DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR - 7 1998

Certified Mail
Return Receipt Requested

Robert A. Fiddes, M.D.
Southern California Research Institute (SCRI)
12291 E. Washington Blvd., Suite 204
Whittier, California 90606

NOTICE OF OPPORTUNITY FOR HEARING

Dear Dr. Fiddes:

The Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (Agency) has information that you repeatedly and deliberately violated the Code of Federal Regulations (CFR) and submitted false information to sponsors in required reports for the following clinical studies of investigational new drugs for which you were the investigator of record:

1. Protocol [ ] "A Multi-Center, Prospective, Randomized, Single-Blind, Parallel Group Comparison of Clotrimazole 1-Day (One 500 mg Vaginal Insert) and the Clotrimazole 3-Day Regimens (One 200 mg Vaginal Insert Daily for 3 Days) with the Clotrimazole 7-Day Regimen (One 100 mg Vaginal Insert Daily for 7 Days) for the treatment of Vulvovaginal Candidiasis," sponsored by [ ]

2. Protocol [ ] "Open, Noncomparative Multi-Center Study of [ ] (Sparfloxacin) in the Treatment of Acute Bacterial Maxillary Sinusitis," sponsored by [ ]

3. Protocol [ ] "Chronic Asthma and Quality of Life: Comparative Study of Salmeterol Versus Current Treatments," sponsored by Glaxo Inc.

4. Protocol [ ] "An Open-Label, Randomized, Parallel-Group, Comparative, Multicenter, Safety and Efficacy study of Triphasic combination Oral Contraceptives, [ ] and [ ] Versus Ortho-Novum® 7/7/7," sponsored by [ ].

Pursuant to section 312.70 of title 21 of the Code of Federal Regulations (21 CFR 312.70), CDER notified you, by the letter dated September 12, 1997, of the matters complained of and offered you an opportunity to explain the matters in writing or in an informal conference. The letter of September 12, 1997,

(copy enclosed) also offered you the opportunity to enter into a consent agreement that would terminate the administrative proceedings against you. By not responding to the letter of September 12, 1997, you waived your opportunity for an informal conference with, or a written explanation to, the Division of Scientific Investigations in CDER.

Pursuant to 21 CFR 16.22 and 312.70(a), you are hereby notified of your opportunity for a regulatory hearing before the Agency to determine whether you are entitled to receive investigational new drugs. Under the Code of Federal Regulations (21 CFR 16.62) you have the right to be advised and accompanied by counsel at all times. Because of the seriousness of this matter, you are strongly urged to exercise this right. The hearing on this matter will be governed by the regulations on regulatory hearings (21 CFR 16) and on electronic media coverage of public administrative proceedings (21 CFR 10, Subpart C). Copies of the governing regulations are enclosed.

The matters to be considered at the regulatory hearing are set forth in sections I, and II below.

I. Submission of false data to sponsors in required reports [21 CFR 312.70(a)].

a. Protocol [ ] sponsored by [ ]

i. Documents available for fifteen (15) individuals, reported as subjects in this study, indicate that none of these 15 individuals ever participated in this study (i.e., subjects [ ] #332, [ ] #333, [ ] #337, [ ] #338, [ ] #342, [ ] #345, [ ] #346, [ ] #347, [ ] #350, [ ] #352, [ ] #354, [ ] #355, [ ] #356, [ ] #359, and [ ] #360).

ii. The signatures on the consent forms for these fifteen individuals were forgeries.

b. Protocol [ ] sponsored by [ ]

For at least nine subjects, Microbiology Data from sinus puncture aspirates on page 15 of their case report forms, were false (i.e., subjects [ ] #9019, [ ] #9139, [ ] #9140, [ ] #9167, [ ] # 9182, [ ] #9183, [ ] #9203, [ ] #9205, and [ ] #9217). It was reported that the sinus puncture procedure for each of these subjects was performed as required by the study protocol, but in fact these reported procedures were not performed.

c. Protocol [ ] sponsored by Glaxo Inc.

i. False information was submitted in required study reports for a 13-year-old minor [ ] who was identified as a study subject (#002). In fact, this 13-year-old minor never participated in the study.

ii. Both the mother's and the daughter's signatures were forgeries on the consent form for subject #002.

d. Protocol [ ] sponsored by [ ]

i. Data were falsified on the study reports for at least three study subjects (identified by subject initials [ ] and [ ] These individuals were not study subjects.

ii. Extra PAP smears were taken from subjects who met the study's inclusion criteria and improperly substituted for other subjects who did not meet the inclusion criteria, including the three false study subjects identified above.

iii. Individuals, who were not study subjects, were paid to give their blood for analyses in place of false study subjects.

II. Failure to conduct studies in accordance with the approved protocols [21 CFR 312.53(c)(1)(vi)(a), and 312.60].

Your response to this letter must be made within fifteen (15) calendar days after receipt of this letter and directed to Dr. James F. McCormack, Coordinator, Bioresearch Monitoring Program, Office of Enforcement, Division of Compliance Policy (HFC-230), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 827-0425, FAX (301) 827-0482. If no response to this letter is received by that time, you will be deemed to have waived any right to a regulatory hearing, and a decision on these matters will be made based on the facts available to the Agency.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that warrants a hearing. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Commissioner or his delegate determines that no genuine and substantial issue of fact has been raised by the material submitted. A hearing will not be granted on issues of policy or law. Written notice of the determination

that a hearing is not justified will be given to the parties explaining the reason for denial of the hearing.

You may respond to this letter by submitting a written request to Dr. McCormack for a regulatory hearing. If you do not wish to avail yourself of the opportunity for a regulatory hearing, but you intend to provide a written response, you should notify Dr. McCormack within fifteen (15) calendar days of receipt of this letter of your intent. Send your written response, which should include the statements that you waive any right to a hearing and that you want a decision on the matters to be based on your written response and the other information available to the Agency, to Dr. McCormack no later than thirty (30) calendar days after receipt of this letter.

The offer to enter into a consent agreement remains available. I emphasize that no final decision by the Agency has been made at this time on whether you are entitled to receive investigational new drugs. Moreover, there will be no prejudgment of these matters if you decline to enter into a consent agreement and decide instead either to request a regulatory hearing or to request that a decision be based on your written response and the information currently available to the Agency.

Resolution of these administrative proceedings, including an Agreement, relative to the specific matters complained of above would not preclude the United States from bringing corollary judicial proceedings in connection with these matters.

Sincerely yours,

Ronald G. Chesemore
Associate Commissioner for
Regulatory Affairs

Enclosures:
FDA letter dated September 12, 1997
21 C.F.R. Part 10, Subpart C
21 C.F.R. Part 16
21 C.F.R. Part 312.70