



Food and Drug Administration
Rockville MD 20857

WARNING LETTER

JUL 6 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Donald W. Davis
President
Northern Westchester Hospital Center
400 East Main Street
Mount Kisco, New York 10594

Ref: 01-HFD-45-0601

Dear Mr. Davis:

From December 5 to 15, 2000, Thomas P. Hansen and L. Glenn Massimilla, investigators with the New York District Office of the Food and Drug Administration (FDA), conducted an inspection of the Northern Westchester Hospital Center (NWHC) Institutional Review Board (IRB). The purpose of this inspection was to determine whether your procedures for the protection of human subjects complied with Title 21, Code of Federal Regulations (CFR), Parts 50 and 56 [enclosure # 1]. These regulations apply to clinical studies of products regulated by FDA. This inspection was also to confirm that adequate correction of the violations noted during the previous inspection of November 19 and December 3, 1992, had been made.

At the conclusion of the inspection, Mr. Hansen and Mr. Massimilla issued a Form FDA 483 [enclosure # 2] to [] M.D., IRB Chairman, which described the deviations from requirements specified under 21 CFR Part 50 and 56 that they had identified during the inspection. We have reviewed the documents and records relating to the IRB's responsibilities for the protection of research subjects of research contained in Mr. Hansen's and Mr. Massimilla's inspection report and the objectionable conditions and practices listed in the Form FDA 483. Our review shows that your IRB is operating significantly out of compliance with FDA regulations as contained in 21 CFR Parts 50 and 56. Further, we find that the IRB has failed to take adequate steps to correct many of the significant violations noted during the previous inspection of November 19 and December 3, 1992, as described in our April 30, 1993, letter to you [enclosure # 3].

The cited violations discussed below may not be all inclusive of the deficiencies in your IRB operation. You are responsible for assuring compliance with all FDA regulations specified under 21 CFR Parts 50 and 56.

Summary of IRB Functions and Operations Violations [21 CFR 56.108(a)(1)(2)(3)(4), (b)(1)(2)(3)(4) and (c)]:

1. The IRB has failed to prepare written procedures that adequately describe how the IRB's functions and operations are to be accomplished in conformance with applicable FDA regulations (21 CFR Part 50 and 56). [Form FDA 483-item # 1]
2. The IRB has failed to assure that a majority of IRB members were present to review proposed research studies at convened meetings. [Form FDA 483-items # 7 and # 8]

Summary of IRB Continuing Review Violation [21 CFR 56.109(f)]

3. The IRB has failed to conduct continuing reviews of three ongoing research studies prior to the expiration date of the specified approval periods. [Form FDA-items # 11, # 12 and # 13]

Summary of IRB Records/Membership Violations [21 CFR 56.115(a)(2) and (5)]

4. The IRB has failed to adequately document the attendance, the vote on IRB actions, and the abstentions for IRB members who have a conflict of interest in the minutes of IRB meetings. [Form FDA 483-items # 6, # 9 and # 10]
5. The IRB has failed to obtain and document the information described in 21 CFR 56.115(a)(5) for each of the IRB members. [Form FDA 483-items # 3, # 4 and # 5]
6. The IRB has failed to maintain copies of records of IRB membership lists and minutes of IRB meetings. [Form FDA 483-items # 4 and # 8]

Summary of Informed Consent Violations [21 CFR 50.20, 50.25(a)(1)(5) and (7)]

7. The IRB has failed to assure that the basic elements of informed consent are addressed in approved consent forms. [Form FDA 483-item # 2]

Administrative Restrictions

We have no assurance that your procedures are adequately protecting the rights and welfare of human subjects of research. *For this reason, in accordance with 21 CFR 56.120(b)(1) and (2),*

- *no new studies that are subject to Parts 50 and 56 of the FDA regulations are to be approved by your IRB; and*

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- *no new subjects are to be admitted to ongoing studies that are subject to 21 CFR Parts 50 and 56 until you have received notification from this office that adequate corrections have been made.*

We note that these restrictions do not relieve the IRB of its responsibility for receiving and responding to reports of unexpected and serious reactions and routine progress reports from ongoing studies.

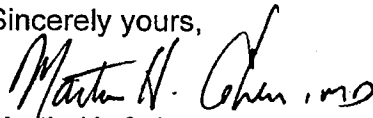
Please inform this office, in writing, within fifteen (15) working days from the date of receipt of this letter, of the actions you have taken or plan to take to bring the procedures of your IRB into compliance with FDA requirements. Please include a copy of any revised documents, such as written procedures, with your response. Any plans of action must include projected completion dates for each action to be accomplished.

We will review your response and determine whether the actions are adequate to permit the IRB to resume unrestricted activities. Your failure to adequately respond to this letter may result in further administrative actions against your IRB, as authorized by 21 CFR 56.120 and 56.121. These actions include, but are not limited to, the termination of all ongoing studies approved by your IRB and the initiation of regulatory proceedings for disqualification of your IRB.

Should you have any questions, please contact Dr. Antoine El-Hage at (301) 594-1032, FAX: (301) 827-5290. Your written response and any pertinent documentation should be addressed to:

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Branch Chief, Good Clinical Practice II, HFD-47
Division of Scientific Investigations
Office of Medical Policy
Center for Drug Evaluation and Research
7520 Standish Place
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Sincerely yours,



Martin H. Cohen, M.D.
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