



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

PURGED ^{RTK}

October 3, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 2

Thomas A. Ewing
President
ASAS, Inc.
222 Starkey Street
St. Paul, Minnesota 55107

Dear Mr. Ewing:

During a recent inspection of your veterinary drug repackaging facility located in St. Paul, MN, our investigator found significant deviations from the Good Manufacturing Practice for Finished Pharmaceuticals (CGMP) regulations [Title 21, Code of Federal Regulations, Part 211 (21 CFR 211)]. Such deviations cause veterinary drugs manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigation found the following deviations:

1. To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated and signed (full signature, handwritten) by one person, and independently checked, dated and signed by a second person [21 CFR 211.186(a)]. None of the master control records are signed by a second person.

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2. Master production and control records do not contain all of the information required by 21 CFR 211.186(b). The weight/volume of each component, the theoretical yield and acceptable limits, and complete specifications including the acceptable range are missing from most of the master records.
3. To assure that a drug product meets applicable standards of identity, strength, quality and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in §211 [21 CFR 211.137(a)]. Most of the labels do not have expiration dates.
4. There shall be 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. The written program shall be followed..[21 CFR 211.166(a)]. The written program is not being followed in that no testing has been done since May 1995. In addition, not all specified tests were performed, the chlorhexidine gluconate was not determined for products containing chlorhexidine gluconate, and some of the pH and specific gravity values reported for CHG Teat Dip are out of the specified range without any explanation.
5. There shall be written procedures designed to ensure that correct labels, labeling, and packaging materials are used for drug products; such written procedures shall be followed. These procedures shall incorporate the following features: identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch [21 CFR 211.130(c)]. Many of your products do not have a control/lot number.

This investigation also revealed that your firm is a veterinary drug repacker. Your firm is not registered as required by 21 CFR 207. A copy of this regulation is enclosed.

The above is not intended to be an all-inclusive list of violations. For a complete list please refer to the form FDA-483 issued by the investigator at the conclusion of the inspection. As a repacker of veterinary drugs you are responsible for ensuring that your overall operation and the products you distribute are in compliance with the law. Enclosed is a copy of 21 CFR 211.

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You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Robert P. Snell at the address indicated on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

RPS/ccl

Enclosures: 21 CFR 207
21 CFR 211

xc: