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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-77

July 20, 1999

James G. Karleskint, President
Future Health Concepts, Inc.
1211 30th Street
Sanford, Florida 32773

Dear Mr. Karleskint:

We are writing to you because on March 1 through 12, 1999, FDA Investigator Scintone Robinson, collected information that revealed serious regulatory problems involving steam sterilizers (Class II), which are remanufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform to the Quality System (QS) regulations for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section 501(f)(1)(B) of the Act, in that the devices were classified under section 513(f) into class III, which under section 515(a) are required to have in effect an approved application for premarket approval, and which is not exempt from section 515 under section 520(g).

The inspection revealed that your 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 the manufacture, packing, storage, or installation are not in conformance with the QS/GMP regulation. These violations include, but are not limited to the following:

- 1) Failure to maintain complaint files and to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, e.g., 43 field work orders were reviewed from September 1997 to February 1999, which revealed 22 complaints that were not adequately evaluated and investigated [21 CFR 820.198].

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- 2) Failure to establish and maintain procedures to implement corrective and preventive action resulting from the identification and investigation of complaints of non-conforming product, e.g., sterilizer doors do not open at the end of sterilizer cycles, doors do not seal properly, door handles damaged, steam generator leaks, sterilizers inability to hold selected pressure, and other reports of defective components and assemblies [21 CFR 820.100].
- 3) Failure to establish and document a quality audit program [21 CFR 820.22].

The inspection also revealed that your devices are misbranded within the meaning of section 502(o) of the Act, in that the devices were not included in a list required by section 510(j), and a notice or other information respecting it was not provided as required by such section, or section 510(k) as the Secretary by regulation requires.

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to you 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 FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should also know that your devices and manufacturing facility are subject to Design Controls as required by 21 CFR 820.30, which were not covered during this inspection. Design Control will be covered during the next inspection of your facility.

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 awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should 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 fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) 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.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407)475-4728.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, stylized initial "D".

Douglas D. Tolen
Director, Florida District