DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
FAX: 504-253-4520

July 23, 2004

WARNING LETTER NO. 2004-NOL-31

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Ms. Susanne W. Jernigan, Chief Executive Officer
DANA Diabecare USA LLC
541 Julia Street, 3rd Floor
New Orleans, Louisiana 70130

Dear Ms. Jernigan:

During an inspection of your establishment, located at 541 Julia Street, 3rd Floor, New Orleans, Louisiana, on February 19, 20 and 27, 2004, an investigator from the U.S. Food and Drug Administration (FDA) determined that your firm is the importer/initial distributor of the DANA Diabecare® II, an insulin infusion pump manufactured by Sooil Development Co., Ltd., Seoul, Korea. This product is a device within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

A copy of the Establishment Inspection Report (EIR) was issued to you on March 17, 2004. The EIR was accompanied by a letter. The letter noted that the EIR was being issued to you because the Agency had concluded that the inspection was "closed," under Title 21 of the *Code of Federal Regulations* (21 CFR), Part 20.64(d)(3). A secondary review of the inspectional findings by FDA's Center for Devices and Radiological Health (CDRH) revealed serious deviations from the requirements of 21 CFR 803, FDA's Medical Device Reporting (MDR) regulation. The findings are discussed below.

The inspection revealed your insulin infusion pumps are misbranded within the meaning of Section 502(t)(2) of the Act because your firm failed to furnish certain information to the FDA as required by the MDR regulation set forth in 21 CFR 803. Significant deviations include, but are not limited to, the following:

1. Failure to establish adequate written MDR procedures as required by 21 CFR 803.17, which provides for timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements, and a standardized review process/procedure for determining when an event meets the criteria for reporting. Specifically, your firm's MDR procedures lack the following information:

a. Timeframes and procedures for when and to whom employees should forward information as soon as they become aware of an event that is subject to MDR reporting as required by 21 CFR 803.17(a). Your procedure is inadequate because you evaluate and forward possible reportable events during weekly staff meetings, which may not allow timely and effective notification.

b. Procedures for the retention of MDR event files for two years from the date of the event or the expected life of the device, whichever is longer as required by 21 CFR 803.17(b)(2) and 803.18(c).

c. Procedures for systems that ensure access to information that facilitates timely follow-up and inspection by FDA as required by 21 CFR 803.17(b)(4).

2. You failed to submit a report to FDA, and a copy of such report to the manufacturer, containing the information required by 21 CFR 803.42 on Form FDA 3500A as soon as practicable, but not later than 30 days after becoming aware that one of your marketed devices may have caused or contributed to a death or serious injury as required by 21 CFR 803.40(a). Specifically, you failed to submit MDR reports to FDA within 30 days for complaints concerning the following pump serial numbers: [redacted] and [redacted] Your firm received complaints regarding these pumps, which represent events that should have been reported as serious injuries as defined in 21 CFR 803.3(bb).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure compliance with each applicable requirement of the Act and regulations. 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.

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

We have received your response letters dated March 11, 2004 and April 29, 2004, concerning our investigator's observations on the Form FDA 483. We have reviewed the letters and concluded that your response is inadequate for the following reasons:

1. You have not provided a revised procedure for "Medical Device Reporting and Recalls." We can assume the procedure collected during the inspection remains in effect. As stated above, the procedure is not adequate because the evaluation of events at weekly staff meetings to determine if they are MDR reportable may not provide timely and effective notification. There should be time frames, procedures, and MDR contacts that employees should notify as soon as they become aware of an event that is subject to MDR reporting.

2. Although your updated "Medical Device Reporting Decision Tree" is not part of your written MDR procedures, the document is confusing and could result in incomplete or inadequate MDR reporting for the following reasons:

a. The stated intent of the decision tree is to determine if an adverse event is MDR reportable. If the decision tree indicates that a call may be a reportable event, then you and the Chief Operating Officer are notified and a copy of the troubleshooting form is sent to both of you. Item #5.3 of the document states the final decision to report the event will be made by you "based on the situation." Item #5.4 of the procedure states "The CEO will make the final determination on reporting any incident not covered in section 5.2." The decision tree should clearly state reporting decisions will be made by following written MDR procedures and pertinent requirements as required by 21 CFR 803.

b. The document also limits the information that should be evaluated to determine if an event is reportable and does not mention the MDR death or serious injury reporting requirements.

Please revise the "Medical Device Reporting Decision Tree" to align it with the reporting requirements in 21 CFR 803.17, 21 CFR 803.40, and 21 CFR 803.42.

Please notify this office in writing within fifteen (15) working days from the date you received this letter of the specific steps you have taken, or will take, 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 frame within which the corrections will be completed.

Your reply should be directed to Mark W. Rivero, Compliance Officer, Food and Drug Administration, 6600 Plaza Drive, Suite 400, New Orleans, LA 70127. You may contact Mr. Rivero at (504) 253-4519.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District

cc: Sooil Development Co., Ltd,
111-1 Heukseokl-dong,
Dongjak-ku
Seoul, Republic of South Korea, 156071