



Purged by S. Davis 3/2/98 7/1/98  
d1462b

Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit, MI 48207-3179  
Telephone: 313-226-6260

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

WARNING LETTER  
98-DT-05

February 6, 1998

Mr. Linn Derickson, President  
Custom Plastics, Inc.  
1950 E. McKinley Highway  
Mishawaka, IN 46545

Dear Mr. Derickson:

We are writing to you because on December 16 through December 19, 1997, an Investigator from the Food and Drug Administration (FDA) conducted an inspection at your facility which revealed a serious regulatory problem involving the sharps containers which are made and shipped by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), the sharps containers are considered to be medical devices. The law requires that manufacturers of medical devices adhere to the Quality System Regulations. 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 Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- 1) Failure to have documented validation for the mixing and molding operations for the 5GR/5GY and IR80/IR180b sharps containers.
- 2) Failure to have written procedures and documentation for quality and manufacturing operations regarding the 5GR/5GY and IR80/IR180b sharps containers, as follows:
  - a. Management reviews and internal quality audits
  - b. Employee training
  - c. Quality plan
  - d. Component specifications, receipt, and testing

- e. Purchasing controls
  - f. Equipment calibration procedures
  - g. Change control procedures
  - h. Validation/Revalidation plans
  - i. Label acceptance and examination
  - j. Approved master labels
  - k. Corrective and preventive actions
  - l. Cleaning and maintenance of manufacturing and testing equipment
  - m. Device packaging
  - n. Handling, storage, and distribution of finished device products
  - o. Statistical rationale for quality control sampling plan
- 3) Failure to have complete device history records for the 5GR/5GY and IR80/IR180b sharps containers. Device history records prior to November 19, 1997 do not have the quantities manufactured and the production/acceptance rejection results. For lots manufactured from November 19, 1997 through December 8, 1997, no finished product quality control acceptance/rejection records were available.
- 3) Failure to have written complaint and MDR handling procedures which ensure that all complaints are processed in a uniform and timely manner.

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 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 cause of the violations identified by the FDA. If the causes are determined to be system problems you must promptly initiate permanent corrective actions.

We acknowledge that you have submitted to this office a response concerning our Investigator's observations noted on the form FDA 483, and that some corrections have been made prior to the completion of the inspection. We have reviewed your response and have concluded that it is inadequate. The response from Mr. Frank Tirota, General Manager, indicates that correction will be made, but does not make any specific commitments for correction of the individual violations and does not provide a timetable for the corrections.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the products, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they might consider this information when awarding contracts.

Warning Letter 98-DT-05  
Custom Plastics, Inc.  
Mishiwaka, IN 46545

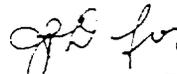
Page 3

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Mr. David M. Kaszubski, Compliance Officer, U.S. Food and Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter only pertains to the issue of Quality System Regulations, and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about the content of this letter, please feel free to contact Mr. Kaszubski at 313-226-6260 Ext 185.

Sincerely yours,



Raymond V. Mlecko  
Acting District Director  
Detroit District

Warning Letter 98-DT-05  
Custom Plastics, Inc.  
Mishiwaka, IN 46545

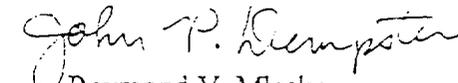
Page 3

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Mr. David M. Kaszubski, Compliance Officer, U.S. Food and Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter only pertains to the issue of Quality System Regulations, and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about the content of this letter, please feel free to contact Mr. Kaszubski at 313-226-6260 Ext 185.

Sincerely yours,

  
for Raymond V. Mlecko  
Acting District Director  
Detroit District