

CERTIFIED/RETURN RECEIPT REQUESTED

May 6, 1994

WARNING LETTER

A.M. Stokes, Chief Operating Officer
Porton International PLC
100 Piccadilly
London, United Kingdom W1V9FN

Dear Mr. Stokes:

During an inspection of your in vitro diagnostic products manufacturing operations d/b/a JRH Biosciences, located in Lenexa, Kansas, USA on April 11 through April 19, 1994, by Investigators of this office, significant deviations from Title 21 Code of Federal Regulations, Part 820 (21 CFR 820), Current Good Manufacturing Practice for Medical Devices (CGMP) were observed. Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) deems a device adulterated if the methods used in, or the facilities or controls used for its manufacture do not conform to current good manufacturing practice.

The serious CGMP deviations observed during the current inspection included, but are not limited to the following:

Failure to conduct and/or document corrective actions and investigations on defects encountered during finished device inspection [21 CFR 820.160]. A lot of penicillin/streptomycin that had less active ingredient than the label claim was distributed after finished device inspection discovered the subpotency.

Failure to have or adhere to written manufacturing specifications and processing specifications [21 CFR 820.100]. Your stability program is inadequate, there is no mixing processing validation, omissions of required analysis in your stability and sterility programs and the lack of testing per USP requirements.

Failure to have adequate specifications for production processes for penicillin/streptomycin solutions in your device master record [21 CFR 820.181(b)].

Failure to have adequate testing and rework procedures for the reprocessing of returned/rejected components [21 CFR 820.115(a)].

Failure to have adequate written procedures for the acceptance of device components [21 CFR 820.80(a)].

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Failure to conduct vendor audits of contract laboratories as required by your SOP #QA-100 [21 CFR 820.100(b)(2)].

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 Practice regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs and devices so they may take this information into account when considering the award of contracts.

At the conclusion of the inspection, the Investigators listed inspectional observations on FDA Form 483 (FDA483) and discussed those findings with Brian A. Burns, Executive Vice President and General Manager. A copy is enclosed for your review.

You, as Chief Operating Officer, are the most responsible individual to ensure complete and lasting compliance and you should take prompt action to correct the deviations. Failure to do so may result in regulatory actions without further notice. These include seizure and/or injunction.

We acknowledge receipt of your firm's letter dated May 2, 1994, submitted by your Lenexa facility, detailing responses to the inspectional observations.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps, in addition to those described in the May 2, 1994 response letter, you have taken to correct the noted violations, including an explanation of each step being 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.

Your reply should be sent to the Food and Drug Administration, Kansas City District Office, 11630 West 80th Street, P.O. Box 15905, Lenexa, Kansas 66285-5905, Attention: Ralph J. Gray, Compliance Officer.

Sincerely,

W. Michael Rogers
District Director
Kansas City District