



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Via Federal Express

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Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

**WARNING LETTER**

Harvey Grossman  
Executive Vice President  
The AMERICA Charitable Fund, Inc.  
National Medical and Research Institute  
8137 Mizner Lane  
Boca Raton, Florida 33433

Dear Mr. Grossman:

During the period September 11-15, 2000, Mr. Victor Spanioli, an investigator with the Food and Drug Administration (FDA), Florida District Office, and Ms. Barbara A. Crowl, a Consumer Safety Officer from FDA's Center for Devices and Radiological Health, conducted an inspection of the Institutional Review Board (IRB) of The AMERICA Charitable Fund, Inc. The purpose of that inspection was to determine whether the IRB's activities and procedures relating to clinical studies of FDA-regulated products complied with applicable FDA regulations.

Our review of the inspection report and exhibits submitted by the district office revealed that there were serious violations of the requirements of Title 21, Code of Federal Regulations (21 CFR), Part 56 - Institutional Review Boards, and Part 50 - Protection of Human Subjects. The violations were listed on the Form FDA 483, "Inspectional Observations," which was presented to and discussed with you and [REDACTED], at the conclusion of the inspection. The inspection revealed that the IRB is currently inactive, has no operational location, and there are no immediate plans to resume operations in the future.

The following description of violations relate to the IRB's operations and its review of clinical research sponsored by [REDACTED] for osteoarthritis knee pain and neurological disorders. This research was conducted between October 1997 and May 1999. It is not intended to be an all-inclusive list of IRB deficiencies.

**1. Failure to ensure adequate initial and continuing review of research [21 CFR 56.108, 56.109, and 56.111]**

Numerous deficiencies were noted with respect to initial and continuing review for both the osteoarthritis and the neurological disorders studies. For example, there was no approval letter specific to [REDACTED] osteoarthritis study. The protocol and any revisions for this study could not be located. No written progress reports were requested and reviewed by the IRB.

There was no documentation that the IRB reviewed specific range-finding protocols/treatment plans for various neurological disorders studies. Risk determinations (significant or non-significant) for these neurological disorders studies were not documented.

**2. Failure to ensure compliance with informed consent requirements [21 CFR 56.109 and 50.25]**

Informed consent documents for studies approved by the IRB did not contain all required information. For example, the consent for the range-finding neurological disorders studies consisted of a standard liability disclaimer form. The consent for the osteoarthritis study was not specific to that study in that it referenced the treatment of chronic pain. There was no documentation that the IRB approved the informed consent form used in the osteoarthritis study.

**3. Failure to have and follow adequate written procedures as required by 21 CFR 56.108(a) and (b)**

The IRB was unaware of FDA requirements relating to IRBs, and there were no standard operating procedures relating to IRB functions and operations.

**4. Failure to prepare and maintain adequate documentation of IRB activities in accordance with 21 CFR 56.115(a)**

No IRB meeting minutes were available. Documentation relating to the studies approved by the IRB was lacking, and there were no records of continuing review.

**5. Failure to meet IRB membership requirements [21 CFR 56.107]**

The composition of the IRB was inadequate. There were no members independent of the AMERICA Charitable Fund/National Medical and Research Institute (ACF/NMRI) operation. Members involved in research projects subject to IRB review were not always excluded from the review and approval of such projects. A quorum may not have been present during review of the studies referenced above.

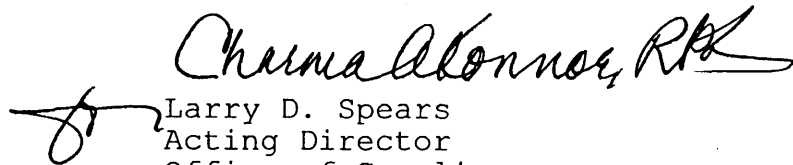
We acknowledge receipt of your letters dated October 3 and October 13 to Ms. Crowl in which you indicated that 1) the IRB had been disbanded and 2) all future research would be carried out under the auspices of a hospital, university, or other accredited institution with an IRB. Furthermore, you stated that because the IRB was disbanded, there was no need to prepare a standard operating manual for your committee. You also indicated that documents relating to previous IRB meetings and memos could not be located and probably had been thrown away.

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No further response or action is necessary on your part because there are no ongoing studies subject to the IRB's oversight. However, should you decide to reconstitute an IRB at ACF/NMRI in the future, you must notify this office in advance and provide assurance that procedures have been developed, documented, and implemented to bring the IRB into compliance with FDA regulations. This is necessary because your current IRB procedures and practices are not adequately protecting the rights and welfare of human subjects of research.

Please direct all questions concerning this matter to Ms. Crowl at (301) 594-4720.

Sincerely yours,

  
Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
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