



Food and Drug Administration
Rockville MD 20857

Notice of Initiation of Disqualification Proceedings and
Opportunity to Explain (NIDPOE)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

JUL - 1 1998

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Alexander Sparkuhl, M.D.
DBA Urology Associates
700 Shadow Lane, Suite 430
Las Vegas, Nevada 89100

Dear Dr. Sparkuhl:

Between March 11 and 13, 1998, Food and Drug Administration (FDA) investigators conducted an inspection of the clinical study of the investigational drug Prostin VR in which you participated. This inspection was conducted as part of the FDA's Bioresearch Monitoring Program, which includes inspections designed to monitor the conduct of research involving investigational products.

Based on our evaluation of information obtained by the Agency, we believe that you have repeatedly or deliberately violated regulations governing the proper conduct of clinical studies involving investigational products as published under Title 21, Code of Federal Regulations (CFR), Part 312 (copy enclosed).

This letter provides you with written notice of the matters under complaint and initiates an administrative proceeding, described below, to determine whether you should be disqualified from receiving investigational products as set forth under 21 CFR 312.

A listing of the violations follows. The applicable provisions of the CFR are cited for each violation.

- a) You failed to follow the protocol in that all subjects were not administered the amount of drug mandated by the protocol [21 CFR 312.60].
- b) You failed to maintain adequate records in that many original records were not available during the FDA inspection [21 CFR 312.62(b)].
- c) You failed to obtain IRB approval of the protocol prior to initiation of the study [21 CFR 312.66].

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- d) You failed to use an informed consent form that was approved by your IRB [21 CFR 50.27(a)].
- e) You failed to maintain adequate drug accountability records [21 CFR 312.62(a)].

This letter is not intended to be an all-inclusive list of deficiencies with your clinical study of an investigational drug. It is your responsibility to ensure adherence to each requirement of the law and relevant regulations.

On the basis of the above listed violations, FDA asserts that you have repeatedly or deliberately failed to comply with the cited regulations and it proposes that you be disqualified as a clinical investigator. You may reply to the above stated issues, including an explanation of why you should remain eligible to receive investigational products and not be disqualified as a clinical investigator, in a written response or at an informal conference in my office. This procedure is provided for by regulation 21 CFR 312.70.

Within fifteen (15) days of receipt of this letter, write or call me at (301)594-0020 to arrange a conference time or to indicate your intent to respond in writing. Your written response must be forwarded within thirty (30) days of receipt of this letter. Your reply should be sent to:

David A. Lepay, M.D., Ph.D.
Director
Division of Scientific
Investigations
Office of Compliance
Center for Drug Evaluation
and Research
7520 Standish Place
Rockville, Maryland 20855

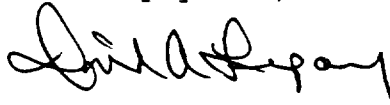
Should you request an informal conference, we ask that you provide us with a full and complete explanation of the above listed violations. You should bring with you all pertinent documents, and you may be accompanied by a representative of your choosing. Although the conference is informal, a transcript of the conference will be prepared. If you choose to proceed in this manner, we plan to hold such a conference within 30 days of your request.

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At any time during this administrative process, you may enter into a consent agreement with FDA regarding your future use of investigational products. Such an agreement would terminate this disqualification proceeding. Enclosed you will find a proposed agreement between you and FDA.

The Center will carefully consider any oral or written response. If your explanation is accepted by the Center, the disqualification process will be terminated. If your written or oral responses to our allegations are unsatisfactory, or we cannot come to terms on a consent agreement, or you do not respond to this notice, you will be offered a regulatory hearing before FDA, pursuant to 21 CFR 16 (enclosed) and 21 CFR 312. Before such a hearing, FDA will provide you notice of the matters to be considered, including a comprehensive statement of the basis for the decision or action taken or proposed, and a general summary of the information that will be presented by FDA in support of the decision or action. A presiding officer free from bias or prejudice and who has not participated in this matter will conduct the hearing. Such a hearing will determine whether or not you will remain entitled to receive investigational products. You should be aware that neither entry into a consent agreement nor pursuit of a hearing precludes the possibility of a corollary judicial proceeding or administrative remedy concerning these violations.

Sincerely yours,



David A. Lepay, M.D., Ph.D.
Director
Division of Scientific
Investigations
Office of Compliance
Center for Drug Evaluation
and Research