



March 16, 2000

Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

WARNING LETTER
SJN-00-07

Certified Mail
Return Receipt Requested

Mr. John Paul Jones III
President
Air Products & Chemicals, Inc.
7201 Hamilton Boulevard
Allentown, PA 18195-1501

Dear Mr. Jones:

From January 26 to February 9, 2000, an Investigator from our Mayagüez, PR Resident Post conducted an inspection of your medical oxygen processing firm, Air Products & Chemicals of PR, Inc., located at Road 127, Km. 12.7, Bo. Magas, Guayanilla, PR. Our review of the results of this inspection determines that the medical oxygen produced by the firm is adulterated within the meaning of section 501 (a) (2) (B) of the Federal Food, Drug and Cosmetic Act (the Act) because they were not produced in accordance with current Good Manufacturing Practice for Pharmaceuticals (GMP) as defined in Title 21, Code of Federal Regulations, Section 211 (21 CFR 211.) Deviations from these regulations which were found during the inspection include:

- 1) Failure to take adequate action to correct deficiencies identified during internal audits in accordance with 21 CFR 211.180 (e). For example:

In a meeting with your representatives in the San Juan District Office, on July 29, 1999, following the previous inspection of your firm in June & July of 1999, your firm committed to conduct internal GMP audits to identify and correct deficiencies related to GMP's.

Results of an internal audit conducted on 11/18/99 included an observation that the lot numbers for finished products were not always being assigned in accordance with the written procedures.

Results of a second audit reported on 12/20/99 reported that the deficiencies in lot number assignment had been corrected.

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During our inspection, review of the filling records determined that on 1/13/00, your firm identified a lot of Oxygen, Compressed, USP with lot number 266-0130-01/0201, which should have been lot # 266-0130-02/0201. When this observation was made to your firm, a voluntary recall of these units was initiated.

- 2) Failure to have adequate records of employee training in GMP's as required by 21 CFR 211.25 (a) as follows:

There are disparities between the employee training records and information obtained during the inspection. For example:

On 2/9/00, in the morning, your firm supplied our Investigator with updated employee training records, identified as prepared on 2/8/00. Records for employees [REDACTED] (Fill Plant Manager), [REDACTED] and [REDACTED] recorded that these employees took a twenty hour training course designated as "LOX/LIN/LAR HLD LSN DEWAR/FLAG", on 2/9/00, the day after the record was prepared.

The same records indicate that employees [REDACTED] and [REDACTED] also took an eight hour course designated as "Guidelines – FDA Inspection" on the same day, 2/9/00, the day after the record was prepared.

Both of these courses were listed in the employee records as taught on the same day, 2/9/00, by the same trainer, [REDACTED]

Between approximately 10:00 am until approximately 12:00 noon on 2/9/00, Messrs. [REDACTED] and [REDACTED] were with our Investigator, concluding the FDA inspection of the plant.

We acknowledge receipt of the letter, dated 2/16/00 and signed by Deborah M. Thomas, Director, Regulatory Compliance, responding to the FD-483 (List of Inspectional Observations). Our evaluation of this letter finds the response to observation # 3 is adequate. However, response to observation #1 is not

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adequate because it commits to essentially the same corrective action as promised after our inspection of July 1999, when a similar problem in failure to follow written procedures was reported. In this previous instance, the problem was also identified by the FDA Investigator during the inspection, although it occurred before the inspection began, and also resulted in a recall.

The response to observation #2 does not address the issue of training being reported as accomplished prior to its completion or how employees and trainers could attend and teach two different training courses on the same date, while also being engaged in other activities. The discrepancy of advance preparation of records was discussed in the findings of the previous inspection. Your commitment at that time was to provide training to employees and to increase the frequency of GMP audits.

These two issues require an evaluation of the systemic problems in documentation and adherence to written procedures which have caused them to be consistently identified during our inspections.

The above identification of violations is 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.

Please notify the San Juan District 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 these or similar violations.

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

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Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00902-3223, Attention: Mary L. Mason, Compliance Officer.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mildred R. Barber".

Mildred R. Barber
District Director

Cc: Mr. Javier Gonzalez
Air Products & Chemicals, Inc.
HC-02 Box 63127
Guayanilla, PR 00656