



MAR 2 2004

Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850**WARNING LETTER****VIA FEDERAL EXPRESS**

Ziyad M. Hijazi, M.D.
University of Chicago
5841 S. Maryland Avenue
MC 4051
Chicago, IL 60637

Dear Dr. Hijazi:

This Warning Letter informs you of violative conditions found during a Food and Drug Administration (FDA) inspection at your clinical site. This letter also requests that prompt corrective actions are implemented in response to the violations cited.

Ms. Lisa Hayka, an investigator from the FDA, Chicago District Office, conducted the inspection during the period of October 22, 27, 30 and November 6, 2003. The purpose of the inspection was to determine whether your activities as a clinical investigator (CI) of investigational devices complied with applicable FDA regulations. The inspection reviewed your research and use of significant risk devices including the [REDACTED] [REDACTED] for treatment of coarctation of the aorta (CoA), fontan baffle, and/or pulmonary artery.

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE) and Humanitarian Device Exemptions (HDE) submissions are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations. The aforementioned product used in studies are devices as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321 (h)].

Our review of the inspection report submitted by the district office revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). At the conclusion of the inspection, the FDA Investigator held a discussion with you detailing the objectionable conditions found.

You implanted significant risk devices that did not have an FDA approved IDE under § 520(g) of the Act or an FDA approved premarket approval application (PMA) under § 515 of the Act and were consequently adulterated devices under section 501(f)(1)(A) of the Act.

Between April 16, 2001 and June 2, 2003, you implanted at least eight patients with the [REDACTED] at the University of Chicago without prior FDA approval. This device is a class III device that requires an FDA approved PMA. Such a device is exempt from the PMA requirement if FDA has approved an IDE for the device under section 520(g) of the Act or an HDE under section 520(m) of the Act. This device does not have an FDA-approved PMA or HDE, nor has an IDE been approved permitting its investigational use. While the device did receive Humanitarian Use Device (HUD) designation in May 2000, there was no subsequent approved HDE or IDE. The device is thus adulterated under section 501(f)(1)(a) of the Act. By receiving and implanting these adulterated devices, you have committed a prohibited act under section 301(c) of the Act.

Continued implantation of these devices will be considered by FDA to be knowingly violating the Food, Drug, and Cosmetic Act. Because you have been implanting this device since 1999, it is unclear how many patients actually received this unapproved device. To protect the rights and welfare of human subjects that you implanted, you should develop a corrective action plan that we recommend include, at a minimum, notification of each recipient by certified mail that they were implanted with an unapproved device, who to contact in the event of an emergency and where to report adverse events. This notification should also advise each patient that FDA may review their medical records. Please provide us with a complete list of all patients that were implanted, including name, date of birth, date of implant and reason for implant. Please describe how these patients are receiving appropriate clinical follow-up. Your corrective action plan, including a draft of the certified patient letter should be submitted to this office and your IRB prior to implementation. In addition, we recommend you maintain copies and return receipts of all letters sent to implanted recipients for review by this office during a subsequent inspection.

This is not intended to be an all-inclusive list of deficiencies at your site. It is your responsibility to ensure that you follow FDA regulations.

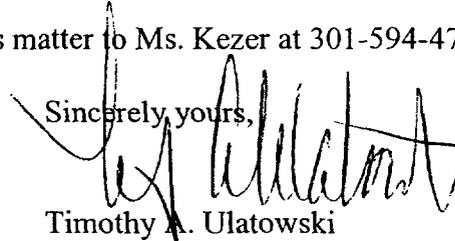
Within 15 days, you must respond to this letter in writing. You should be aware that FDA considers your actions to be serious violations of the law and your failure to respond may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, investigator disqualification, seizing product inventory, obtaining an injunction to prevent further violations of the law, assessment of civil money penalties, and criminal prosecution.

You should direct your response to the Food and Drug Administration, Centers for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch I (HFZ-311), 2098 Gaither Road, Rockville, Maryland, 20850. Attention: Doreen Kezer, MSN, Consumer Safety Officer.

A copy of this Warning letter was sent to the Food and Drug Administration's Chicago District, 550 W. Jackson, Suite 1500, Chicago, IL 60661. We request that a copy of your response also be sent to that office.

Please direct all questions concerning this matter to Ms. Kezer at 301-594-4718.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski". The signature is written in a cursive style with a large, prominent initial "T".

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: (purged copy)

[REDACTED]

The University of Chicago Hospitals
And Health Systems
5841 S. Maryland Ave.
Chicago, IL 60637

[REDACTED]

The University of Chicago IRB
5841 S. Maryland Avenue
Chicago, IL 60637
AMB S-138, MC 1108

[REDACTED]

[REDACTED]

Kristina C. Borrer, Ph.D
Director of Division of Compliance Oversight
Department of Health and Human Services
Office of Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852