



DEPARTMENT OF HEALTH & HUMAN SERVICES

March 25, 1999

Food and Drug Administration
Rockville MD 20857

Certified Mail
Return Receipt Requested

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Re: In the matter of Eugen O. Grecu, M.D., Ph.D.

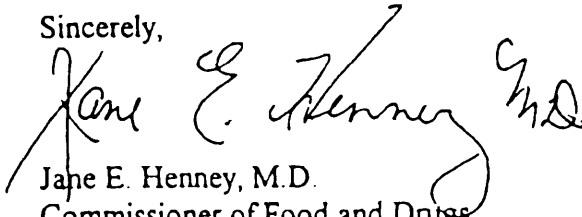
Mr. Gregory F. Gilbert, Esq.
Counsel for Eugen O. Grecu, M.D., Ph.D.
8776 Kildee, Suite 100
Orangevale, CA 95662

Dear Mr. Gilbert:

Please see the enclosed opinion in which I am affirming and adopting the Summary Decision of the Presiding Officer in the above-referenced matter. I have found that Dr. Grecu has repeatedly or deliberately failed to comply with the requirements of 21 CFR Parts 312, 50 or 56, and has repeatedly or deliberately submitted to FDA or to the sponsor false information in required reports.

In accordance with 21 C.F.R. § 312.70(b), you are hereby advised that Dr. Grecu is no longer eligible to receive investigational new drugs. Please direct Dr. Grecu to return all investigational drugs currently in his possession to their supplier. Further, by this letter, I am providing a copy of the Summary Decision to counsel for the Center for Drug Evaluation and Research and to the Dockets Management Branch to be placed on display in the public reading room.

Sincerely,


Jane E. Henney, M.D.
Commissioner of Food and Drugs

cc: Peter Rheinstein, M.D., J.D., HFY-40
Brian J. Mallin, Esq., HFY-20
Barbara Stradling, Esq., GCF-1
Denise Zavagno, Esq., GCF-1
Kara Parker, Esq., GCF-1

00R-0176

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In the Matter of Eugen O. Grecu, M.D., Ph.D

I have reviewed the record of the regulatory hearing regarding whether to disqualify Dr. Grecu from receiving investigational new drugs. I have considered the Summary Decision of the Presiding Officer and all other portions of the administrative record.

Following are my conclusions on the specific charges:

1. On the first charge, I am affirming the decision of the Presiding Officer that Dr. Grecu violated 21 CFR § 312.62(b) by deliberately or repeatedly failing to maintain adequate case histories for both the glipizide and medroxyprogesterone acetate ("MPA") study.
2. On the second charge, I am affirming the decision of the Presiding Officer that Dr. Grecu violated 21 CFR § 312.70(a) by deliberately or repeatedly submitting false information to a sponsor in required reports.
3. On the third charge, I am affirming the decision of the Presiding Officer that the Center has not shown that Dr. Grecu violated 21 CFR § 312.60 by failing to obtain informed consent of subjects.
4. On the fourth charge, I am affirming the decision of the Presiding Officer that Dr. Grecu violated 21 CFR § 312.62(c) by failing to retain the records of the MPA study for two years after the investigation had been discontinued.

I am hereby affirming and adopting the decision of the Presiding Officer in this matter. I find that Dr. Grecu has repeatedly or deliberately failed to comply with the requirements of 21 CFR parts 312, 50, or 56, and has repeatedly or deliberately submitted to FDA or to the sponsor false information in required reports.

In accordance with 21 CFR 312.70(b), I hereby find that Dr. Grecu is no longer eligible to receive investigational drugs.


Jane E. Henney, M.D.

Commissioner of Food and Drugs

Date

March 16, 1999