 609, Phentermine HCl, lots CS0144 and CS0696, were extended beyond that assigned by the drug manufacturer. Even though small samples were submitted to a laboratory from unrepackaged stock in inventory, the extension of the expiration dates was not based on adequate stability studies.
3. Failure of the Master Control and Production Records to include specifications of drug product containers and closures used for repackaging drug products, which includes ~~LDPE~~ bottles, amber plastic vials, heat sealed pouches, zip-lock bags, and plastic child-resistant closures; and failure of Batch Control and Production Records to include the identification, i.e., lot number, of containers and closures used in each repackaging operation.
4. Failure of inventory records to include a reconciliation of the use of each lot of component used in repackaging; failure of ~~LDPE~~ Effective date September 15, 1998, to require a thorough investigation when maximum and minimum percentage theoretical yields are not met; and failure of ~~LDPE~~ to consider the accountability of drug products documented in repackaging records, i.e., ~~LDPE~~ does not account for losses (or gains) during repackaging, returns to inventory, or disposals.
5. Failure of the quality control unit, i.e., the complaint coordinator, to always evaluate drug product returns to determine if the drug products failed to meet specifications and, when necessary, to determine the cause, extent, and impact of the failure on other products. For example, of ~~LDPE~~ returned shipments of Product 609, Phentermine, ~~LDPE~~ involved expired or about to expire product with one identified as a complaint. Also, on January 14, 1999, a complaint identified three different products in plastic bags with faulty heat seals, but the impact on other similarly packaged drug products was not determined nor documented.
6. Failure to have Master Control and Production Records and Batch Control and Production Records for cleaning and sieving procedures that are required on certain drug products, e.g., Products 511, 600 through 606, 629, 630, 643, 648, 677, 704, and 705.
7. Failure of Batch Production and Control Records to include copies of all labeling used. For example, product inserts are not included in the repackaging records.

We are in receipt of your letter dated November 24, 1999 responding to the FDA 483, List of Observations, issued at the conclusion of the inspection. Your promised corrective actions, if fully implemented, should bring your firm into compliance. However, we have concerns about your intent to fully implement these corrections. As you are aware, we issued a previous Warning Letter to you dated October 21, 1998. Many of the violations detailed therein have not been fully corrected, in particular, adequate stability studies to support expiration dates used for repackaged drug products. Your firm has had adequate prior warning. We expect that our next inspection will find all corrections in place as promised.

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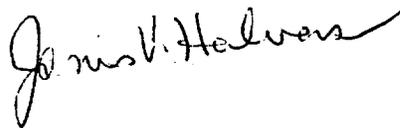
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The violations identified at the beginning of this letter are not intended to be an all-inclusive list of deficiencies at your facility. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters for drug products so that they may take this information into account when considering the award of contracts.

Please advise this office, in writing, within 15 working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response may refer to your November 24, 1999 letter where applicable, but should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time; and (4) any documentation necessary to indicate correction has been achieved.

Your response should be directed to Mr. H. Thomas Warwick, Compliance Officer, at the above address.

Sincerely,



Janis V. Halvorsen
Acting District Director

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