



AUG 2 2004

**WARNING LETTER**

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

**FEDERAL EXPRESS**

Mr. Giuseppe Sala  
Vice President, Research and Development  
SinTea Biotech S.p.A  
VIA Aquilea 33/H  
Baranzate (Milano), Italy 20221

Dear Mr. Sala:

During the inspection of your establishment located in Baranzate, Italy on March 18, 2004, our investigator determined that your firm is the manufacturer of orthopedic devices, such as the Traumafix System. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 351(h).

Our inspection revealed that your firm is not in conformance with the Quality System (QS) regulation, Title 21, Code of Federal Regulations (CFR), Part 820. As a result, your firm's devices are adulterated within the meaning of Section 501(h) of the Act.

**Quality System Regulation**

The investigator noted the following violations of the QS regulation as follows:

1. Failure to establish and maintain Corrective and Preventive Action Procedures to analyze processes, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1). For example, the procedures ( ) and ( ) -- *Preventive Actions* do not identify the quality data sources analyzed to identify existing and potential quality problems.

Please provide revised corrective and preventive action procedures that fully address all the requirements of 21 CFR 820.100(a), including the requirements of 820.100(a)(1).

2. Failure to establish and maintain procedures for evaluating complaints to determine whether the complaint represents an event which is required to be reported to FDA under part 803, Medical Device Reporting, as required by 21 CFR 820.198(a)(3). For example, the procedure ( ) Complaint Management does not explain how a complaint is evaluated to determine if a Medical Device Report (MDR) should be filed with the FDA.

FDA acknowledges at the time of the close out of the inspection, your firm modified the complaint form to indicate whether or not an MDR has been filed. This modification does not address all the issues concerning your complaint handling process. Please

provide your firm's procedures for determining when to file an MDR. The MDR decision process may be folded into the complaint procedure or be independent of the complaint procedure (if the complaint procedure references the MDR procedure), either approach is acceptable.

3. Failure to establish and maintain adequate procedures for reviewing, evaluating and investigating complaints involving possible failure of a device, labeling or packaging to meet any of its specifications, as required by 21 CFR 820.198(c). For example, the procedure ( ) Complaint Management does not explain how SinTea Biotech determines which complaints are investigated and how SinTea Biotech documents the justification for not investigating a complaint.

FDA acknowledges at the time of the close out of the inspection, your firm modified the complaint form to indicate whether or not an MDR has been filed. This modification does not address all the issues concerning your complaint handling process. Please provide a revised complaint procedure to address when an investigation of a complaint is warranted and how your firm documents and justifies any decision not to investigate a complaint

4. Failure to establish adequate design control procedures, as required by 21 CFR 820.30 Design Controls. For example, the procedure ( ) Design Controls, among other things, does not:
  - a. Identify the mechanism used to address incomplete, ambiguous or conflicting input requirements. (21 CFR 820.30(c))
  - b. Contain or make reference to established acceptance criteria for design outputs. (21 CFR 820.30(d))
  - c. Ensure that formal documented design reviews are planned and conducted at appropriate stages of the device development; that the reviews include participants from all the functional area involved in the stage under review; and the reviews include an independent reviewer. (21 CFR 820.30(e))
  - d. Require that validation activities be conducted using production units or their equivalents; or ensure that design validation also includes software validation and risk analysis, where appropriate. (21 CFR 820.30(g))

Based on our review of the design control procedure collected during the inspection, your design control procedure is inadequate. The procedure is vague and fails to satisfy all the requirements outlined in 21 CFR 820.30. This violation is not an all inclusive list of what is missing in your firm's design control procedure. It is merely intended to highlight some of what is wrong with the procedure. Please supply a design control procedure that satisfies all the requirements outlined in 21 CFR 820.30.

#### **MDR Regulation**

Additionally, the investigator noted the following violation of the MDR regulation:

5. Failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17. For example SinTea Biotech does not have any written MDR procedures.

Please provide your firm's written MDR procedure.

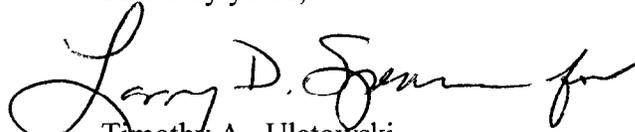
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in action without further notice, which may include detaining your devices without physical examination upon entry into the U.S. until corrections are completed. Section 801(a) of the Act, U.S.C. 381(a)). 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.

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 how you plan to prevent these violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this letter as well. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to: Ms. Christy Foreman, Deputy Director, HFZ-340, Division of Enforcement B, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. If you have any questions concerning this matter, you may contact Ms. Erin Keith at 301-594-4659 ext. 117.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Larry D. Ulatowski for". The signature is fluid and cursive, with a large initial "L" and a long, sweeping underline.

Timothy A. Ulatowski  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health