



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

M23921

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-30

February 3, 1999

Mr. Carroll Neubauer
Chairman & CEO
B. Braun/McGaw, Inc.
824 Twelfth Avenue
Bethlehem, Pennsylvania 18018

Dear Mr. Neubauer:

We are writing to you because on November 16, 18, 19, and 30, 1998, FDA Investigator Victor Spanioli inspected your Miami Lakes facility and collected information that revealed serious regulatory problems involving saline and heparin flush syringes (Class II) manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform to the Quality System (QS) regulations for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

1. Failure to adequately investigate and evaluate complaints related to the use of the wrong expiration date to assure all lots similarly affected were identified and recalled, e.g., complaints related to lot #980090 dated 10/21/98, lot #04800211 dated 8/6/98, lot #04800239 dated 8/20/98, lot #s 048240-241 dated 8/21/98, lot #04800258 dated 8/27/98, lot #04800272 dated 9/1/98, lot #04800278 dated 9/3/98, and lot #04800282 dated 9/4/98. [21 CFR 820.198(c)]

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2. Failure to establish, maintain, and follow written procedures relative to the expiration dating of heparin flush syringes, which require a 60 day expiration, e.g., no assessment was conducted prior to distribution to assure that expiration dating was correct. Several lots of commercially distributed product were determined to declare an incorrect expiration date. [21 CFR 820.90]
3. Failure to establish and maintain procedures to ensure that all purchased or otherwise vendor supplied product meets specified requirements, e.g., components such as heparin, saline, syringes and caps, and manufacturing materials such as reservoir containers and dispensing pump sets meet specifications. [21 CFR 820.50]
4. Failure to conduct appropriate in process and finished device testing that assures flush syringes meet written specifications, e.g., there is no testing to verify that heparin flush syringes meet USP requirements pursuant to USP 23, Heparin Lock Flush Solution, page 735, fill volume, or for label accountability. [21 CFR 820.70]
5. Failure to validate and document certain processes with a high degree of assurance according to established procedures, e.g., syringe filling processes including the semi automated syringe labeling process, various batch sizes of filled syringes for various concentrations of heparin, and aseptic fill processes. [21 CFR 820.75]
6. Failure to establish and maintain procedures to control product that does not conform to specifications, e.g., lot #04800507-B dated 11/18/98 was rejected for lack of a protective tip cap. [21 CFR 820.90]
7. Failure to establish and maintain procedures for implementing corrective and preventive action. [21 CFR 820.100]

Your devices are also misbranded within the meaning of section 502(t)(2) in that your firm failed to establish and maintain written MDR procedures to effectively identify and evaluate events that may be subject to MDR requirements. [21 CFR 804.34]

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 violations noted in this letter and in the Inspectional Observations (FDA 483) issued

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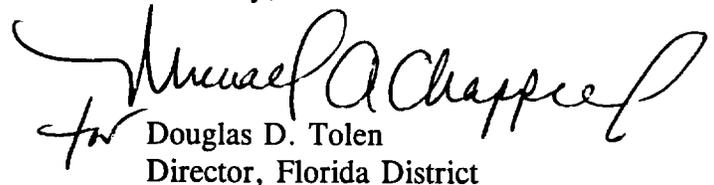
to Thomas J. Wilverding, R.Ph., MBA, Area Manager, Operations, at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. We acknowledge receipt of your firm's response to the FDA 483 signed by William John Brandon, Vice President Operations, dated December 28, 1998, which stated that your firm ceased compounding flush syringes on November 19, 1998. Your response will be made part of the file. Should your firm decide in the future to compound and distribute these products, you should notify us of that decision prior to distribution. Also, the Agency is currently reviewing the investigator's observations and your firm's response related to drug compounding and understands that you have requested a meeting with FDA personnel located in the Center for Drug Evaluation and Research (CDER) to discuss these drug compounding issues. You may receive other correspondence concerning the pharmaceutical portion of the operation.

If you wish to make additional responses, they should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4728.

Sincerely,


Douglas D. Tolen
Director, Florida District

cc: Wm. John Brandon
Vice President Operations
Central Admixture Pharmacy Services, Inc.
211 Summit Parkway
Suite 122
Homewood, Alabama 35209