



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

gS47d

Center for Biologics Evaluation and  
Research  
1401 Rockville Pike  
Rockville MD 20852-1448

AUG 25 2005

By Certified Mail – Return Receipt Requested  
And by Facsimile Transmission

CBER – 05--027

Warning Letter

Robert S. Hotchkiss, CEO  
Efoora, Inc.  
900 Asbury Drive  
Buffalo Grove, Illinois 60089

Dear Mr. Hotchkiss:

This letter describes the results of Food and Drug Administration (FDA) inspections of two investigator sites, [REDACTED] on your clinical study entitled *Efoora HIV Rapid Test Clinical Trial -- Protocol #01-046*, and of [REDACTED]

[REDACTED] The inspections of the trial sites were conducted from [REDACTED] by FDA investigator Diane Thibodeau and from [REDACTED] by FDA investigator Kim Downing, and the inspection of [REDACTED] was conducted from [REDACTED] by FDA investigators M. Patricia Murphy and Karen McNabb-Noon. FDA conducted these inspections under the agency's Bioresearch Monitoring Program, which includes inspections designed to review the conduct of research involving investigational devices.

At the end of the inspections, a Form FDA 483, Inspectional Observations, was issued and discussed with [REDACTED] President, and [REDACTED] Vice President, of [REDACTED]. Copies of the Form FDA 483 for [REDACTED] are enclosed for your information.

We have determined that you violated regulations governing the proper conduct of clinical studies involving investigational devices, as published in Title 21, Code of Federal Regulations (CFR), Part 812 (available at <http://www.access.gpo.gov/nara/cfr/index.html>). The applicable provisions of the CFR are cited for each violation listed below.

1. You failed to ensure proper monitoring of the investigation.  
[21 CFR § 812.40].

- A. In your investigational plan submitted to the FDA as part of your IDE application, you designated [REDACTED] and according to section [REDACTED] you agreed to do the following: 1) monitor each site regularly throughout the study, 2) perform quality control testing on a daily basis, 3) conduct training at each site, 4) conduct the study in accordance with the study protocol, and 5) assure that all records and required reports were accurate, complete and current. The inspections of [REDACTED] disclosed violations, described below, so numerous and pervasive that they demonstrate that you failed to properly monitor the study.
- 1) The sites enrolled ineligible subjects, [REDACTED] and [REDACTED], and failed to document that all of the subjects enrolled met the inclusion criteria of health status and age, as required by protocol sections [REDACTED]
  - 2) The monitor instructed both of the sites to conduct repeat testing on [REDACTED] in violation of protocol section [REDACTED] and the informed consent form signed by the subjects.
  - 3) The sites failed to run controls at least daily, as required by protocol section [REDACTED]
  - 4) The sites failed to send samples to the central reference laboratory daily as required by protocol section [REDACTED] and for [REDACTED] reviewed during the inspections.
  - 5) The sites failed to have testing personnel complete the "Proficiency Panel Testing" prior to initiation of subject study testing, as required by the investigational plan.
  - 6) The [REDACTED] site also deviated from protocol section [REDACTED] and FDA regulations by failing to [REDACTED]
  - 7) Both [REDACTED] and [REDACTED] failed to maintain accurate and complete records of each subject's case history, including data on the condition of each subject upon entering, and during the course of, the investigation. As described in item A.1) above, the sites failed to document that the [REDACTED] and the [REDACTED] met the enrollment criteria of health status and age.
- B. Monitoring reports were inaccurate. After making Clinical Site Visits to [REDACTED] [REDACTED] reported that upon "review of procedure for collecting samples, processing blood and forwarding samples to the reference laboratory, all testing is done in accordance

with the study protocol.” In fact, as described above in 1.A., this was not the case.

- C. There were inconsistencies between the source documents prepared by the investigators (the Efoora Results Forms, Control Forms, Discordance Forms, and Training forms) and the data submitted to the FDA.
- 2. You failed to use monitors qualified by training and experience.**

**[21 CFR § 812.43(d)].**

One of the [REDACTED] monitors for the sites appears not to have had any experience in compliance with FDA regulations governing clinical trials prior to her employment at [REDACTED]. Her positions prior to this were for a manufacturing company where she worked in areas unrelated to clinical trials. There is no documentation that she had any training in applicable FDA regulations.

- 3. You failed to submit a complete IDE application to FDA, failed to ensure that FDA was promptly informed of significant information about an investigation, and began part of an investigation before FDA approved the supplemental application.** [21 CFR §§ 812.20(b)(4),(7), 812.40, and 812.42].

You advised FDA that this investigation would be conducted at seven sites, by seven principal investigators. However, in your original PMA submission, [REDACTED] submitted [REDACTED], you identify two additional study sites, which were not identified in your IDE filings. Your IDE application was incomplete because you failed to identify the [REDACTED] as institutions participating in the investigation. You never notified the FDA of this significant information and you began this part of the investigation before receiving FDA approval.

- 4. You failed to prepare and submit a current investigator list.**  
**[21 CFR § 812.150(b)(4)].**

You failed to submit a current list of the names and addresses of all investigators participating in the investigation to the FDA. This list is to be provided at 6-month intervals, submitting the first such list 6 months after FDA approval. According to section [REDACTED] of the original IDE submission, dated [REDACTED], you are “presently recruiting study sites.” The studies started [REDACTED] and ended [REDACTED]. Only one submission, dated [REDACTED], provided a list of principal investigators to FDA; that list did not identify all of the investigators who participated in the study before it concluded.

Several of the items listed above are described in the [REDACTED]

[REDACTED]

Page 4 – Efoora, Inc.

This letter is not intended to contain an all-inclusive list of deficiencies in your clinical study of investigational devices, and FDA is continuing to investigate the conduct of this trial. It is your responsibility as the sponsor to ensure adherence to each requirement of the law and applicable regulations and to protect the rights, safety, and welfare of subjects under your care.

You should notify this office, in writing, within fifteen (15) business days of receipt of this letter, of the steps you plan to implement to prevent the recurrence of similar violations in future studies. Your response should include any documentation necessary to show that correction has been achieved.

Please send your written response to:

Janet K. White  
Division of Inspections and Surveillance (HFM-664)  
Office of Compliance and Biologics Quality  
Center for Biologics Evaluation and Research  
1401 Rockville Pike, Suite 200N  
Rockville, Maryland, 20852-1448  
Telephone: (301) 827-6339

We request that you send a copy of your response to the FDA District Office listed below.

Sincerely,



Mary A. Malarkey  
Director  
Office of Compliance and Biologics Quality  
Center for Biologics Evaluation and Research

Enclosures:



cc: Scott MacIntire, Director  
Chicago District Office, HFR-CE600  
Food and Drug Administration  
550 West Jackson Blvd., Suite 1500  
Chicago, IL 60661