



JUL 20 2000

VIA FEDERAL EXPRESS

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

**WARNING LETTER**

Ms. Rita L. Sparks  
Manager, Quality Assurance  
and Regulatory Affairs  
National Healthcare Manufacturing Corp.  
251 Saulteaux Crescent  
Winnipeg, MB R3J 3C7  
CANADA

Ref: OTRACK 83691

Dear Ms. Sparks:

During an inspection of your firm located in Winnipeg, MB on April 4 through 6, 2000, our investigator determined that your firm manufactures sterile, non-critical, ophthalmic, orthopedic and angiography convenience kits. These products are devices, as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act ("the Act").

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that methods used in, or the facilities or controls used for manufacturing, packing, storing or installation are not in conformance with the Good Manufacturing Practice (GMP) requirements of the Quality System Regulations, as specified in Title 21 of the Code of Federal Regulations (CFR), Part 820, as listed below:

1. Failure to establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g). For example, design control procedures do not include an established procedure for performing risk analyses. Risk analyses have not been performed on new convenience kits developed since [REDACTED].
2. Failure to establish and maintain procedures for the identification, documentation, validation, or where appropriate verification, review and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example:

- a. Header bag substitution for [REDACTED] and [REDACTED] has no record of approval prior to implementation, and
  - b. Complaints [REDACTED] and [REDACTED] showed substitution of components not meeting product design input requirements.
3. Failure to maintain device master records, as required by 21 CFR 820.181. For example, the device master record does not have an established procedure for determining the product expiration date that appears on the product labeling.
  4. Failure to maintain device history records, as required by 21 CFR 820.184. For example,
    - a. Information regarding [REDACTED] indicates two different header bag sizes, and
    - b. Information regarding [REDACTED] lacks product labeling information with the expiration date.

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 on 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 Food and Drug Administration. If the causes are determined to be systematic in nature, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they take this information into account when considering the awarding of contracts.

Page 3 - Ms. Sparks

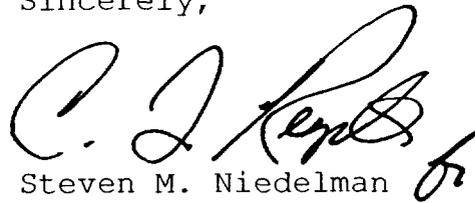
Please notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to identify and correct any underlying systematic problems that will assure that similar violations will not occur in the future.

Please include any and all documentation that indicates adequate correction has been achieved, and in the case of future corrections, please provide an estimated date of completion and plan(s) for correction.

Your response should be addressed to Mr. James R. Miller, Radiation Scientist, and forwarded to:

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Compliance  
Division of Enforcement I  
Diagnostic Devices Branch (HFZ-322)  
2098 Gaither Road  
Rockville, Maryland 20850

Sincerely,

A handwritten signature in black ink, appearing to read "S. M. Niedelman". The signature is written in a cursive style with a large initial "S" and a stylized "M".

Steven M. Niedelman  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health