



Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

June 1, 2004

WARNING LETTER

VIA FEDERAL EXPRESS

John P. Cheatham, M.D.
Division of Cardiology
Columbus Children's Hospital
6th Floor, Education Building
700 Children's Drive
Columbus, OH 43205

Dear Dr. Cheatham:

This Warning Letter informs you of violative conditions found during a Food and Drug Administration (FDA) inspection at your clinical site and to request that prompt corrective actions be taken. Mr. Phillip Pontikos and Ms. Allison Sincek, investigators from the FDA, Cincinnati District Office, conducted the inspection during the period of February 9 through 12 and February 20, 2004. The purpose of the inspection was to determine whether your activities as a clinical investigator (CI) in an investigational study involving significant risk devices complied with applicable FDA regulations. The inspection reviewed your research and use of significant risk devices including the [REDACTED], as well as your "compassionate use" of other significant risk devices. The aforementioned products are devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act)[21 U.S.C. 321 (h)].

The FDA conducted the inspection under a program designed, in part, to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval (PMA) Applications, and Premarket Notification [510(k)] submissions are scientifically valid and accurate. The program also ensures that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Our review of the inspection report prepared by the district office revealed serious violations of the Federal Food, Drug, and Cosmetic Act. At the close of the inspection, Mr. Pontikos and Ms. Sincek presented a Form FDA 483 "Inspectional Observations" to you for review and discussed the listed deviations. The deviations noted on the FDA 483 and our subsequent inspection report review are discussed below:

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

Between September 25, 2002 and May 23, 2003, you implanted at least [REDACTED] patients with [REDACTED] at Columbus Children's Hospital without prior FDA approval. In addition, you performed a [REDACTED] on a patient using the unapproved [REDACTED] on May 19, 2003, which also requires prior FDA approval. These are class III devices that require an FDA-approved PMA unless they are exempt from the PMA requirement because FDA has approved an IDE for the device under section 520(g) of the Act. These devices do not have an FDA-approved PMA nor has an IDE been approved permitting their investigational use, therefore, these devices are adulterated under section 501(f)(1)(B) 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.

For your information, there is published guidance available through the FDA web site at <http://www.fda.gov/cdrh/ode/idepolicy.html> which also includes specific guidance for "Expanded Access to Unapproved Devices." FDA recommends that these suggested guidelines be followed at Columbus Children's Hospital before any future "compassionate use" devices are implanted.

The above-described violations are not intended to be an all-inclusive list of deficiencies that may exist at your site. It is your responsibility as a clinical investigator to assure adherence to each requirement of the Act and all applicable federal regulations.

Within 15 days, you must respond to this letter in writing. During a June 17, 2003 meeting between [REDACTED] in which you participated, you verbally committed to stop implanting the [REDACTED]. However, as noted above, you also implanted other unapproved devices. FDA seeks your commitment in writing that you will not implant any unapproved device in human subjects without prior approval of the Agency. 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, 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, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch

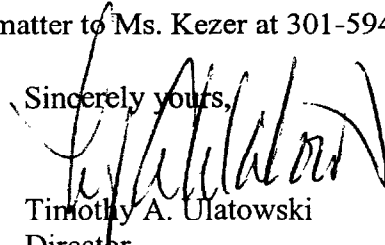
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Monitoring, Program Enforcement Branch I (HFZ-311), 2098 Gaither Road, Rockville, Maryland 20850. Attention: Doreen Kezer, MSN, Consumer Safety Officer.

A copy of this Warning letter was sent to the Food and Drug Administration's Cincinnati District, 6751 Steger Drive, Cincinnati, OH 45237. 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, sweeping initial "T".

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