DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

February 25, 1999

WARNING LETTER

Gerald A. Miller, Owner and
Chairman
Continental Manufacturing Chemists, Inc.
dba Clinical Resources International, Inc.
1769 West Armitage
Chicago, IL 60622

KAN #99-013

Dear Mr. Miller:

We are writing to you because on September 30 through October 13, 1998, an FDA Investigator from this office conducted an inspection at your facility known as Clinical Resources International, Inc., 912 South State Street, Madrid, Iowa, which revealed serious regulatory problems involving your sterile surgical procedural kits.

Under the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices. The law requires that manufacturers of medical devices adhere to the Quality System Regulations (QSR). This helps protect the public health by ensuring that medical devices are safe and effective.

In legal terms, your devices are adulterated under 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 QSR, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- failure of internal quality audits to identify and correct deviations from standard operating procedures (SOPs), and regulations [21 CFR 820.22];

- failure to conduct process validation of the SunVac packaging machine, and of the visual post-sterilization seal integrity test [21 CFR 820.75];

- failure to maintain complete and accurate Device History Records which ensure that each batch or lot of device is manufactured in accordance with the Device Master Record and SOPs [21 CFR 820.184];

- failure to develop SOPs with adequate instructions for device kit assemblies [21 CFR 820.40];
- failure to establish and document training procedures to ensure that all personnel are trained to adequately perform their assigned responsibilities [21 CFR 820.25(b)];
- failure to conduct annual evaluations of your contract sterilizer and laboratory, per instructions contained in your SOP [21 CFR.820.50(a)].

This letter is not intended to be an all-inclusive list of deficiencies at Clinical Resources International, Inc. Violations were previously brought to your attention in Warning Letters issued to your firm on November 6, 1995, and August 12, 1997. It is your responsibility to ensure that Clinical Resources International, Inc., adheres to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued to Mr. Donald W. Larson, Operations Manager, 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.

While we acknowledge there appears to be a commitment to correct the identified deficiencies, we note that your firm has in the past, promised to correct deficiencies noted during FDA inspections, and our subsequent inspections, in particular the most recent inspection, have found your efforts to be ineffective.

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

The initial certifications of audit and corrections should be submitted to this office by Monday, August 30, 1999. A time frame should be provided for corrections and subsequent audits that will be completed after August 30, 1999.

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 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 FDA 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 the specific steps you will be taking to comply with our request.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

Attachment - Selecting a Consultant?

cc: Donald W. Larson, Operations Manager
Clinical Resources International, Inc.
1769 West Armitage
Chicago, IL 60622

CRP:tlw