



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Central Region
New Jersey District

July 30, 2004

North Brunswick Resident Post
120 North Center Drive
North Brunswick, NJ 08902
(732) 940-8996

Bruce Gollob, President & Owner
Atlantic Analytical Laboratory
P.O. Box 220
Whitehouse, New Jersey 08888

Dear Mr. Gollob:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises at Salem Industrial Park #4, Route 22 East, Whitehouse, New Jersey on June 21-23, 2004 on behalf of the U.S. Food and Drug Administration (FDA). This report is being provided to you for information purposes.


This new procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it reflects redactions made by the Agency in accordance with the FOIA and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and, possibly, obtaining any additional information under FOIA.

If there is any question about the released information, feel free to contact Ray Abrahams at (973) 526-6002 or write to:

U.S. Food and Drug Administration
10 Waterview Blvd.
Parsippany, New Jersey 07054

Sincerely,


Meyer J. Slobotsky
Supervisory Investigator

Encl.

Establishment Inspection Report

Atlantic Analytical Laboratory
Whitehouse, NJ 08888

FEI: 2246907
EI Start: 06/21/2004
EI End: 06/23/2004

SUMMARY

Inspection of this analytical laboratory was conducted per FACTS Assignment ID 515912, Operation ID 1844573, as part of NWJ-DO FY '04 drug workplan. CP 7356.002, Drug Manufacturing Inspections, provided inspectional guidance. At present, the firm does analytical testing of one pharmaceutical gas, Nitrogen, as well as gases used for non-FDA regulated purposes.

The previous inspection was conducted in 1/2003. The inspection was classified VAI and an FDA 483, Inspectional Observations, was issued. Observations included lack of qualification of analytical instruments, lack of validated analytical methods, inadequate recording of method and data in laboratory notebooks, lack of signatures and second signatures in laboratory notebooks, lack of SOPs regarding OOS test results and preventative maintenance of laboratory equipment and lack of GMP training for employees.

The current inspection was a limited inspection, focusing on the Quality and Laboratory systems. Voluntary corrections promised from the previous inspection were completed and verified. No FDA-483, Inspectional Observations, was issued. No samples were taken.

All parts of this report were written by Amy M. Codella unless otherwise noted.

ADMINISTRATIVE DATA

Inspected firm: Atlantic Analytical Laboratory
Location: Salem Industrial Park #4, Rte 22 E
Whitehouse, NJ 08888
Phone: (908) 534-5600
FAX:
Mailing address: P.O. Box 220
Whitehouse, NJ 08888

Dates of inspection: 6/21/2004, 6/22/2004, 6/23/2004

Days in the facility: 3

Participants: Amy M. Codella, Investigator
Stephen J. Koniers, Analyst

On June 21, 22 and 23, I, Investigator Amy M. Codella, and Analyst Stephen J. Koniers conducted an inspection of Atlantic Analytical Laboratory, Inc., a contract analytical laboratory of drug-related

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gases and non-FDA regulated gases. Credentials were presented to Mr. Richard F. Frisch, Vice President – Analytical Services, and Dr. Hans H. Stuting, Vice President of Business Development. An FDA-482, Notice of Inspection and a copy of Resources for FDA Regulated Businesses, was issued to Mr. John Leatherdale, Quality Control Director. Present for the entire inspection were Dr. Stuting and Mr. Leatherdale. Present for part of the inspection were Mr. Bruce Gollob, President and Owner, Mr. Frisch, Mr. Ralph Ciotti, Laboratory Manager, and Mr. Dave Latter, Supervisor, Mass Spec Department. The above people furnished all information for this report.

Discussion with management and close-out was held on June 23, 2004. For the close-out, Mr. Frisch, Dr. Stuting and Mr. Leatherdale were present. An FDA-483, Inspectional Observations, was not issued.

The firm’s hours of operation are 8:00 AM – 5:00 PM for offices and laboratory. The firm experiences no seasonal variation in demand for its services.

HISTORY

Atlantic Analytical Laboratory, Inc. was incorporated in New Jersey in 1988. [REDACTED]
[REDACTED]
[REDACTED]

The previous inspection was conducted in January, 2003 and was classified VAI. An FDA-483 was issued and an untitled letter was sent.

INTERSTATE COMMERCE

According to Mr. Gollob, approximately [REDACTED] of the firm’s business is for out-of-state firms. [REDACTED]
[REDACTED]
[REDACTED]

RESPONSIBILITY

The most responsible person at the firm is Mr. Gollob, President and Owner. Responsible for day-to-day GMP activities is primarily Mr. Leatherdale. Dr. Stuting and Mr. Leatherdale stated that official correspondence should be addressed to Mr. Leatherdale.

Key operating personnel with whom we dealt during the inspection are Mr. Frisch, Mr. Leatherdale, Mr. Ciotti, and Mr. Latter.

OPERATIONS AND EQUIPMENT

General Facility (Written by Amy Codella)

The firm’s facility, approximately 6,000 square feet, consists of approximately 20% offices and 80% laboratory space. [REDACTED]

Water and sewer services are provided by the municipality. Trash disposal is by contractor, and pest control is provided twice per year and as needed by the landlord of the building. No water is used for pharmaceutical testing, but the firm purchases distilled water for general laboratory purposes and for non-FDA product analysis.

General Laboratory Operations (Written by Steve Koniers)

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There is a controlled entrance from the administrative area. Between the administrative area and the main laboratory space are several small rooms where small laboratory equipment and operations are located. At the rear of the building is a loading dock that is also controlled. The main lab is a large space with a high ceiling. Benches for instruments and cabinets for storage are located throughout the laboratory area. The laboratory area appeared to be clean and well organized.

Various methods are in use for the various types of industrial testing. For the testing of gases for pharmaceutical use, official methods include the USP/NF, and other methods validated by the laboratory.

Samples come in under contract, generally without prior notice. They are assigned sample numbers and various work forms. Raw data is entered into bound and numbered notebooks. Each page is signed by an analyst, and is reviewed and signed by a supervisor or member of management. A report is generated by management and sent to the requesting firm. Samples come in by cylinders of various sizes. Some are owned by AAL, others by the requesting firms. After the reports are sent out, samples are not retained.

Samples arrive in gas cylinders. After samples are analyzed, the cylinders are flushed and cleaned and ready for further use.

Equipment and Instrumentation (Written by Steve Koniers)

The laboratory has a wide array of analytical instrumentation for the analysis of gases. For the purposes of this inspection, only the instruments involved with the analysis of Nitrogen, NF were reviewed. On the first day of inspection, instrumentation for the analysis of CFC's were reviewed, including a Nicolet 550 II Fourier Transform Infrared Spectrophotometer (FTIR), a Varian 3800 Gas Chromatograph (GC), and a Panametrics Series 35 Moisture Monitor, but the review was terminated when it was determined that no future work would be coming in this area.

The official method for the analysis of Nitrogen NF is a gas chromatographic method. The firm uses a mass spectrometric method "AAL SOP-114," that they validated in, 2004. A Dupont 21-614 Mass Spectrometer, S/N 1143 is one of two mass spectrometers used in the laboratory. This instrument is identified as MS1 by the lab, and is the only one qualified for nitrogen analyses for pharmaceutical purposes. The instrument is in continuous use 8 hours a day, 5 and occasionally 6 days a week. The instrument is calibrated daily and before any nitrogen analyses.

LIMS System (Written by Steve Koniers)

The Laboratory has a limited LIMS system for the laboratory computers. The computers controlling the analytical instrumentation are stand alone systems. All data collection and processing are performed by installed software (EZChrom). The systems are connected by a simple network to a designated computer, and the data is collected and stored on the hard drive. The data is backed up daily onto tape, and taped archives are created monthly and transferred to Bruce Gollob's residence. For the analysis of nitrogen, the raw data from the instrument is immediately printed out and saved for archives. The data is also copied to a floppy disk and immediately placed in another computer, where a BASIC program takes several runs, inverts the data so that a matrix of several runs is printed out. This printout is used for manual calculations for all MS results. These two systems are not password protected, but the data is not saved after the printouts are made and the data copied on floppy diskette for saving on the designated computer for tape backup and archives. Mr. Leatherdale

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is in the process of writing an Excel spreadsheet to replace the manual calculations now being done. We expressed the importance of validating the spreadsheet before it is used for regular work.

Plans for future improvements include a barcode system for sample and standard cylinders. Also planned is a keycard or coded badge type system so that it can be quickly determined who worked on a sample and when.

Analytical Records Review (Written by Steve Koniers)

The following records were reviewed:

1. AAL SOP-114, "Assay N2 and Limit of O2 with a 10 ppm/v Quantitation Limit in 99+% NF N2 by Mass Spectrometry."
2. The Validation Protocol used by the firm for validation of the Assay and Limit of Oxygen
3. One of the two samples performed by the firm since the last inspection (January, 2003).

No deficiencies were observed, except for No. 2. In the validation Protocol, the method was not compared to the official NF method for assay of Nitrogen and limit of Oxygen. Since the method is more sensitive and more selective than the official method, it was brought up in the Discussion with Management on June 23, 2004, that this should be done. The data from the method validation otherwise met the validation specifications for quantization limits for oxygen, linearity, accuracy, and reproducibility of the method.

CHANGES IN OPERATIONS AND PERSONNEL

Since the last inspection Mr. Travis Toth, QA/QC Manager, left the firm and was replaced by Mr. John Leatherdale, Quality Control Director.

PRODUCTS

Since the last inspection the firm has ceased performing analysis on CFCs 11 and 12. The last time such analysis was performed was August, 2003. Since then, the firm's only customer for CFC analysis, [REDACTED], has informed the firm that they will no longer be using CFCs and therefore will no longer be using the firm's services for them.

The firm briefly discontinued their services analyzing Nitrogen, but resumed such services in April, 2004. According to Mr. Leatherdale and Mr. Gollob, the firm expects to continue testing Nitrogen for various customers. The firm also plans to expand their activities regarding the testing of pharmaceutical gases.

Analysis of pharmaceutical gases makes up [REDACTED] of the firm's business. Most of the firm's activity is for the semiconductor industry and other non-FDA related industries.

MANUFACTURING CODES

For purposes of tracking samples received and tested, the firm's computer system assigns each sample a consecutive four-digit sample number.

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VOLUNTARY CORRECTIONS

In response to the FDA-483 issued during the previous inspection the following corrections were made and verified:

- Observation 1: Lack of qualification for analytical instruments used to test pharmaceutical CFCs and Nitrogen. Mr. Leatherdale and Mr. Ciotti reported that the Varian 6000 gas chromatograph formerly used for testing of CFCs was no longer in use. In addition, since the firm no longer tests CFCs, there is no further need for these instruments. Regarding the instruments used to analyze Nitrogen, the Varian 6000 gas chromatograph formerly used to test Nitrogen has been replaced by a Varian CP 3800, S/N 100927, which has undergone qualification. The hygrometer cited in the FDA-483 from previous inspection has been replaced by a GE Series 35 moisture monitor, which has undergone qualification. In addition, the instrument currently used to analyze Nitrogen, a mass spectrometer, "MS-1," has undergone qualification.
- Observation 2: Lack of validation for GC/MS methods to determine the presence of impurities in CFC-11 and CFC-12. This point is no longer applicable since the firm no longer tests CFCs; however, for the samples received for sampling in August 2003 the firm held the samples until validation was performed on the Varian CP 3800.
- Observation 3: Lack of documentation in a laboratory notebook for three instances of CFC testing. For the CFC samples analyzed in August 2003, the firm documented the analysis in a laboratory notebook. The firm no longer performs CFC testing.
- Observations 4,5,6, and 7: Lack of adequate recording of preparation of standards, calculations and signatures in laboratory notebooks for analysis of CFCs. Mr. Gollob and Mr. Leatherdale explained that, although the firm no longer tests CFCs, these conditions have been corrected for the future and for other pharmaceutical activities.
- Observation 8: Lack of SOPs for OOS results and for preventative maintenance of analytical equipment. The firm had both SOPs in place. The SOP for OOS results was effective as of 8/2003. The SOP for preventative maintenance was effective as of 3/2004.
- Observation 9: Lack of GMP training for personnel having GMP responsibilities. Mr. Leatherdale provided records of GMP training received by senior operating personnel, including Mr. Gollob, Mr. Leatherdale and Mr. Frisch. Training records have been established for other employees. Mr. Leatherdale reported that the firm will be conducting GMP training on a regular basis in anticipation of increased activities in the pharmaceutical area.

REFUSALS

There were no refusals.

GENERAL DISCUSSION WITH MANAGEMENT

Discussion with management was held on June 23, 2004. Present at the discussion were Mr. Frisch, Dr. Stuting and Mr. Leatherdale, as well as Analyst Steve Koniers and myself. Discussion points included the following:

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1. Although the firm's mass spec method (MS-1) has been validated, no equivalency study has been done to demonstrate that the method is as good or better than the USP method for determining Nitrogen. Mr. Koniers noted that the firm issues their analysis reports for "NF 22 Nitrogen," which claims that the analysis was done in accordance with the USP/NF; and since no equivalency study has been done, this cannot be shown to be true (see **Exhibit 1**). Mr. Leatherdale and Dr. Stuting responded that the firm would conduct such a study before the next instance of Nitrogen testing.
2. The firm's preventative maintenance SOP requires that a copy of the preventative maintenance measures and criteria for each instrument is to be kept in the qualification / validation report for each instrument. That is not the case. Mr. Leatherdale responded that preventative maintenance criteria are kept in the operator's manual for each instrument, but that a copy of each will be put in the validation binder for each instrument in order to comply with SOP.
3. The firm's SOP regarding calibration of instruments using gas standards mentions the expiration date of calibration gases; however, pure gases do not have expiration dates. Mr. Leatherdale stated that this reference would be removed from that SOP.

No FDA-483 was issued.

EXHIBITS AND SAMPLES COLLECTED

1. Atlantic Analytical Nitrogen Analysis Reports, April, 2004, 4 pages.

ATTACHMENTS

FDA-482, Notice of Inspection, dated June 21, 2004.



Amy M. Codella, Investigator

Stephen J. Koniers, Analyst