



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

MJ30511

Telephone (973) 526-6004

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

February 12, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Feinberg, President & CEO
Hydro Med Sciences, Inc.
8 Cedar Brook Drive
Cranbury, New Jersey 08512

FILE NO.: 99-NWJ-15

Dear Mr. Feinberg:

This letter is regarding an inspection of your facility located at 8 Cedar Brook Drive, New Jersey by the U.S. Food and Drug Administration from January 4 through January 11, 1999. During the inspection our investigator documented serious deviations from the current Good Manufacturing Practices (cGMP) Regulations (Title 21, Code of Federal Regulations, Part 210 and 211) in conjunction with your firm's manufacture of veterinary drugs.

These deviations were presented to your firm's attention on a FDA-483, List of Inspectional Observations, at the close of the inspection on January 11, 1999. The cGMP deficiencies cause your products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

The significant observations are as follows:

1. The process validation for the product Syncro-Mate-B Implants is inadequate in that your firm's 1994 retrospective validation report evaluated batches that were manufactured and tested at a different manufacturing facility (New Brunswick, New Jersey). Your firm failed to perform any new process validation or revalidate the manufacturing process, at your current Cranbury site. Additionally, your firm failed to validate the testing methods used to analyze the batches in your retrospective validation report and the equipment used to manufacture and test the validation batches was never qualified.

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2. Failure to validate the test methods used to analyze Syncro-Mate B raw materials and the finished product. Your firm failed to validate two critical methods used to evaluate the quality of the finished product, Method #TM-011 Norgestomet Assay (active drug substance) and Method #TM-0112, Elution Rate, a critical parameter which measures the amount of drug that elutes from the implant.
3. No process qualification for the laboratory instruments (1 [REDACTED] Spectrophotometer, 1 [REDACTED] Liquid Chromatographer, and 2 [REDACTED] Chromatographers) used to perform in-process and finished product testing for Syncro-Mate B Implants.
4. The firm's computer software programs ([REDACTED]), which operate all of the laboratory equipment during the analysis of raw materials and Syncro-Mate B Implant finished product, have not been qualified and/or validated. The software programs do not secure files from accidental alteration or losses of data. The functions that modify and delete partial or whole data files are available for use by all analysts. In addition, the firm has not established any security procedures for the laboratory computer systems. There are no procedures for backing-up data files and no levels of security access established.
5. The firm has no established acceptance and/or rejection levels for theoretical and actual batch yields for the product Syncro-Mate B Implants. There are no established levels for rejection of a batch based on in-process and finished product results and no established levels of rejection that would initiate an investigation.
6. Your firm failed to perform investigations into Out-Of-Specification (OOS) Weight and Diameter test results for Syncro-Mate B Implants, noted during the manufacture of lots #98001, #98002, #98007, #98011, #98014, #98017, #98018. The Weight Specification is [REDACTED] grams and Diameter Specification is [REDACTED] (two critical parameters). In addition, your firm failed to follow your own Standard Operating Procedure #010, "Investigation into OOS Results", which requires that a investigation be conducted as a result of any OOS test result.

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We have received your response letter dated January 15, 1999, regarding the inspectional observations noted on the FDA-483. The cover page of your response requests a follow-up inspection in June 1999. We will schedule the follow-up inspection as soon as you inform us that all cGMP deficiencies have been corrected. We will review the implementation and the adequacy of your proposed corrective actions during the follow-up inspection of your firm.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practices Regulations. We request that you take prompt action to correct any noted violations not already corrected and undertake a comprehensive evaluation of your cGMP compliance. You should respond within 15 working days with any additional information regarding the steps you are taking to correct the identified deficiencies and assure a comprehensive approach to compliance with cGMP's. Failure to promptly correct these violations may result in regulatory action without further notice. This includes seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts. In addition, pending new drug applications (NDA's), abbreviated new drug applications (ANDA's) or export approval requests may not be approved until the aforementioned violations are corrected.

Any additional information you wish to submit should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Very truly yours,



DOUGLAS ELLSWORTH
District Director
New Jersey District Office

AC: slm