



JUL 24 2000

WARNING LETTERFood and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Ron Peacock  
U.K. Operations Manager  
Griffith Micro Science, Ltd.  
Cotes Park Estate, Somercotes  
Alfreton, Derbyshire  
DE55 4NJ  
United Kingdom

Dear Mr. Peacock:

During an inspection of your firm located in Alfreton, Derbyshire, United Kingdom on June 1 and 2, 2000, our investigator determined that your establishment is a contract sterilizer for medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated under Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the good manufacturing practice (GMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

**21 CFR 820.75(a)**

Failure to validate a process with a high degree of assurance where the results of the process cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). For example, process validation activities for [REDACTED] were inadequate in that they were not performed for worst case conditions, as required by validation protocol number [REDACTED], dated March 14, 1996. Process validation was performed for surface sterilization and did not include the [REDACTED] material.

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The response, dated June 15, 2000, received from Mr. Hans Aeschlimann, your European Regulatory and QA Director, is not adequate. The actions described in this response have not yet been performed.

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. The specific violation noted in this letter and the FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that Mr. Hans Aeschlimann, European Regulatory and QA Director, has submitted a response dated June 15, 2000, concerning our investigator's observations noted on the form FDA 483. We have reviewed your response and have concluded that it is inadequate for the reasons cited above.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these and any other manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a follow-up inspection, and may result in the detention of your device(s) without physical examination upon entry into the United States.

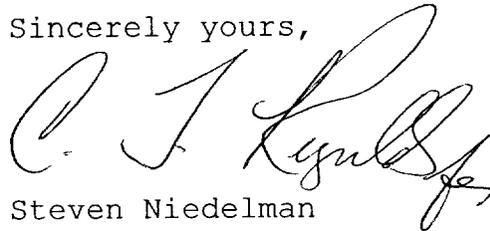
Please notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future

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corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to Sarah Mowitt at the above letterhead address. If you have questions or need further assistance contact Mrs. Mowitt by telephone at (301) 594-4595 or by FAX at (301) 594-4636.

Sincerely yours,



Steven Niedelman  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health

cc:

