

**VIA FEDERAL EXPRESS**

September 22, 2004

Mr. David W. Swanson, President  
Daavlin Distribution Company  
205 West Bement Street  
Bryan, Ohio 43506-0626

**Warning Letter CIN-04-22469**

Dear Mr. Swanson:

During an inspection of your establishment located in Bryan, Ohio, on June 14-18, 2004, our Investigator determined that your firm manufactures various phototherapy units used to treat skin conditions such as psoriasis, vitiligo, and eczema. Your phototherapy units are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated under 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 Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to establish a quality plan, as required by 21 CFR 820.20(d). For example, a written quality plan that defines the quality practices and the resources and activities relevant to the devices being manufactured has not been implemented.
2. Failure to establish procedures for management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency, as required by 21 CFR 820.20(c). For example, there are no written procedures defining management reviews to include the frequency of the review meetings.
3. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, there are no written procedures defining quality audits to include formal planned checks of all elements of the quality system. Also, you have not conducted any quality audits to determine the effectiveness of the quality system.
4. Failure of management with executive responsibility to appoint, and document such appointment of, a member of management who shall ensure that quality system requirements are effectively established and effectively maintained in accordance with this part and report on the performance of

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the quality system to management with executive responsibility for review, as required by 21 CFR 820.20(b)(3). For example, no management representative had been appointed to ensure that quality system requirements are met, and to report to management on the performance of the quality system.

5. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a). For example, the DermaPal and the 3 Series Full Body Phototherapy Device were recent design projects that were developed into marketed devices. There was no design control process established or implemented detailing the design requirements such as documentation of design inputs, design outputs, verification, validation, design review, and design transfer.
6. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example, design changes made to the 3 Series Full Body Phototherapy Device software to correct design defects were conducted without controlling the design process.
7. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example, corrective and preventive action procedures have not been implemented.
8. Failure to establish and implement procedures to verify and validate corrective and preventive action to ensure that such action is effective and does not adversely affect the finished product, as required by 21 CFR 820.100(a)(4). For example, corrective actions taken regarding updating the software provided with the 3 Series Full Body Phototherapy device were not fully verified and validated.
9. Failure to document all activities required under this section, and their results, as required by 21 CFR 820.100(b). There was no documentation to demonstrate that the software changes implemented with the 3 Series Full Body Phototherapy Device performed as intended. Also, there was no documentation to show that changes made to the software do not adversely affect the finished device.
10. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, there is no written complaint handling procedure that has been implemented that defines receipt of complaints and their evaluation by a formally designated unit.
11. Failure to maintain device master records (DMR's), as required by 21 CFR 820.181. For example, there are no established and implemented DMR's for any of the medical devices manufactured, which includes the 3 Series Full Body Phototherapy Device, the Spectra Series of Phototherapy devices, and DermaPal.
12. Failure to establish and maintain procedures to ensure that the device history records (DHR'S) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance

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with the DMR and the requirements of this part, as required by 21 CFR 820.184. For example, there are no established and implemented DHR's for any of the medical devices manufactured, which include the 3 Series Full Body Phototherapy Device, the Spectra Series of Phototherapy devices, and DermaPal.

13. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a). For example, process control procedures for the 3 Series Full Body Phototherapy Device, the Spectra Series of Phototherapy devices, and DermaPal have not been implemented. Also, the procedures are not signed and approved by management and QA.
14. Failure to establish procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b). For example, there are no written procedures identifying the training necessary to adequately perform their assigned responsibilities.

Additionally, the above-stated inspection revealed that you distributed at least six (6) 3 Series Full Body Phototherapy Devices with Smart Touch Control Systems (a class II phototherapy device) domestically and an additional seven (7) devices to foreign consignees without complying with 510(k) of the Act. In a letter dated March 1, 2004, The Office of Device Evaluation (ODE), Center for Device and Radiological Health (CDRH) responded to your February 5, 2004 letter, titled "Model Change Report," informing you that because of the information that you provided to ODE it appeared that you significantly changed or modified the design, components, methods of manufacture, device labeling, or intended use of the device and that therefore you needed to submit a new 510(k) for that device. During the inspection you told the investigator that you willfully sold these unapproved devices because you did not want to lose potential sales.

In legal terms, the 3 Series Full Body Phototherapy Device with Smart Touch Control System is adulterated under section 501(f)(1)(B) in that it is a class III device under section 513(f) and does not have an approved application for premarket approval in effect pursuant to section 515(a) or an approved application for an investigational device exemption under 520(g). Your 3 Series Full Body Phototherapy Device with Smart Touch Control System is also misbranded under section 502(o) because a notice or other information respecting the device was not provided to the FDA as required by section 510(k) and 21 CFR 807.81 (a)(3)(i).

Further, the above-stated inspection revealed that your devices are misbranded under section 502(t)(2) of the Act, in that your firm failed or refused to furnish any material or information required by or under section 519 respecting the device and 21 CFR Part 803 (Medical Device Reporting) regulation. Specifically, there is no written MDR procedure detailing timely and effective identification of events, the standardized review process, ensuring timely transmission of MDR's, and ensuring record keeping requirements are met, as required by 21 CFR 803.17.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating

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and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

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 the Quality System regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

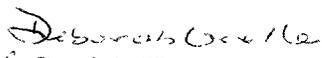
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.

We acknowledge the receipt of your letter dated July 6, 2004, responding to the FDA 483 Inspectional Observations that our Investigator issued. Please note that your letter does not address any specific timeframes for when you will accomplish your corrective actions; therefore, your response is inadequate.

Please notify this office in writing within fifteen (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 similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Stephen J. Rabe, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of the letter, you may contact Mr. Rabe at (513) 679-2700, extension 163.

Sincerely yours,

  
for Carol A. Heppe  
District Director  
Cincinnati District