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VIA FEDERAL EXPRESSFood and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751**WARNING LETTER**

FLA-00-63

July 6, 2000

Lenoir E. Zaiser, President
Inovo, Inc.
3786 Mercantile Avenue
Naples, Florida 34104

Dear Mr. Zaiser:

We are writing to you because on May 8-24, 2000 FDA Investigator Michelle S. Dunaway inspected your facility in Naples, Florida and collected information that revealed serious regulatory problems involving your firm's manufacturing of medical devices.

Under the Federal Food, Drug, and Cosmetic Act (the Act), the products that your firm manufactures are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers conform to the Quality System (QS) regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that devices that you manufacture are adulterated within the meaning of section **501(h)** of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

QS Regulation/GMPs

1. Your firm fails to exercise management responsibility to ensure that the quality system is adequate and effective as required by 21 CFR 820.20. For example, Your firm's organizational structure is not adequate. You have not established a quality plan that defines the practices, resources, and activities relevant to devices that are designed and manufactured to ensure they meet established quality requirements. You have failed to provide adequate resources including the assignment of trained personnel and management to ensure performance of work, assessment activities, including conducting

quality audits in a timely manner by individuals who do not have direct responsibility for the operation being audited (FDA 483, Item #s 1,2, 3, 5,7, 8 & 11).

2. You have failed to establish, maintain and implement adequate procedures to conduct management reviews and quality audits as required by 21 CFR 820.20(e) and 820.22. For example, procedures for management reviews and quality audits are incomplete or are not specific enough to describe how reviews are to be accomplished or what documents are to be reviewed (FDA 483, Item #s 4, 6 & 9).
3. You have failed to establish, maintain and implement adequate corrective and preventive action as required by 21 CFR 820.100. For example, you have not established and implemented adequate procedures for identifying, reviewing, and analyzing nonconforming product or other quality problems (FDA 483, Item #s 14, 15, 16, 17, 19, & 21).
4. You have failed to verify or validate corrective and preventive actions to ensure that the actions taken do not adversely affect the finished device, have been reviewed by management and that all corrective and preventive actions were documented as required by 21 CFR 820.100 (4) & (7). For example, replacing Teflon tape with Lox-8 on all assemblies on June 1, 1999 and the change back to Teflon tape with Formula-8 on June 11, 1999 because of loose connections being discovered after shipment. (FDA-483, Item #22).
5. You have failed to establish, maintain and implement procedures to ensure that all complaints are received, reviewed, evaluated and documented as required by 21 CFR 820.198. For example, complaints involving the oxygen conserving pressure regulator submitted by the specification developer were not investigated. Reported non-conformities involving replacement of slave diaphragms in the oxygen pressure regulators was not investigated. Customer complaints are not always fully investigated and documented. Discrepant material reports are not fully investigated, documented and closed (FDA 483, Item #s 18, 19, 20, 23 & 24).
6. Your firm's device master records (DMR) are incomplete as required by 21 CFR 820.181. For example, the DMR does not include or refer to the location of all drawings, components, specifications required to manufacture each device (FDA 483, Item #s 26 & 27).
7. Your firm's device history records (DHR) are not complete as required by 21 CFR 820.184. For example, the DHRs reviewed failed to document quantities of in-process assemblies or components forwarded to another

manufacturing operation, rejected, or released. Other DHRs identified the wrong process sequence, assembly process or work instructions. DHRs fail to list dates of manufacture, acceptance records lack signatures of persons performing acceptance activities and a minimum of 23 lots were released to distribution prior to completion of the DHR (FDA 483, Item #s 28, 29 & 30).

8. You failed to follow your own written procedures as required by 21 CFR 820.70. For example, inspection equipment specified in the test plan was not used, devices presented for finished product testing were already stamped as released for distribution, and DHRs from several work stations were not reviewed and approved as required (FDA 483, Item #s 31 & 32).
9. You failed to establish procedures or identify training needs and ensure all personnel are adequately trained to perform their assigned duties as required by 21 CFR 820.25(b). For example, no procedures for training have been established and a programmer was not aware of internal procedures for documenting in-process inspections (FDA 483, Item #s 33 & 34).
10. You failed to calibrate and maintain equipment to ensure that it is suitable for its intended purposes as required by 21 CFR 820.72. For example, the pressure gauge used to test flow disk operation was used past its calibration due date and maintenance activities are not documented (FDA 483, Item #s 35 & 36).
11. You failed to document sampling plans to show they are based on accepted statistical rationale as required by 21 CFR 820.250 (FDA 483, Item #38).

DESIGN CONTROL REGULATIONS [21 CFR 820.30(i)]

12. You failed to establish and maintain procedures to ensure that device design is correctly translated into production specifications as required by 21 CFR 820.30(h). For example, the work instructions, drawings, process travelers do not accurately reflect the design of the oxygen conserving pressure regulator device manufactured under contract (FDA 483, Item #12).
13. You failed to establish and maintain procedures for the approval and implementation of design changes for devices manufactured under contract as required by 21 CFR 820.30(i) (FDA 483, Item #13).

MEDICAL DEVICE REPORTING

Your devices are misbranded within the meaning of section 502(t)(2) in that there was a failure to furnish material or information required by or under section 519 respecting the devices. These violations include, but are not limited to the following:

14. You failed to maintain and implement written Medical Device Reporting procedures to ensure timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements as required by 21 CFR 803.17(a)(1). For example, there is no written procedure to review, evaluate and document non-conformities and/or complaints pursuant to the MDR requirements (FDA 483, Item #s 25).
15. You failed to report to FDA within 30 days after you received or otherwise became aware of information, from any source, that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a serious injury, if the malfunction were to recur as required by 21 CFR 803.50(a)(2). For example, investigation of a series of non-conformities and/or complaints resulting in the September 1999 recall of the oxygen regulator identified quality problems that were not properly evaluated and reported to FDA (FDA 483, Item #26).

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to Kevin W. Confoy, General Manager, at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations 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. We are in receipt of your response received in the Florida District on June 7, 2000. Our review of your response determined it to be inadequate because it does not address each observation specifically, fails to address the systems problems that may be responsible for the reported and observed deficiencies and fails to provide documentation of items that have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

A handwritten signature in cursive script, appearing to read "Emma R. Singleton".

Emma R. Singleton
Director, Florida District