



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Mason

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-17

December 4, 1998

Jean F. Hakim, President
Soft Computer Consultants
34350 US Hwy. 19 N.
Palm Harbor, Florida 34684

Dear Mr. Hakim:

We are writing to you because on August 10 through 14, 1998, FDA Investigator Christine M. Humphrey collected information that revealed serious regulatory problems involving Softbank II computer software, which is developed and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a medical device that is used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with 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 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 the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

DESIGN CONTROLS

- 1) Failure to establish and maintain plans that describe or reference the design and development activities, and define responsibility for implementation including the plans that describe the interfaces with different groups that provide input to the design and development process [21 CFR 820.30(b)].

Mr. Jean F. Hakim

Page 2

December 4, 1998

2) Failure to establish and maintain a Design History File (DHF) containing or referencing records necessary to demonstrate that the design was developed in accordance with the approved design plan and the Design Control requirements [21 CFR 820.30(j)].

3) Failure to establish and maintain procedures for validating the device design to ensure that devices conform to defined user needs and intended uses including testing of production units under actual or simulated use conditions. Failure to document the results of the design validation in the DHR. For example, Softbank II application software, Release 1.21, dated 7/14/98 was not validated using the original protocol. [21 CFR 820.30(g)]

4) Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review and approve of design changes before their implementation. For example, quality assurance and approval of design changes did not occur before release and implementation of Softbank II software. [21 CFR 820.30(i)]

QS REGULATIONS

5) Failure to review, evaluate, and investigate any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications in that, there are no records of investigations reported into hardware and/or system failures documented in Task Sheets MOBIL-01988S; CHICA-01399S; WNVL-01468S; STFRH-00967S; COFFE-00888S; AND MOBIL-01042 [21 CFR 820.198(c)].

6) Failure to establish and maintain procedures for implementing corrective and preventive action in that, Root Cause Analysis(RCA) reports for Task Sheets NIH-01141S, MTSIN-02028-S, ALLIA-0051, and MTSIN-02030 all identified programmer error as the root cause for each complaint, however, there are no procedures for analyzing or investigating the root cause(s) of non-conforming product to correct and prevent the problem from recurring [21 CFR 820.100(a)].

7) Failure to establish and maintain procedures to control all documents in that, obsolete and/or unapproved standard operating procedures (SOP) are referenced in approved SOPs [21 CFR 820.40]. For example:

Mr. Jean F. Hakim
Page 3
December 4, 1998

- a. SOP 1053A, entitled Softbank II Change Control, which is an approved procedure, references use of unapproved procedure, SOP 1012;
- b. SOP 1078, entitled Configuration Management, which is an approved procedure, references use of unapproved and/or obsolete procedures, SOP 1081, SOP 1011, and SOP 1024B; and
- c. SOP 1024C, entitled Complaint Handling, referenced use of unapproved procedure, SOP 1014.

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-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.

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.

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 timeframes within which the corrections will be completed, (2) any documentation indicating the correction has 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.

Mr. Jean F. Hakim
Page 4
December 4, 1998

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, appearing to read "Douglas D. Tolen". The signature is written in a cursive style with a large, stylized initial "D".

Douglas D. Tolen
Director, Florida District