Inspections, Compliance, Enforcement, and Criminal Investigations

Napoli LLC (dba Precision Reproduction 1/21/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

WARNING LETTER

VIA UPS EXPRESS

JAN 21 2011

Michael M. Kamrava, M.D.
Chairman, Institutional Review Board
Napoli LLC (dba Precision Reproduction)
c/o LA IVF Lab/ West Coast IVF Clinic
9730 Wilshire Blvd., Suite 211
Beverly Hills, CA 90212-2022

Dear Dr. Kamrava:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection of your Institutional Review Board (IRB) from August 24, 2010 to September 24, 2010 by an investigator from the FDA Los Angeles District Office. The purpose of this inspection was to determine whether your IRB is in compliance with applicable federal regulations. IRBs that review investigations of devices must comply with applicable provisions of Title 21, Code of Federal Regulations (21 CFR) Part 56-Institutional Review Boards. This letter also requests prompt corrective action to address the violations cited.

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval (PMA) applications, and Premarket Notification submissions (510(k)) 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.

Our review of the inspection report prepared by the district office revealed severalviolations of 21 CFR Part 56-Institutional Review Boards, and Section 520(g) (21 USC 360j(g)) of the Federal Food, Drug, and Cosmetic Act (the Act). At the close of the inspection, the FDA investigator presented an inspectional observations Form FDA 483 for your review and discussed the observations listed on the form with you. The deviations noted on the Form FDA 483 and our subsequent review of the inspection report are discussed below:

Failure to ensure that the IRB is composed of at least five members; at least one IRB member's primary concerns are in nonscientific areas; and no IRB member participates in the initial or continuing review of any projects in which the member has a conflict of interest. [21 CFR 56.107(a), (c), and (e)]

An IRB must be composed of at least 5 members. There must be at least one IRB member whose primary

concerns are in nonscientific areas. No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. You failed to adhere to the above stated regulations, in that your sworn, signed affidavit states you conducted a clinical study that was approved by the "local IRB at West Coast IVF Clinic," whose membership consisted of yourself and an embryologist.

In your response to this letter, please describe how you plan to ensure the IRB will have at least 5 members, including one whose primary concerns are in nonscientific areas, and how you will exclude from participation in annual or continuing review any member who has a conflicting interest. Please also provide the implementation dates, any relevant written procedures you plan to adopt, and dates you plan to train staff on these procedures.

Failure to have adequate written procedures governing the functions and operations of the IRB. [21 CFR 56.108(a), (b), and (c)]

An IRB must prepare, maintain, and follow written procedures that describe the IRB's functions and operations. Examples of these failures include, but are not limited to, the following:

The IRB has no written procedures for the following:

- A procedure for ensuring that the IRB reviews proposed research at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas.
- A procedure for reporting all IRB findings and actions to the investigator and the institution.
- A procedure for determining which studies require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review.
- A procedure for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects.
- A procedure for ensuring prompt reporting to the Food and Drug Administration of any unanticipated problems involving risks to human subjects or others, and any instance of serious or continuing noncompliance with regulations or the requirements or determinations of the IRB.
- A procedure for ensuring prompt reporting to the IRB, appropriate institutional officials, and the FDA of any instance of serious or continuing noncompliance with the regulations or the requirements or determination of the IRB.
- A procedure for ensuring prompt reporting to the IRB, appropriate institutional officials, and the FDA of any suspension or termination of IRB approval.

In your response to this letter, please describe how you plan to establish and implement the written procedures listed above. Please provide these written procedures and their implementation dates, and dates you plan to train staff on these procedures.

The violations described above are not intended to be an all inclusive list of problems that may exist at the IRB. The IRB is responsible for ensuring compliance with the Act and applicable regulations.

Within fifteen (15) working days of receiving this letter, please provide written documentation of the additional actions you have taken or will take to correct these violations and prevent the recurrence of similar violations. Failure to respond to this letter and take appropriate corrective action could result in the FDA taking regulatory action without further notice to you. Send your response to: Attention: Anne Hawthorn, Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, 10903 New Hampshire Avenue, WO66-3500, Silver Spring, Maryland, 20993-0002.

A copy of this letter has been sent to the FDA Los Angeles District Office, 19701 Fairchild, Irvine, CA 92612. Please send a copy of your response to that office.

The Division of Bioresearch Monitoring has developed introductory training modules in FDA regulated device clinical research practices, which are available on the FDA website. The modules are for persons involved in FDA regulated device clinical research activities. These modules are located at the following website address: http://www.fda.gov/Training/CDRHLearn/ucm162015.htm [1]

If you have any questions, please contact Anne Hawthorn at (301)796-6561 or Anne.Hawthorn@fda.hhs.gov.

Sincerely yours,
/S/
Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

Links on this page:

1. http://www.fda.gov/Training/CDRHLearn/ucm162015.htm