



August 24, 2001

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863**WARNING LETTER**  
**CHI-46-01****CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Creighton White, President  
Getinge/Castle, Inc.  
1777 East Henrietta Road  
Rochester, NY 14623-3133

Dear Mr. White:

During the inspection of the Arjo, Inc. facility in Roselle, IL, from April 16 to April 27, 2001, Investigator Matthew Sienko determined Arjo manufactures and distributes patient lifts and bath systems. Patient lifts and bath systems are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these 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 manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints to ensure that all complaints are processed and documented in a uniform and timely manner. For example:
  - 1.1. Arjo did not document complaints as required in their Product Complaint Procedure, QSP # 4.6.2, Section 6.2, dated October 14, 1999.
  - 1.2. In 2001, **81** service calls were received complaining of transport problems with the Marisa lift. Arjo did not review, evaluate, or investigate these complaints. Arjo lacked documentation that explained why an investigation was not needed.
  - 1.3. Arjo did not have a consistent and uniform system for categorizing complaints. Eleven complaints that were Medical Device Reports (MDR) were categorized as potential malfunctioning problems with the Maxilift but should have been categorized as sling products. **Two** MDR complaints lacked the product model name.
- 1.4. The following MDR complaints were not evaluated or investigated in a timely manner:



We reviewed your firm's response to our investigator's FDA-483, in a letter dated May 17, 2001, from Mr. Ross Scavuzzo, President of Arjo, Inc. We determined the response is adequate. We also acknowledge receipt of documents provided by Mr. Scavuzzo and other Arjo representatives in a meeting with the Chicago District on August 1, 2001.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing, within 30 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. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Michael Lang, Compliance Officer. If you have any questions regarding this letter, please contact Mr. Lang at (312) 353-5863 x171.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director

Attachment

cc: Mr. Ross Scavuzzo, President  
Arjo, Inc.  
50 N. Gary Avenue  
Roselle, IL 60172

Mr. Johan Malmquist  
President and CEO  
Getinge Industrier  
Box 69  
SE-310 44 Getinge  
Sweden