



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

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Certified/Return Receipt Requested

April 1, 1997

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

WARNING LETTER

Lloyd M. Jungmann, President
Hawkeye Breeder's Services, Inc.
3257 Portland Road
Adel, Iowa 50003

Ref.# - KAN-97-012

Dear Mr. Jungmann:

During an inspection of your liquid nitrogen transfilling operation located at the above address, conducted on January 16 and 17, 1997, a Food and Drug Administration Investigator from this office documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211) which cause your firm's transfilled liquid nitrogen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations to 21 CFR, Part 211 include, but are not limited to the following:

Failure to adequately test each batch of Nitrogen NF for conformance to final specifications for the drug product, prior to release [21 CFR 211.165(a)].

For example, your firm failed to analyze the storage tank after each delivery of liquid nitrogen.

In addition, since your firm fails to receive a certificate of analysis with every delivery, you are required to perform all of the tests listed in the U.S.P. monograph, i.e., identification, odor, and carbon monoxide, not only the oxygen assay.

Failure to assure that each person engaged in the transfilling of medical gases has the education, training or experience to enable that person to perform the assigned function [21 CFR 211.25(a)].

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For example, your firm failed to establish an adequate training program addressing both on-the-job and GMP training.

Failure to establish adequate written procedures for production and process controls covering all aspects of the firm's operations designed to assure that the drug product has the strength, quality, and purity it purports or is represented to possess [21 CFR 211.100(a)].

For example, your firm failed to establish written procedures for all aspects of its operation.

Failure to establish adequate batch production and control records for each batch of drug product, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance [21 CFR 211.188(b)].

For example, your firm failed to establish a batch production record.

Failure to establish adequate written procedures assuring that the correct labels are used for all drug products, and that each drug product is identified with a lot or control number [21 CFR 211.130(b) & (c)].

For example, your label that is applied to the cryogenic vessels fails to bear the statement "Caution: Federal law prohibits dispensing without prescription"; the lot number; the warnings; the directions for use; the net contents; and the name and address of the manufacturer of the drug product.

Additionally, your transfilled liquid nitrogen is misbranded within the meaning of the following sections of the Act:

Section 502(b) since the label fails to bear the name and place of business of the manufacturer, i.e., Hawkeye Breeder's Services, Inc.

Section 501(o) since the firm has failed to register and list in accordance with Section 510.

Section 503(b)(4) since the label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription."

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This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations, as it pertains to your operation.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

We are enclosing a copy of FDA's draft nitrogen labeling requirements for you to use as a guide in developing your labels. We are currently working with the Compressed Gas Association to develop specific labeling guidance and until that document is finalized, the information contained in the draft document is valid.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps, that are being taken to correct the noted violations and to prevent their recurrence. 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 Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

Enclosure - Draft Labeling Requirements

bcc: LF; FF(1931862); HFA-224; HFD-325 (Sylvia); HFI-35/DIB(via
FOI); HFC-210; HFC-120(GWQAP); RRW; DM/RP; RF