



DEPARTMENT OF HEALTH AND HUMAN SERVICES

74234
Food and Drug Administration

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April 30, 2003

Hand Delivered

John B. Nycz
Acting CEO & Vice President of Marketing
System O₂, Inc.
1090 Upper Hembree Rd.
Roswell, GA 30076

Warning Letter
(03-ATL-18)

Dear Mr. Nycz:

During an inspection of your firm located at 4460 Commerce Circle, Atlanta, Georgia 30076 on December 10-17, 2002, Atlanta District Investigator Christie B. Rice determined that your firm manufactures and distributes the System O₂ and the Rejuv O₂ portable oxygen generators. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) because they deliver a drug, respirable oxygen, and are intended to affect the structure or function of the body. The System O₂ is also intended for use in the cure, mitigation, treatment, or prevention of disease.

The investigator documented significant deviations from the Quality System (QS) Regulation, as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause your devices to be adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice Requirements under the Quality System Regulation. These deviations include:

1. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization [21 CFR 820.20]. For example:
 - a) Your firm does not have adequate resources, including money and personnel, to ensure that finished devices have been manufactured in accordance with the Quality System Regulation.
 - b) Management reviews and quality audits have not been conducted by the firm.
 - c) Quality objectives have not been implemented.
2. Failure to maintain quality system records in a location that is reasonably accessible to responsible officials of the manufacturer and FDA employees [21 CFR 820.180]. For example, all of the firm's quality system records, including the quality manual, quality procedures, device history records, and design control records are being held by another firm. Your firm was unable to obtain these records.

3. Failure to review associated data and documentation prior to the release of finished devices for distribution. [21 CFR 820.80(d)(2)]. For example, your firm released approximately 100 finished System O₂ devices for distribution without reviewing the manufacturing documentation or finished product testing results. You informed our investigator that these records cannot be obtained because they are held by another firm.
4. Failure to implement complaint handling procedures for receiving, reviewing, and evaluation of complaints. [21 CFR 820.198 (a)]. Review of your complaint file revealed that you did not document and evaluate the two complaints received by your firm. In addition, you did not conduct investigations to determine the root cause of the complaints or maintain a record documenting the reason no investigation was conducted.
5. Failure to document procedures for rework of nonconforming product. [21 CFR 820.90 (b)(2)]. Your firm was in the process of reworking all System O₂ devices in stock due to the hardening of the powder. Your firm did not have an established rework procedure for the change in the powder containers. Your firm also does not have any verification activities planned to evaluate the effectiveness of the rework.

The intended use of the System O₂ cleared in premarket notification (K991569) is to provide oxygen for emergency first aid and is for prescription use only. The labeling for the System O₂ device now states "Caution: for emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Caution: Federal (USA) restricts this device to sale by or on the order of a licensed physician." The addition of an OTC use, as well as the addition of the intended use for "all other medical applications", are major changes in intended use that require the submission of a new 510(k) (21 CFR 807.81(a)(3)(ii)).

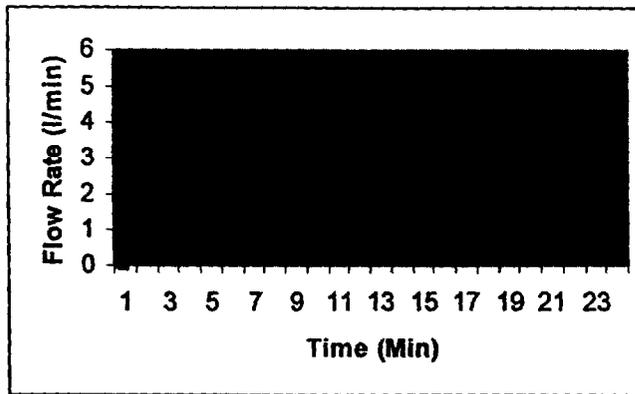
The investigator also documented that you changed the intended use of the System O₂ device by modifying its cleared indication and by marketing it as Rejuv O₂. The Rejuv O₂ is labeled as an "oxygen spa" for increasing energy, mental alertness, concentration, memory, stamina, improving sleep, and relieving stress and anxiety. This is a new intended use for the device that has not been cleared by FDA and, therefore, requires the submission of a new 510(k) (21 CFR 807.81(a)(3)(ii)).

The law requires that manufacturers of medical devices obtain clearance for their products before they may offer them for sale. The law also requires that manufacturers submit registration and listing information to the FDA. A review of our records reveals that your firm did not obtain marketing clearance before your firm began offering the System O₂ and Rejuv O₂ devices for sale for the new intended uses described above, and that your firm did not register or list with FDA. The kind of information you need to submit in order to obtain this clearance and to register and list is described on FDA's medical device website at <http://www.fda.gov/cdrh/devadvice>.

Your promotion and introduction into interstate commerce of the devices for their uncleared uses renders them adulterated under section 501(f)(1)(B) of the Act, for failure to obtain FDA premarket approval, and misbranded under section 502(o) of the Act, for failure to notify the agency of your intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act. For a product requiring premarket approval before marketing, the notification required by section 510(k) of the Act is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency. 21 CFR 807.81(b).

The law also requires that manufacturers of medical devices ensure that the labeling for the products they market is truthful and not misleading, and that their products have the quality they are represented

to have. Your System O₂ device is labeled as capable of producing “Over 6 liters per minute volumetric humidified flow rate”. Your Rejuv O₂ device is labeled as capable of producing “Over 5 liters per minute volumetric humidified flow rate”. At the time of the December 2002 inspection, FDA collected samples of your System O₂ device for testing. Our test results revealed that none of the devices delivered in excess of five liters per minute (5 l/min) for more than 15 minutes. The following is a graphical representation of a typical sample’s flow rate over time.



Our test results corroborate the results of testing submitted by your firm in [REDACTED]. The testing submitted in [REDACTED] was performed for your firm by [REDACTED] on September 1-2, 2000, with a report date of September 22, 2000. These same test data, with a cover letter dated December 10, 2002, were collected by our investigator during the December 2002 inspection. These statements and representations cause your devices to be further adulterated under Section 501(c) because the devices do not have the quality they are represented to possess, and misbranded under Section 502(a) because the flow rates identified in the labeling are false.

We acknowledge receipt of your letter dated January 4, 2003. We have reviewed the letter and determined that you have not adequately addressed the FDA 483 observations in that you did not provide specific corrective actions and timeframes for corrections of the FDA 483 observations. Your written response also did not address the devices which have already been distributed.

You should know that these serious violations of the law may result in the FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. FDA may assess civil money penalties against you as an individual, and against System O₂ Inc., for violations of Section 301(a) of the Act, i.e., the introduction or delivery for introduction into interstate commerce of any...device...that is adulterated or misbranded. Under Section 303(f)(1)(A) of the Act, FDA may impose civil money penalties of up to \$15,000 on you as an individual, and a like amount on System O₂ Inc., for each violation of a requirement of the Act, up to a total of \$1,000,000 per respondent for all violations. In this case, a violation of section 301(a) occurs each and every time System O₂ ships a Rejuv O₂ or a System O₂ device.

In addition, United States federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Also no requests for Certificates For Product Export will be approved until the violations related to the subject devices have been corrected.

It is necessary for you to take action on this matter now. Please let this office know, within 15 working days from the date you receive this letter, the steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these deficiencies from occurring again and how you plan to address the devices that have already been distributed. If you need more time, let us know why and when you expect to complete your corrections.

Sincerely yours,

A handwritten signature in cursive script that reads "Mary Woleske".

Mary H. Woleske, Director
Atlanta District