



Telephone (201) 331-2901
November 7, 1996

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

WARNING LETTER

**CERTIFIED MAIL-
RETURN RECEIPT REQUESTED**
Mr. Donald Lapone
President and CEO
NutraMax Products, Inc.
9 Blackburn Dr.
Gloucester, MA 01930

RELEASE

REVIEWED BY YPR 11/12/96
C.O. DATE

FILE NO.: 97-NWJ-04

Dear Mr. Lapone:

From August 26 to September 5, 1996, investigators from our office conducted a GMP inspection of your pharmaceutical and medical device manufacturing facility, Optoptics Laboratories Corp., located at 40 Main Street, Fairton, NJ. Our investigators documented deviations from the current Good Manufacturing Practices (Title 21, Code of Federal Regulations, Parts 210 and 211) in conjunction with your firm's manufacture and testing of sterile Ophthalmic Solutions, causing these drugs to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act as follows:

1. There is no assurance that your firm adequately validated the container closure system used in the manufacture of Sodium Chloride Ophthalmic Solution, 0.44%. For example:
 - A. Media Fill # [REDACTED], conducted 5/16/96 to qualify the use of 16 oz. CRW eyewash bottle with [REDACTED] mm natural friction plugs, resulted in 92 damaged, leaking units.
 - B. The media fill summary report ([REDACTED]) concluded that the friction plugs need to be redesigned and that the media fill does not support operations associated with the use of these plugs. The [REDACTED] mm friction plugs were used in the manufacture of the following lots of Sodium Chloride Ophthalmic Solution, 0.44%:

<u>LOT NO.</u>	<u>MFG. DATE</u>
6E021	5/06/96
6E022	5/07/96
6G011	7/08/96
6H051	8/07/96
6H211A	8/26/96
6H213	8/28/96

1. Your firm has agreed to cease manufacturing further lots of Sodium Chloride Ophthalmic Solution 0.44% with the [REDACTED] mm friction plug. In your response, your firm states that a [REDACTED] mm friction plug will be employed and the neck of the bottles will be redesigned. A revised media fill was to be conducted on 9/23/96.

This response appears adequate and will be confirmed during a reinspection of your facility.

2. Your firm's response to item #2 above is not adequate. Your firm distributed those lots of Sodium Chloride Ophthalmic Solution mentioned above, subsequent to media fill #SV96-010, although, your media fill summary report concluded that the friction plugs need to be redesigned and that the media fill does not support operations associated with the use of the [REDACTED] mm plugs.

We recognize that Optotics/NutraMax performed a 100% inspection of their remaining stock ([REDACTED] lots) and have asked your consignees to perform a 100% inspection of remaining stock. Your correspondence to the FDA stated that no leakers were found. However, written detailed procedures, i.e. amount of pressure to be applied and for how long; were not provided to consignees nor to the FDA.

In October 1996, the FDA began field exams of Optotics Sodium Chloride Ophthalmic Solution 0.44% at several consignees. To date, the FDA has inspected lot numbers #6E022 and 6H211A for leakers at one of Optotics consignees and has found one leaking unit in lot 6E022.

As of November 6, 1996, these lots, with an expiration date of 1999, remain in the market place.

3. Your response appears adequate.
4. Your response appears adequate.

The above identification of violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the good manufacturing practice regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

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You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should 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.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054, Attention: Compliance Branch.

Very truly yours,

Edward-H. Wilkins, for
MATTHEW LEWIS
District Director
New Jersey District Office

VPR:slw