



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

m2613n

October 5, 1998

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-1-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Kreighton White, CEO
Getinge America
1777 East Henrietta Road
Rochester, New York 14623-3133

Dear Mr. White:

During the inspection of the Arjo Inc., facility in Morton Grove, IL, conducted from July 14 to August 6, 1998, Inspector Patricia McIlroy determined your firm is an initial distributor of Patient Lifts and Hygiene Chairs, which are manufactured in England and Sweden. The products that your firm distributes are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that the devices you distribute 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 Quality System Regulation (QSR) for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

You failed to establish and maintain procedures for receiving, reviewing and evaluating complaints. Procedures shall ensure that all complaints are processed in a uniform and timely manner, that oral complaints are documented upon receipt and that complaints are evaluated to determine whether reporting under the Medical Device Reporting regulations are required.

In addition, the investigation found your complaint handling policies do not address all sources of complaints. All service reports, including reports for customers who do not enter into a maintenance contract, should be analyzed for events that must be reported to FDA. Safety notices issued by the foreign manufacturers of your devices should be reviewed and evaluated to determine if there are similar safety concerns for the devices you distributed within the United States.

Please be advised that 21 CFR Part 806 requires device manufacturers and distributors report promptly to FDA certain actions concerning device corrections and removals. Manufacturers are required to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA.

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Also, 21 CFR Section 803.50 requires manufacturers to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer may have caused or contributed to a death or serious injury. According to Section 803.3(d), "Caused or contributed means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result" of failure, malfunction, improper or inadequate design, manufacture, labeling or user error.

This letter is not intended as 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 Form FDA 483 (enclosed) issued to Subhash Patel, Senior QA/RA Manager, at the closeout of the inspection, may be symptomatic of serious underlying problems in your firm's 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 receipt of Mr. Patel's response to our Form FDA 483, dated August 18, 1998. We also acknowledge receipt of documents provided as a result of our September 25, 1998 meeting with you at the Chicago District office.

We remain concerned about the lack of communication, with regards to product safety notifications, between Arjo, Morton Grove, IL, and the foreign manufacturers of the devices. All other responses appear adequate.

Until FDA has documentation to establish that all corrections have been made, Federal agencies will be 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 deviations. Failure to correct these deviations 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.

Please notify this office in writing within 15 working days of receipt of this letter regarding the specific steps you have taken to correct the above violations. Include an explanation of each step being taken to ensure all future safety notifications issued by the foreign device manufacturers will be communicated to your office.

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Your response should be sent to Rachel T. Evans, Acting Compliance Officer, Food and Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

/s/
Raymond V. Mlecko
District Director

Enclosure

cc: John Malmquist, President/CEO
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P.O. Box 69
SE-310 44 Getinge
Sweden

cc: Thomas Barton, President
Arjo, Inc.
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Morton Grove, IL 60053