

Purged



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M33351

JAN 12 2000

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

Mr. James R. Chatterton
Vice President, Regulatory Affairs/Technical
Ansell Perry, Inc.
1875 Harsh Avenue, S.E.
Massillon, Ohio 44648-0550

Dear Mr. Chatterton:

It has come to our attention that your firm, Ansell Perry, Inc. has been marketing ~~XXXXX~~ latex surgical gloves without receiving marketing clearance from the Food and Drug Administration (FDA) for the labeling currently included with the surgical gloves. Surgical gloves are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The ~~XXXXX~~ latex surgical gloves are misbranded under section 502(a) of the Act. The labeling for the products, namely, the Encore package labeling, contain statements that represent or suggest that the products are Ultra-Thick. For example, your labeling has the statement ~~XXXXX~~ "Ultra-Thick", and "Powder-free ultra-thick latex surgical gloves, textured". The term, "Ultra-Thick" is not acceptable, and that labeling was not submitted for review with your premarket notification (510(k)) submission prior to its clearance. Also, as illustrated in the manual "Guidance for Medical Gloves: A Workshop Manual", page 6-16 under "Misbranding Labeling Claims", the term "Ultra-Thick" is not permissible.

This letter is not intended to be an all inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

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.

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 prevent the recurrence of similar violations. 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.

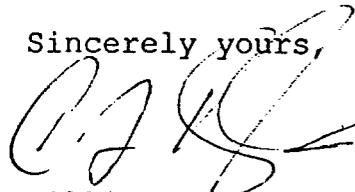
You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting

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our Division of Small Manufacturers' Assistance at phone number:
1-800-638-2041, FAX: 301-443-8818, or through our Internet
website at <http://www.fda.gov>.

Please submit your response to the Director, Division of
Enforcement I (HFZ-323), Office of Compliance, Center for Devices
and Radiological Health, 2098 Gaither Road, Rockville, Maryland,
20850 USA. If you have any questions, please contact Ms. Carol
Shirk of the General Surgery Devices Branch at (301) 594-4595 or
FAX (301) 594-4636.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health