



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *M 41517*

Telephone (973) 526-6006

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

August 11, 2000

WARNING LETTER

Mr. Clifford E. Holland
President
Ethicon, Inc.
a Johnson & Johnson Company
P.O. Box 151 (Route 22 West)
Somerville, NJ 08876-0151

FILE NO: 00-NWJ- 46

Dear Mr. Holland:

During an inspection of your firm located at U.S. Highway 22, Somerville, New Jersey, between May 9 and May 30, 2000, our investigator determined that your firm was the designer and original 510(k) holder of the ENDOPOUCH™ PRO, a specimen retrieval bag used during surgery. The ENDOPOUCH™ PRO is a medical device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above stated inspection revealed that the ENDOPOUCH™ PRO 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, packaging, storage, or installation are not in conformance with the Quality System Regulation (QSR) for medical devices as set forth in Title 21, Code of Federal Regulations (CFR) Part 820. The ENDOPOUCH™ PRO is also misbranded within the meaning of section 502(t)(2) of the Act in that material required under section 519(f)(1) of the Act was not supplied to Food and Drug Administration (FDA) within ten days as specified in Title 21, CFR Part 806.

Deficiencies from the QSR regulation that were noted during the inspection include the following:

- 1. Your firm's failure investigation procedures contained within your "Operating Procedure for the Corrective and Preventative Action (CPA) Process OP615-001", do not contain provisions for the analysis of design control procedures, activities, and results (design history file) as potential causes of nonconforming product as required by 21 CFR 820.100(a)(2).**

2. Your firm's design validation did not ensure that the ENDOPOUCH™ PRO specimen retrieval bag would conform to defined user needs and intended uses as required by 21 CFR 820.30(g). Specifically:

- a. The written procedure "Operating Procedure for Creating a Design and Development Plan OP650-002, Version 6", utilized to initiate and control the design and development for the ENDOPOUCH™ PRO did not include provisions to ensure that design validation activities were planned and executed. There is no evidence that the final ENDOPOUCH™ PRO labeling design was challenged under actual or simulated use conditions (using initial production units, lots, batches, or their equivalents) to ensure that the labeling conformed to user needs and intended uses.
- b. The current "Operating Procedure for the Design Validation OP650-014, Version 3, Section 8.9", does not specify that design validation activities will include product packaging and labeling as human factor considerations (e.g., label, Instructions for Use, etc.).

3. Your firm failed to establish and maintain procedures for the identification, documentation, and validation (or verification), review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example:

- a. Changes to the ENDOPOUCH™ PRO specimen retrieval bag labeling were not reviewed and approved as a design change before their implementation. This labeling change was implemented in response to product complaints and failure investigations. Neither the written procedure titled "Operating Procedure for Design Control Compliance OP650-001, Version 10" (in effect at the time of the cited changes), nor Version 14 (currently in effect) specify that design controls be considered when labeling changes are made

4. Your firm failed to establish and maintain procedures to ensure that the design input requirements relating to a device are appropriate and address the intended use of the device, including the needs of both the user and the patient as required by 21 CFR 820.30(c). These procedures also do not have a mechanism for addressing incomplete, ambiguous or conflicting requirements (21 CFR 820.30(c)). For example:

- a. The written procedure titled "Operating Procedure for Creating a Design and Development Plan OP650-002, Version 6", used to initiate and control the design and development of the ENDOPOUCH™ PRO, did not include provisions to ensure appropriate human factor requirements (expectancies developed from the use of similar devices, etc.) were sought and considered when initial design inputs

were developed.

- b. The current procedure titled "Operating Procedure for Creating a Design and Development Plan" OP650-002, Version 12", used to develop design input, failed to specify how tools such as customer surveys and existing product performance data are to be used (e.g., analyzed to identify user expectancies, etc.) during the development of human factor requirements.

5. Failure to submit a written report (Medical Device Corrections and Removals) to the FDA within 10 working days of initiating the over-labeling, Instructions for Use revisions, and in-service remedial actions implemented in response to complaints (including MDR serious injury events) and failure investigations regarding the ENDOPOUCH™ PRO specimen retrieval bag (21 CFR 806.10(a)).

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 to you may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the cause of the violations identified by the Food and Drug Administration (FDA). If the causes are determined to be system problems, you must promptly initiate permanent corrective actions.

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, requests for Certificates of Exportability and to Foreign Governments will not be cleared until the violations related to the subject devices have been corrected.

You should take prompt measures to correct these deviations. Failure to promptly 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.

The agency is in receipt of your written response, dated June 6, 2000 to the FDA 483 issued to your firm on May 24, 2000. While we acknowledge your firm's commitment to comply with the Quality System Regulations for devices, we have some comments to offer concerning your response. You mentioned several changes that you have made to your procedures. Have these changes been implemented yet? Your response for #5 indicates that you do not feel your actions constitute a recall; however you supplied the information for Part 806 because it was requested by the investigator. Your firm should report to FDA within 10 days all corrections and removal that were undertaken to reduce a risk to health posed by your device or to remedy a violation of this Act caused by your device which may present a risk to health (Section 519(f)(1), the Act). Please feel free to contact New Jersey District Recall Coordinator, Mimi Roa-Remache, concerning questions about whether future actions constitute a recall.

Several of the observations in the Warning Letter concern your general procedures for developing designs. Have you looked at any other designs that were developed during the time period that these procedures were in effect to determine if there are any other design problems that need to be corrected or validations that need to be re-conducted? Are there other failure investigations that may have concluded "user error" was the cause of the problem without investigating the design control activities employed to develop the design.

We are also in receipt of your July 26, 2000, response. This response is currently under review and comments will be provided under a separate cover. Please notify this office in writing, within 15 working days of receipt of this letter, of any additional steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. This response should also include answers to the questions listed in the above two paragraphs. Your written reply should be directed to Diane B. Radice, Compliance Officer, FDA, 10 Waterview Blvd., Parsippany, NJ 07054.

Sincerely,



DOUGLAS I. ELLSWORTH
DISTRICT DIRECTOR
New Jersey District

DBR:slm