



**WARNING LETTER**  
**VIA EXPRESS MAIL**

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

JUL 19 2000

Mr. Tomas Hammergren  
CEO & President  
Biora AB  
IDEON  
S-205 12 MALMÖ  
SWEDEN

Dear Mr. Hammergren:

During an inspection of your facility located in Malmo, Sweden, on May 22 & 25, 2000, our investigator determined that your firm manufactures EMDOGAIN® (dental bone filling material). This product is a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The current inspection revealed that your firm has made a change in the product from a 2-vial system (mixing) to the Emdogain Gel filled sterile syringes (no mixing).

The above-stated inspection revealed that this device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures must include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. Also, the design input requirements must be documented, reviewed and approved by a designated individual(s). The approval must include the date and signature of the individual(s) approving the requirements, must be documented, as required by 21 CFR 820.30(c). For example, the firm failed to designate an individual at BIORA AB to document the approval of the product and process design inputs for the new product form and packaging of the Emdogain Gel.
2. Failure to establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met, as required by 21 CFR 820.75(b). For example, the firm failed to validate the packaging material used on the Emdogain Gel.

We acknowledge that you have submitted a response dated June 29, 2000, concerning our investigator's observations noted on the FDA 483. We have reviewed your response and have concluded that it is inadequate for the following reasons:

- Your firm must submit corrected procedures that identify those persons responsible for approving the inputs. Also, your firm must state when the approvals occurred (Item #1 above); and
- Your firm must provide the results of the microbial challenge or similar test in order to verify this correction (Item #2 above).

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 and any other manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a follow-up inspection, and may result in the detention of your device(s) without physical examination upon entry into the United States.

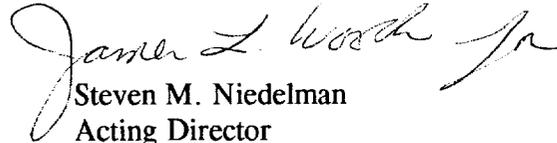
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be 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 Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Please notify this office, in writing, within 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 identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If the documentation is not in English, please provide a translation to facilitate our review.

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Your response should be sent to the attention of Mr. Ronald L. Swann, Dental, ENT, and Ophthalmic Devices Branch, at the above Gaither Road address.

Sincerely,

A handwritten signature in cursive script, appearing to read "Steven M. Niedelman".

Steven M. Niedelman  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health