



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

4/1/98
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Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-38

March 16, 1998

Richard Weaver, President
Rawcar Group LLC dba
Contour Fabricators of Florida, Inc.
4100 E. Baldwin Road
Grand Blanc, Michigan 48439-9336

Dear Mr. Weaver:

We are writing to you because on January 29 through February 3, 1998 FDA Investigator Christine M. Humphrey collected information that revealed serious regulatory problems involving equipment covers including band bags and dome bags, which are manufactured and distributed by your firm (Class I & II).

Under the Federal Food, Drug, and Cosmetic Act (The Act), these products are considered to be medical devices because they are used to test or protect medical devices which are subsequently used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation which incorporates the device GMP.

The inspection revealed that the 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 manufacture, processing, packing, storage, or distribution are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to establish and maintain validation procedures to assure process parameters are met, are documented, and a review and evaluation is performed when changes or process deviations occur, e.g., established cycle temperatures were not followed and were accepted without investigation; there are no written bioburden

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specifications for each device to be sterilized; no validation has been performed to assure the parameters of the heat sealing process; no validation has been performed to assure seal integrity after sterilization, and there are no written procedures for the resterilization/reprocessing of devices (FDA 483, Items #1-6).

- Failure to establish and maintain written procedures for the testing and release of finished devices (FDA 483, Item #8).
- Failure to establish and maintain Device History Records (DHR) for each lot of device manufactured (FDA 483, Item #9).
- Failure to establish and conduct quality audits to assure the effectiveness of the quality system (FDA 483, Item #10).

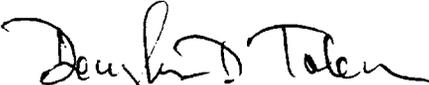
You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. 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 to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. It was noted on the FDA 483 that you promised correction to Item #s 1, 3, 6, and 7 by May 1998 and Item #s 2, 4, 5, 8, 9, and 10 by August 1998. These timeframes appear to be excessive considering the complexity of the device, the types of equipment requiring validation and the documentation required. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your corrections. Please direct your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, Florida District, 555 Winderley Place, Suite #200, Maitland, Florida 32751.

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If you have more specific questions about the Quality System Regulation and how they affect your particular device, or about the content of this letter, please contact Tim Couzins at (407) 475-4728.

Sincerely,


Douglas D. Tolen
Director, Florida District