



110798A

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-74

July 1, 1999

William Wachter, Group President
Anspach Effort, Inc.
4500 Riverside Drive
Palm Beach Gardens, Florida 33410

Dear Mr. Wachter:

We are writing to you because on March 16 - 29, 1999, FDA Investigator Angela K. Rhodes, collected information that revealed serious regulatory problems involving the Blackmax and Minimax cutting burrs and drill bits (Class II), which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products 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 of medical devices conform to the Quality System (QS) regulations for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices 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:

- 1) Failure to validate and document your firm's radiation sterilization and device packaging systems as required by 21 CFR 820.75. For example, bioburden levels for differing manufactured products of varying materials, design and manufacturers were not determined prior to setting the sterilization dose, which is not documented (Inspectional Observations, FDA 483, Item #3).

Mr. William Wachter
Page 2
July 1, 1999

Product packaging was not considered when changes in radiation dose and processing were made (FDA 483, Item #1 & 13).

Your firm's responses dated April 16, 1999 to FDA 483, Item #1a & c are inadequate because they fail to address the need to validate and document various manufacturing operations, i.e., the bioburden reduction, radiation sterilization and packaging processes. Validation is defined as documented evidence, which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality characteristics. Therefore, it is necessary for you to establish specifications for bioburden and validate both operations to reduce bioburden and to sterilize the product. Validation typically consists of three consecutive batches or lots of manufactured product, which results are measurable, quantifiable, and consistent demonstrating that all processes are reproducible.

Your response to FDA 483, Item #1b is inadequate because quarterly dose audits do not replace well-designed and documented process validation. Quarterly audits are good for monitoring an on-going process to assure all required attributes or specifications are being met on a consistent basis once they have been validated.

Your response to FDA 483, Item #1d appears to be adequate.

Your response to FDA 483, Item #3 appears to be adequate.

Your response to FDA 483, Item #13 is inadequate because the equipment has not been validated under worst case conditions. Your response states the equipment builds up heat internally during heavy use. You have no procedure based on a validated study to deal with or handle this condition. Changes were made to operating procedures without documented verification or validation.

- 2) Failure to assure that labeled expiration dates are appropriate based on supporting stability data as required by 21 CFR 820.120(b). For example, your devices were found to be labeled with 5 year expiration dates with only 3 year stability data. It was explained that this was done per ISO requirements. You should know that the FDA QS regulation/GMP does not always coincide with ISO regulations. Product manufactured and distributed in the U.S. must first meet FDA requirements, which take precedence over any other regulation or standard (FDA 483, Item #2).
- 3) Failure to establish and document radiation current dose levels in an up-to-date contract with the vendor as required by 21 CFR 820.50. For example, the contract with your sterilization

Mr. William Wachter
Page 3
July 1, 1999

contractor was allowed to renew on an annual basis without an annual review to assure current specifications were reflected in the document (FDA 483, Item #4).

Your firm's response to FDA 483, Item #4 appears to be adequate.

- 4) Failure to establish and maintain procedures to implement corrective and preventive action as required by 21 CFR 820.100. For example, changes made revising the print on the Ejector lock body was not properly communicated to operational personnel (FDA 483, Item #5); changes in product design or manufacturing processes were not properly validated and documented (FDA 483, Item #s 6, 7 & 8), and changes made to improve a problem with the 1.0 mm cutters identified by a customer were not adequately validated to ensure that documented actions were effective and did not adversely affect the device (FDA 483, Item #22).

Your firm's response to FDA 483, Item #5 is inadequate because a change was made to a device and communicated to the vendor without determining the status of the current contract. Because of this failure an accommodation was made to allow an outdated component to be dispositioned for use. Your response fails to address how you will correct this from occurring again.

Your firm's responses to FDA 483, Item #6 are inadequate because the changes made to the devices were not verified and validated in accordance with a specific protocol. Your own experience with these changes determined that errors in judgement (actually assumptions) were made that resulted in other problems requiring further attention and correction. Since these changes were made, Design Controls were implemented, which will affect all future changes. You state that no corrective action was taken. This is a serious deviation and must be addressed immediately to prevent similar occurrences.

Your response to FDA 483, Item #7 is inadequate because your firm's actions to effect changes made to the Ejector-Lock Body pursuant to ECO #98-103 fail to address the effectiveness of the action and ensure the changes do not adversely affect the finished device. Established verification or validation procedures were not followed and properly documented, e.g., changes identified as ECO 97-133 and ECO 98-016 involving the locking mechanism and ECO #98-161 involving the laser marking or the cutters.

Your response to FDA 483, Item #8 states there is a misunderstanding of the Anspach procedures involving changes to manufacturing processes. It appears the misunderstanding is due to your firm's failure to provide adequate management oversight of critical manufacturing operations, to provide adequate training in

Mr. William Wachter
Page 4
July 1, 1999

the use of procedures and to establish an effective corrective and preventive action program. Our investigator was provided documentation that contradicts your response, e.g., the investigator collected QDR 98-057 which directly relates to the observation and states under "Corrective Action", "The hoses burst at the same pressure and rate as previously purchased hoses. Therefore, use as is. Our testing method is not accurate, need to design a proper test."

This observation not only describes a failure to conduct a proper corrective and preventive action program, it appears management oversight and responsibility is not being properly exercised and implemented over the entire quality assurance program as required by 21 CFR 820.20.

Your response to FDA 483, Item #22 is inadequate because there appears to be a definite problem identified by the customer. The problem was also verified by further inspection of product on hand and several devices were scrapped because they failed to meet new specifications. Your response provided no documentation covering the complaint (recommendation) or that covered the steps taken within your corrective and preventive action program. In the future similar changes to devices will require to be addressed and approved through Design Controls before implementation can take place at the manufacturing level.

Your response to FDA 483, Item #s 9-11 appear to be adequate.

5) Failure to establish and maintain procedures to control product that does not conform to specified requirements as required by 21 CFR 820.90. For example, reworked products, 60 lots since July of 1998, were not documented in the individual Device History Records (DHRs) as required (FDA 483, Item #12).

Your response to FDA 483, Item #12 is inadequate because rework procedures have never been verified and validated and the procedures fail to address the need for corrective and preventive action to ensure recurring quality problems associated with work operations, nonconforming product, complaints, and returned products are addressed. Rework procedures are now subject to Design Controls and your response fails to address this aspect of the rework operation.

Your responses to FDA 483, Item #s 14 - 17 appear to be adequate.

6) Failure to establish and maintain procedures to ensure that DHRs for each batch or lot are maintained to demonstrate that the device is manufactured in accordance with the Device Master

Mr. William Wachter
Page 5
July 1, 1999

Record (DMR) as required by 21 CFR 820.184). For example, all required or completed procedures are not documented in the DHR including: cleaning procedures and rework operations (FDA 483, Item #18).

Your responses to FDA 483, Item #18 are inadequate for the following reasons:

FDA 483, Item #18a because it is not enough to make pen and ink changes to a Work Order Router without making permanent documented changes to the DHR and communicating these changes to employees. When required training is conducted with employees, it should be documented and made part of each employees personnel file. Further, when DHRs are changed, the old DHR should be filed in a chronological file and a new revision of the record issued for use effective on a specific date.

Your responses addressing Item #s 18c and 18d are inadequate. We fail to understand how operations identified in 18c and 18d relate to a cleaning process identified in 18a. The observation identified a failure in your firm's processes that does not document work that was performed in the DHR.

Your response to Item #18b appears to be adequate as long as the change is properly documented. This will be verified during the next inspection.

Your response to Item #18e is inadequate because it fails to address what action was taken to ensure the employee(s) are aware of their responsibilities and are properly trained. This should also be documented.

Your response to Item #18f is inadequate because it fails to address the reason for the miscount. Your SOP #AQP-10-1 states a requirement to check the "correctness of the required documentation". This appears to have been ignored and not conducted until a final inspection. The focus of the QS regulation/GMP has always been to build in quality throughout the manufacturing process, not inspect quality in at the end. More attention needs to be paid to in-process testing and documentation to catch problems or discrepancies early so they don't turn into big problems later.

Your responses to FDA 483 Item #19-21 appear to be adequate and will be verified during the next inspection.

Your response to FDA 483, Item #s 23 & 24 appear to be adequate if in-process and quality control tests are properly documented

Mr. William Wachter
Page 6
July 1, 1999

according to specifications and that all process controls are properly established and maintained in written procedures. Your response states that all requirements have not been completely documented in the Device Master Record. These requirements should be established and documented as soon as possible. These corrections will be verified during the next inspection.

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to you 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 awards of contracts. Additionally, no premarket submissions for 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.

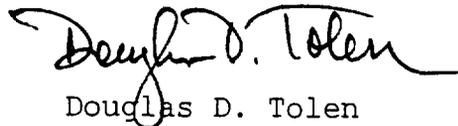
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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.

Mr. William Wachter
Page 7
July 1, 1999

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 black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, looping initial "D".

Douglas D. Tolen
Director, Florida District