



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Los Angeles District
Pacific Region
19900 MacArthur Blvd.
Suite 300
Irvine, CA 92612-2445

Telephone: 949-798-7600
FAX: 949-798-7690

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 20-03

February 5, 2003

Gerald W. Moreland, President/CEO
Master Industries, LLC
238 Taft Ave.
Orange, CA 92865

Dear Mr. Moreland:

During an inspection of your medical device manufacturing facility conducted on September 23, 2002 our investigators determined that you are manufacturing and selling a product, the Master Industries System 2000 Water Purification System, also known as the "UV Module 10-003," which is intended to reduce bacteria levels in dental operatory water lines. This product is considered a medical device as defined in section 201(h) of the Federal Food, Drug and Cosmetic Act ("the Act"). This device is therefore considered misbranded under Section 502(o) of the Act in that a notice or other information respecting the device was not provided to the Food and Drug Administration as required by section 510(k) of the Act. The inspection also revealed that the Master Industries System 2000 Water Purification System is adulterated under section 501(f)(1)(B) for failing to have an approved premarket approval application in effect under section 515(a) or an approved application for an investigational device exemption under 520(g) of the Act. These approvals are required unless you have submitted a premarket notification submission that shows that the Master Industries System 2000 Water Purification System is substantially equivalent to other devices that are legally marketed and you have been notified by FDA that you may market the Master Industries System 2000 Water Purification System.

In addition our investigators found significant deviations from the Medical Devices: Current Good Manufacturing Practice, Quality System Regulations (Title 21, Code of Federal Regulations (CFR), Part 820). These deviations cause your medical device to be adulterated within the meaning of Section 501(h) of the Federal Food, Drug and Cosmetic Act as follows:

1. Failure to establish and maintain a quality system that is appropriate for the specific medical device designed and manufactured. Specifically you designed and are manufacturing the "U.V. Module 10-003" water purifier, a medical device, but you have not implemented a quality system (21 CFR 820.5).

2. Failure to establish a quality policy and objectives. Specifically, management with executive responsibility has not ensured that the quality policy has been established that satisfies the requirements of the quality system regulations [21 CFR 820.20(a)].
3. Failure to appoint a management representative to ensure that quality system requirements are effectively established and maintained, and to report to management on the performance of the quality system [21 CFR 820.20(b)(3)].
4. Failure to conduct quality audits at sufficient regular intervals, as prescribed by internal procedures to verify that the quality system is effective in fulfilling your quality system objectives. Specifically, there is no evidence that internal quality audits have been performed, and there is no documented procedure to define a quality audit program (21 CFR 820.22).
5. Failure to establish procedures to control the design of the device [21 CFR 820.30(a)].
6. Failure to establish procedures for implementing corrective and preventive actions [21 CFR 820.100(a)].
7. Failure to establish process control procedures that describe any process controls necessary to ensure conformance to specifications [21 CFR 820.70(a)].
8. Failure to maintain a Device Master Record which includes device specifications, production process specifications, quality assurance procedures, packaging and labeling specifications, and installation, maintenance, and servicing procedures (21 CFR 820.181).

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. At the conclusion of the inspection, a list of observations (form FDA-483) was issued to and discussed with Mr. Troy B. Moreland, Vice President. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice regulation and other applicable regulations. Federal agencies are advised of the issuance of all warning letters about drugs and medical devices so that they may take this information into account when considering the award of contracts.

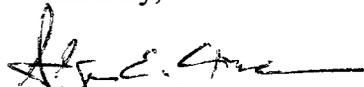
You should take prompt action to correct these deviations by identifying specific corrective actions you have made or will make to assure that such deviations will not reoccur. Failure to do so may result in regulatory actions being initiated by FDA, including product seizure and/or a permanent injunction requiring you to cease manufacture of drug or device products. You should notify this office, within fifteen (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 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.

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Master Industries, LLC

If you have any questions regarding this letter, please contact Mr. J. Lawrence Stevens, Compliance Officer at 949-798-7732. Your written reply should be addressed to:

Director of Compliance
U. S. Food and Drug Administration
19900 MacArthur Blvd, Suite 300
Irvine, CA 92612

Sincerely,



Alonza E. Cruse
District Director