



April 10, 2000

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-16-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dennis Batchos, Owner
ESB Enterprises, L.L.C.
P.O. Box 426
12130 Illinois Route 173
Hebron, IL 60034-0426

Dear Mr. Batchos:

During an inspection of your establishment located in Hebron, IL, from January 19 to January 25, 2000, our investigator, Matthew Sienko, determined that your establishment manufactures tanning beds. Tanning beds are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This 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 manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish procedures for corrective and preventive action that include requirements for analyzing processes, quality audit reports, service records, complaints, and other sources to identify potential causes of nonconforming product.
2. Failure to establish procedures for receiving, reviewing, and evaluating complaints. Failure to maintain complaint files.
3. Failure to establish procedures for incoming component inspection or other acceptance activities.
4. Failure to establish process control procedures that describe any process controls necessary to ensure that tanning beds conform to specifications.
5. Failure to establish quality audit procedures and conduct quality audits.

6. Failure to establish procedures for identifying training needs.

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 Form 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment'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 requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

In order to facilitate FDA in making the determination that corrections to the deviations from the Quality System Regulation have been made, thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts for medical devices, and to resume Certificates to Foreign Governments for medical devices manufactured at your facility located in Hebron, IL, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the requirements of the device Quality System Regulation (21 CFR Part 820). You should also submit a copy of the consultant's report, and certification by your establishment's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your establishment, located in Hebron, IL, has initiated and completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections should be submitted to this office on the following dates:

- Initial certifications by consultant and establishment: October 15, 2000 (or sooner)
- Subsequent certifications of updated audits and corrections: October 15, 2001

We request that you 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 penalties.

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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. 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 Michael Lang, Compliance Officer at the above address.

Sincerely,

\s\
Raymond V. Mlecko
District Director