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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3128

February 9, 2007

Ref: 2007-DAL-WL-9

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Dana William Ryan, President and CEO
Rymed Technologies, Inc.
137 3rd Avenue North
Franklin, Tennessee 37064

Dear Mr. Ryan:

During an inspection of your firm located at 6000 W. William Cannon Drive, Building B, Suite 300, Austin, Texas 78749 on October 18 through November 8, 2006, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures and markets the Invision-Plus® Neutral™ I.V. Connector Models RYM-5000/5001 and catheter extension sets intended for single patient use in intravenous and blood administration. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(h)), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

At the conclusion of the inspection, FDA issued to your firm a list of Inspectional Observations, Form FDA 483 (copy enclosed), which identified a number of significant QS Regulation violations including, but not limited to, those described below.

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1. Failure to establish and maintain procedures for monitoring and control of process parameters for a validated process to ensure that the specified requirements continue to be met, as required by 21 CFR § 820.75(b). FDA 483 Item 7. Your firm's foreign contract manufacturer assembles and welds the molding pieces of the referenced devices using a [REDACTED] welder provided by your firm. Your firm has neither monitored the validated welding process via an increased sampling plan nor reviewed the test results of the weld integrity of the female luer and the spike body in order to detect changes in the welding process which caused weld failures and your firm's subsequent recall of ten lots of the referenced devices.
2. Failure to identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems, as required by 21 CFR § 820.100(a)(3). In May 2006, your firm initiated a recall of the referenced devices due to weld failures. However, your firm failed to ensure that all the affected lots of the referenced devices were effectively retrieved from the market and the users were adequately notified of your firm's recall to prevent further use of the nonconforming devices. For example, your firm received a user complaint on September 25, 2006 (Complaint Report 06012) which documented that the product came apart into pieces, and the samples of Lot 405 returned to your firm had weld failures. Your firm's complaint reports for another five user complaints documented that the users will be notified. However, there was no documentation proving that these users were in fact notified. In reviewing the FDA's Maude Reports, FDA identified two additional adverse events, dated 9/22/06 and 10/6/06, which reported that the device parts came apart or the device parts were disassembled.
3. Failure to ensure that information relating quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems, as required by 21 CFR § 820.100(a)(6), and failure to document the results of corrective action activities, as required by 21 CFR § 820.100(b). FDA 483 Item 4. For example, although your firm had a teleconference call with the foreign contract manufacturer and subsequently visited them to discuss the issue of weld failures and initiated additional testing and trouble shooting of your welding machine on April 3, 2006, your firm failed to maintain documentation of your teleconference call minutes, the test results of nonconforming Lot 509924, and the root cause of the misalignment of your [REDACTED] welding machine's components.

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4. Failure to establish and maintain adequate complaint handling procedures for receiving, reviewing, and evaluating complaints by a formally designated unit and to ensure that all the requirements of 21 CFR § 820.198(a) through (e) are met. FDA 483 Item 2, 8, and 9. For example, in reviewing six of the eight complaints of weld failures, your firm failed to document sufficient detail to describe the complaints, including whether the devices were used on patients and whether any complications occurred, and to include in the complaint file adequate records of complaint investigations.
5. Failure to establish and maintain procedures for the identification, documentation, validation or verification, review, and approval of design changes before their implementation, as required by 21 CFR § 820.30(i), and failure to establish and maintain a design history file for each type of device which contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan, as required by 21 CFR § 820.30(j). FDA 483 Item 5 and 6. Your firm failed to establish and maintain a design history file for the referenced devices according to your Design Control Plan, Procedure 110, effective dated 11/2/98. Your design change records are incomplete in that you failed to maintain design verification or validation results for a design modification to the Invision-Plus® Neutral™ I.V. Connector from the RYM-3000 series to RYM-5000 series.

Our inspection also revealed that your above-referenced devices are also misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the devices that is required by or under by Section 519(f)(1) of the Act, 21 U.S.C. § 360i(f)(1), and 21 CFR § 806 - Reports of Corrections and Removals Regulation. FDA 483 Item 1. Significant deviations include, but are not limited to, the following:

1. Failure to promptly report to FDA any correction or removal of a device to reduce a risk to health within 10 working days, as required by 21 CFR § 806.10(a)(1). FDA 483 item 1. For example, the inspection documented that in May 2006, your firm contacted your independent distribution centers to have them return the specific lots of devices due to incomplete welds between the [REDACTED] and the [REDACTED]. Defective welds may result in patients not receiving adequate dosage of drugs, the patient's blood backing up (retrograding) into the catheter lumen and bleeding from your I.V. connector, air bubbles being trapped in the I.V. line, migration of the micro-organisms, or disruption in I.V. therapy due to leakage. These conditions pose a potential risk to health. Your firm's action to retrieve the specific lots

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of the nonconforming devices to prevent their further use meets the definition of a "removal" in 21 CFR § 806.2(i), yet no report was submitted to FDA, in violation of 21 CFR § 806.10(a)(1), which requires manufacturers or importers to submit a written report to FDA of any correction or removal of a device if the correction or removal was initiated to reduce a risk to health.

The above-referenced devices are further misbranded under Section 502(o) of the Act, 21 U.S.C. § 352(o), in that the devices were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the Act, 21 U.S.C. § 360, and the Establishment Registration and Device Listing Regulation, 21 CFR § 807. You failed to update your firm's current establishment registration to list the address of your firm's manufacturing site at 6000 W. William Cannon Drive, Building B, Suite 300, Austin, Texas 78749. Your firm still lists its manufacturing site at your corporate office's address at 2154 Kidd Road, Nolensville, Tennessee 37135. This corporate office has moved to another address in Tennessee identified above.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Also, 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, premarket approval applications for Class III devices to which the QS regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.


Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of these corrections. If the 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.

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Your response should be sent to Thao Ta, Compliance Officer, DAL-DO, Food and Drug Administration, HFR-SW140, 4040 N. Central Expressway, Suite 300, Dallas, TX 75240. If you have any questions about the contents of this letter, please contact Mr. Ta at 214-253-5217.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Form FDA-483 issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,


for Michael A. Chappell
Dallas District Director

MAC:txt

cc:
Mr. Jim M. Kaiser, Vice President
Rymed Technologies, Inc.
6000 W. William Cannon Drive
Building B, Suite 300
Austin, Texas 78749