

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service ^{d1889b}
Food and Drug Administration

Refer to: CFN 1119193

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

July 2, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Michael C. Winn, CEO
Hollister, Inc.
2000 Hollister Drive
Libertyville, Illinois 60048

Dear Mr. Winn:

A Food and Drug Administration (FDA) inspection conducted June 8-12, 1998 at your Stuarts Draft, Virginia facility, determined that your firm manufactures body fluid pouches. Body fluid pouches are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that this device is 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 Current Good Manufacturing Practice (CGMP) requirements as set forth in the Quality System Regulation (QSR) for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to validate the VTAD packaging procedure to assure that the device conforms to its original specifications.
2. Failure to establish and maintain rework procedures to ensure that nonconforming product meets its current approved specifications after rework.
3. Failure to withhold from distribution TAD products that were sterilized under new, validated parameters until the revalidation data had been reviewed and approved.
4. Failure to maintain the lot trace record for VTAD lot 7D58 that includes the lot numbers of all components used for each VTAD assembly.

Mr. Michael C. Winn
Page 2
July 2, 1998

5. Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating device complaints.

At the conclusion of the inspection, Mr. C. Richard Ammons, Production Manager, was given a written list of deficiencies (Form FDA-483, enclosed) which was discussed with him.

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 FDA-483 issued at the closeout 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 action.

We acknowledge that Mr. Lester D. Herman, Management Representative, submitted to this office a response dated June 22, 1998, concerning our investigator's observations noted on the FDA-483. While the majority of the response appears adequate, your response fails to adequately address FDA-483 Item #5. Although you conduct trend analysis of complaints, there is no written procedure covering this activity.

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 pending submissions for pre-market clearance for devices to which the GMP violations are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved.

You should take prompt action to correct these deviations, whether identified by our investigators or your internal systems audit. Failure to do so 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, 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 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Mr. Michael C. Winn
Page 3
July 2, 1998

Your response should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at 804-379-1627, Ext. 14.

Sincerely,



CARL E. DRAPER
Acting Director, Baltimore District

Enclosure

cc: Mr. C. Richard Ammons
Production Manager
Hollister, Inc.
P.O. Box 228
Route 608
Stuarts Draft, Virginia 24477-9998