



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

T1926M

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED LETTER
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-37

June 24, 1998

Mr. Jugal Taneja, CEO
Nu-Wave Health Products, Inc.
5905-A Hampton Oaks Parkway
Tampa, Florida 33610

Dear Mr. Taneja:

During an inspection of your facility located in Tampa, Florida on January 21-29, 1998, FDA Investigator, Karen G. Hirshfield determined that you manufacture Arth-Rx with Neurocaine topical lotion, which is labeled for conditions which cause it to be considered a drug within the meaning of Section 201 (g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that the drugs you manufacture are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for its manufacturing, processing, packing, or holding do not conform or are not operated or administered in conformity with the Good Manufacturing Practice (GMP) Regulations to assure that your drugs meet the requirements of the Act as specified in Title 21, Code of Federal Regulations, Part 211, as follows:

1. Failure to validate either the manufacturing processes for Arth-Rx, or the accuracy, sensitivity, and reproducibility of test methodologies differing from the USP used to determine conformance of finished products to meet specifications and product stability.
2. Failure to have a written procedure that establishes specifications, test procedures, or a sampling plan for the testing of finished products;
3. Failure to establish the reliability of the finished product analysis performed by the contract testing laboratory [REDACTED]
4. Failure to hold drug products in quarantine until all analytical work is completed, in that seven of the last ten lots of Arth-Rx were distributed before the analytical test

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results were received and reviewed by the quality control unit.

5. Failure to conduct a stability testing program using the current marketed container/closure system and to establish a written stability test program that addresses impurities and degradation products.
6. Failure to validate cleaning procedures to prevent the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products.
7. Failure to have or maintain environmental controls (e.g., dust control system, building maintenance, equipment maintenance), to reduce the potential for contamination or cross-contamination of products, product contact surfaces or product packaging, with microorganisms, chemicals, filth, or other extraneous materials.
8. Failure to establish and maintain master production records for products manufactured;
9. Batch records are inadequate and incomplete; and
10. Failure to have written procedures for:

Stability studies performed by a contract testing facility;
The operation of the retain/reserve sample area;
The operation and maintenance of the deionized water system;
The documentation of in-process checks for each product; and,
The calibration and maintenance of manufacturing equipment.

In addition, two (2) lots of Arth-Rx, lots A26 and A27, are adulterated within the meaning of Section 501(c) of the Act, in that analysis found that the lots contain 130-150% of the declared capsaicin.

Arth-Rx is also misbranded within the meaning of section 502(o) in that it is manufactured in an establishment not duly registered under Section 510 of the Act.

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. Please refer to the Form FDA 483, which was left with Dr. Kotha S. Sekharam, President, by the investigator at the close of the inspection.

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You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent the recurrence of similar violations. Please include in your response your intentions regarding the two lots found by analysis to be superpotent. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to the Food and Drug Administration, Orlando District Office, 555 Winderley Place, Maitland, Florida 32751, Attention: Martin E. Katz, Compliance Officer.

Sincerely,



Douglas D. Tolen
Director, Florida District

cc: Kotha S. Sekharam, Ph.D.
President
Nu-Wave Health Products, Inc.