



April 7, 1997

WARNING LETTER  
CHI-24-97

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Hymen L. Milgrom, President  
Milex Products, Inc.  
5915-21 Northwest Highway  
Chicago, Illinois 60631

Dear Mr. Milgrom:

During an inspection of your firm from February 19 to March 5, 1997, Investigators Theodore Thorsen and Chad Schmeier determined that Milex manufactures a spermatocidal cervical cream, which is a drug as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The investigators also determined that your firm manufactures obstetrical/gynecological curettes, cannulas and pessaries which are devices as defined by Section 201(h).

The investigators documented deviations from the Good Manufacturing Practice Regulations for Drugs (Title 21, Code of Federal Regulations, Part 211) causing your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act as follows:

1. Failure to sample and test water used for drug manufacturing, or to specify, via written guidelines, its quality upon use in such manufacturing.
2. Failure to monitor environmental conditions in the drug compounding area to assure the absence of dust, particulates or other airborne contaminants.
3. Failure to appropriately investigate the stability failure of Amino-Cerv Cervical Creme, Lot #024, at thirty-six months.
4. Failure to assure that all batch production records include complete information relating to the production and control of each batch.

The devices your firm produces are adulterated under 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 Good Manufacturing Practice Regulations (GMP) for Medical Devices (Title 21, Code of Federal Regulations, Part 820) as follows:

1. Failure to maintain all complaints about devices relative to their performance.
2. Failure to completely document a vendor audit.

Additionally, we note the instruction labeling for the device product "Milex Pro-Ception Fertility Cannula" contains the claim that the product is pyrogen free. Unless you have evidence substantiating this claim, it should be deleted from the product labeling.

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 pertinent regulations. You are responsible for investigating and determining the causes of the violations identified by the FDA and you must promptly initiate permanent corrective actions.

Until corrections are made, Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

Additionally, no pre-market pending applications for premarket approval (PMA's) or export approval requests will be approved and no premarket notifications (Section 510(k)'s) will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

You should 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 action include, but are not limited, seizure, injunction, and/or civil penalties.

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Please notify this office within 15 days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your response should be sent to Richard Harrison, Acting Director, Compliance Branch.

Sincerely,

*RSI*

Raymond V. Mlecko  
District Director

Enclosure: FD 483

cc: Robert E. Shaw  
Vice President  
Milex Products, Inc.  
5915-21 Northwest Highway  
Chicago, IL 60631