



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

d/2042b

SEP 17 1998

WARNING LETTER
FEDERAL EXPRESS

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Michel R. Mounier
President and Chief Executive Officer
Synthelabo Biomedical S.A.
Centre D'Affairs LaBoursidiere
92357 Le Plessis-Robinson
Cedex, France

Dear Mr. Mounier:

During an inspection of your firm located in Montrouge, France, on July 9 through 17, 1998, our investigator determined that your firm manufactures pacemakers and implantable defibrillators. These products 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 within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacture, packing, storage, or installation are not in conformity 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 make records, including those not stored at the inspected establishment, readily available for review and copying by FDA employee(s), as required by 21 CFR 820.180. For example, our investigator requested the complaint files for the products identified as the Chorus RM, Opus RM, and the Opus S, marketed both in the United States and other countries. The investigator was only provided those complaint files for those products marketed in the United States. Complaint files for those products marketed in other countries were refused. Because these files can reveal problems associated with products marketed in the United States, we believe it is important that we have access to these files.

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

Page 2 - Mr. Michel R. Mounier

regulations. The specific violations noted in this letter might 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 devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected.

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.

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 correct 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. Please address your response to:

Donald W. Serra
Chief, Cardiovascular and Neurological Devices Branch,
HFZ-341
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Enforcement III
2098 Gaither Road
Rockville, Maryland 20850
USA

Page 3 - Mr. Michel R. Mounier

If you have any questions, please contact Kent A. Berthold at the above address, by telephone at (301) 594-4648, by FAX at (301) 594-4672, or by e-mail at KAB@CDRH.FDA.GOV.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian J. Gill". The signature is fluid and cursive, with the first name being the most prominent.

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc:

Mr. Peter M. Jacobson
Vice President, Research and Development
ELA Medical
2950 Xenium Lane North
Plymouth, Minnesota 55441