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WARNING LETTER

VIA FEDERAL EXPRESS

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850Hillard W. Welch
Owner
Medical Device Consulting
344 Annabelle Point Road
Centerville, MA 02632

SEP _ 3 2003

Dear Mr. Welch:

The purpose of this Warning Letter is to inform you of objectionable conditions found during a Food and Drug Administration (FDA) inspection conducted at Medical Device Consulting and to request your prompt corrective actions. Ms. Sandra White, an investigator from FDA's New England District Office, conducted the inspection from April 23 to May 8, 2003. The purpose of the inspection was to determine if your activities as a sponsor complied with applicable FDA regulations in sponsoring the study of [REDACTED] which is a device as that term is 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 to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval Applications (PMA), and Premarket Notification [510(k)] submissions are scientifically valid and accurate. Another program objective is to ensure that human subjects are protected from undue hazard or risk during scientific investigations.

Our review of the inspection report prepared by the district office revealed serious violations of Title 21 Code of Federal Regulations (21 CFR), Part 812-Investigational Device Exemptions. You received a Form FDA 483 "Inspectional Observations," at the conclusion of the inspection that listed the deviations noted and these deviations were discussed with you. The deviations noted on the FDA 483 and our subsequent review of the inspection report are discussed below.

1. Failure to obtain FDA approval of your investigation (21 CFR 812.42)

The FDA approved the supplement to your IDE application for Phase III studies on June 29, 2001. However, your records indicate that investigators enrolled approximately 18 subjects prior to the June 29, 2001, approval date. Examples include subjects [REDACTED], and [REDACTED] enrolled on March 10, May 30, and June 27, 2001, respectively. Sponsors must secure FDA approval for applications or supplemental applications prior to beginning an investigation or part of an investigation.

2. Failure to promptly secure compliance from or to terminate participation by a non-compliant investigator (21 CFR 812.46 (a))

Several times between March 2001 and April 2002 you contacted [REDACTED], a Phase II investigator, about his failure to follow the study protocol and the investigator agreement. However, after your unsuccessful efforts to secure prompt compliance from him, you failed to promptly notify [REDACTED] that you were terminating him from study participation as required in 21 CFR Part 812.46 (a). We note your April 30, 2003, letter to [REDACTED] terminating him from study participation and your notification to the FDA of this action.

3. Failure to ensure proper monitoring of the investigation (21 CFR 812.40)

Sponsors must monitor studies at adequate intervals to assure that investigators are complying with the signed agreement, investigational plan, and all applicable FDA regulations. There have been no monitoring visits conducted since the beginning of Phase III studies on July 1, 2001. Proper monitoring also should identify incomplete patient records. You failed to identify deficient patient consent forms which you kept in the records. For example, there were unsigned or undated informed consent forms for three subjects ([REDACTED]). Another consent form contains a dated signature for the day following the surgical procedure ([REDACTED]).

4. Failure to have adequate written monitoring procedures as part of the investigational plan (21 CFR 812.25 (e))

Your written monitoring procedures for the [REDACTED] study are incomplete and do not specify a monitoring interval. There are also no general monitoring procedures as part of your standard operating procedures (SOPs). We note that you revised your procedures during the inspection and have established a minimum monitoring interval of every two years. Although the regulations do not specify minimum monitoring intervals, the frequency should be more often than every two years to promptly identify and correct deficiencies such as those noted above and to take action against noncompliant investigators. You should also include a general, written monitoring procedure in your SOPs.

5. Failure to maintain device accountability records (21 CFR 812.140 (b) (2))

The device accountability inventory records are incomplete, and several entries for shipment dates, invoice and patient identification numbers are omitted for each study site. There are also no records to account for six devices sent from the manufacturer to the clinical investigator at one site. FDA regulations require study sponsors to maintain records documenting shipping and disposition of study devices including information such as shipment dates and patient and invoice identification numbers.

6. Failure to submit progress reports to the IRB and FDA (21 CFR 812.150 (b)(5))

You failed to submit an annual progress report to the FDA and the IRB in 2002. You indicated that this report is in progress.


The deviations listed above are not intended to be an all-inclusive list of deficiencies that may exist at your facility. As a sponsor, you are responsible for ensuring that you conduct clinical trials according to FDA regulations.

The FDA is particularly concerned about these violations because we observed similar deficiencies during a November 28 to December 14, 2000, inspection. In your February 21 and June 1, 2001, and April 22, 2002, responses to the FDA, you promised to correct the deficiencies and comply with FDA regulations. Although you have corrected some deviations, FDA review of the April 23 to May 8, 2003, inspection report finds persistent deficiencies as described earlier in this letter.

Please advise this office, in writing, within fifteen (15) working days after receiving this letter of the specific steps you have taken or plan to take to correct these violations and prevent the recurrence of similar violations. Failure to respond and to implement appropriate corrective actions could result in enforcement action without further notice to you. Please direct your response to the following address: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch II (HFZ-312), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Sybil Wellstood, Ph.D.

We are also sending a copy of this letter to FDA's New England District Office and request that you also send a copy of your response to that office. If you have any questions, please contact Dr. Wellstood by phone at (301) 594-4723, ext. 140, or by email at saw@cdrh.fda.gov.

Sincerely yours,


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