



DEPARTMENT OF HEALTH & HUMAN SERVICES

JR

Food and Drug Administration
Rockville MD 20857

JUL 30 2002

Certified Mail
Return Receipt Requested

Eduardo Caro Acevedo, M.D.
Calle Marginal 51 #57
Urbanization Santa Rosa
Bayamon, Puerto Rico 00959

Copy to:
Nelson Rivera-Cabrera
P.O. Box 195277
San Juan, PR 00919-5277

Notice of Disqualification to
Receive Investigational New Drugs

Dear Dr. Caro:

On August 18, 1999, the Food and Drug Administration (FDA) sent to Mr. Nelson Rivera-Cabrera, your attorney, a Notice of Opportunity for a Hearing (NOOH, Attachment 1) to determine whether you would remain entitled to receive investigational new drugs [Title 21 of the Code of Federal Regulations (CFR) Parts 16 and 312.70 (21 CFR 16, 312.70)]. A copy of this NOOH was hand delivered by FDA to your attorney on October 15, 1999 (Attachment 2). Your response to the NOOH was due within 10 business days of its receipt. The only response FDA received was a letter from your attorney dated April 26, 2000, in which he stated your understanding and agreement that FDA would make a decision on your eligibility to receive investigational new drugs, based on the information on file with the agency. FDA considers this to be a refusal of the offer for a hearing and, therefore, no hearing will be held [21 CFR § 16.22 (b)].

On the basis of all information available to FDA, I have determined that you have deliberately or repeatedly submitted false information to sponsors in required reports for studies of investigational new drugs that are subject to section 505 of the Federal Food, Drug, and Cosmetic Act. Furthermore, I have concluded that you have repeatedly or deliberately failed to comply with pertinent regulations governing the conduct of clinical investigators and the use of investigational new drugs. These violations occurred in the following protocols sponsored by Daiichi Pharmaceutical Corporation:

1. Protocol - 8280 A-PRT002, "A Multicenter, Randomized, Evaluator Blind Study to Compare the Safety and Efficacy of Ofloxacin Otic Solution with that of Cortisporin[®] Otic Solution in the Treatment of Acute Otitis Externa in Adults;"

2. Protocol 8280A-PRT003, "A Multicenter, Randomized, Evaluator-Blind Study to Compare the Safety and Efficacy of Ofloxacin Otic Solution with that of Cortisporin[®] Otic Solution in the Treatment of Acute Otitis Externa in Pediatric Patients."

Specifically:

1. You violated 21 CFR § 312.70 by submitting false data to sponsors in required reports.
2. You violated 21 CFR § 312.62(b) and (c) by failing to maintain adequate and accurate records of all observations and other data pertinent to the investigation on each individual administered the investigational new drug or employed as a control in the investigation.
3. You violated 21 CFR § 312.64(b) and § 312.53(c)(1)(vi)(e) by failing to report in Case Report Forms (CRFs) all the adverse events experienced by study subjects.
4. You violated 21 CFR § 312.60 and § 312.53(c)(1)(vi)(a) by failing to conduct clinical studies in accordance with the approved protocols.
5. You violated 21 CFR § 50.20 and § 50.27(a) by involving human beings as subjects in research without obtaining the legally effective informed consent of either the subjects or the subjects' legally authorized representatives, prior to their study participation.
6. You violated 21 CFR §§ 312.60, 312.66, and 312.53(c)(1)(vii) in that you failed to obtain approval for the studies at the Bayamon Municipal Hospital from an IRB that complied with 21 CFR §§ 56.103(a) and 56.107(a). To be in compliance with Part 56, the IRB must be sensitive to community attitudes and the acceptability of the proposed research. In fact, no such approval would have been possible because research was not permitted at Bayamon Municipal Hospital.
7. You violated 21 CFR §§ 312.62(a) and (c) by failing to prepare and maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects.
8. You violated 21 CFR § 312.60, § 312.66, and § 312.53(c)(1)(vii), by failing to report to the IRB all changes in the research activity.

In accordance with 21 CFR Parts 16 and 312.70, you are hereby advised that you are no longer entitled to receive investigational new drugs. All such products in your possession should be promptly returned to their suppliers.

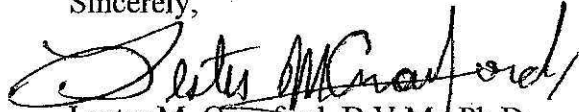
FDA will notify the sponsors of the clinical studies of investigational drugs in which you participated as an investigator that you are no longer entitled to receive investigational products.

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The notifications will include the basis for your disqualification, and the steps that the sponsors should take.

FDA will make this notice available to interested parties under the Freedom of Information Act (FOIA). Your name will also be added to the list of clinical investigators who have been disqualified that is available under FOIA and posted on FDA's Internet website.

Sincerely,



Lester M. Crawford, D.V.M., Ph.D

Deputy Commissioner of Food and Drugs

Attachments

1. Copy of NOOH to Dr. Caro, dated August 18, 1999
2. Memo regarding hand-delivery of NOOH to Nelson Rivera-Cabrera, dated October 15, 1999

cc:

Joanne L. Rhoads, M.D., M.P.H.
Director, Division of Scientific Investigations (HFD-45)
Office of Medical Policy
Center for Drug Evaluation and Research
7520 Standish Place
Rockville, Maryland 20855

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cc:

GCF-1 (Hayes)

HFA-224

HFC-230 (McCormack)

HFD-1: All Review Divisions

HFD-7 (Varki)

HFD-45 (Rhoads)

HFD-47 (RF)

HFD-47/Chron

HFD-47/GCPB File #9343

HFD-47-MTT

HFD-205

HFR-SE550

HFR-SE550/Mason

HFR-NE2560/Dewoskin

HFH-520(FDAOCI)

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