DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 21 2003

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William B. Schultz, Esquire
Zuckerman Spaeder LLP
1201 Connecticut Avenue, N.W.
Washington, D.C. 20036-2638

Re: Docket No. 02P-0472

Dear Mr. Schultz,

This letter responds to your citizen petition dated October 24, 2002, on behalf of your client, Dr. Frank Marcus, requesting that the Food and Drug Administration (FDA) immediately post his response to the FDA warning letter on its website for as long as the April 27, 2001 warning letter is posted.

Your petition raises important issues of transparency and access, which we recognize and value. The importance of those issues, however, must be balanced against substantial resource constraints facing the agency and the importance of not misleading the public. Accordingly, after review and consideration of your citizen petition, we have granted your petition in part, if you follow the procedures announced in a pilot program that is described below.

You are correct that we post warning letters on the Internet, because they are, or are likely to be, frequently requested documents under FOIA. Such posting is in compliance with the Electronic Freedom of Information Act Amendments of 1996 (EFOIA). Keeping the public informed and making information available in a manner that is accessible and fair are indeed important goals.

We plan to test a pilot program for six months. Specifically, we intend to give warning letter recipients the option to have their responses posted on our website. For the purposes of this pilot only, FDA considers warning letter recipients to be the addressee and any other individuals or entities specifically named in a warning letter.

We plan to post a recipient's response if the recipient: (1) specifically requests that the response be posted; and (2) submits to us an electronic version of the response in a word processing format on a disk or CD-ROM. (The disk or CD-ROM should be submitted to the FDA office that issued the warning letter and should be submitted with the response.) We will review the responses and redact, if appropriate, certain information to ensure that the responses comply with protections available under FOIA, 5 U.S.C 552, and are in a format that is consistent with 29 U.S.C. 794d.

In addition, we reserve the right not to post responses in some cases, such as when a response would likely mislead the public concerning the safety or efficacy of a company's product. Once we have had a sufficient opportunity to assess our experiences

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in implementing the pilot program, we will decide whether to make the program permanent. If we determine that the pilot is too burdensome or resource-intensive, or find that the posting of responses misleads the public, we reserve the right to discontinue the pilot. In accordance with our decision to post responses to warning letters that are submitted to us electronically in a six-month pilot program, we also intend to place a disclaimer on our website stipulating the following:

NOTE: The Food and Drug Administration cannot assure the accuracy of information submitted to the agency without a complete review of the submitted materials and resolution of the issues discussed therein. To make certain information available to the public, the agency has undertaken a pilot project to post responses to warning letters before evaluating the documents and resolving the issues. The responses are redacted to the extent permitted by the Freedom of Information Act.

We believe the disclaimer allows us to properly inform the public as to the accuracy of the information contained on our website. We reserve the right to change the language in the disclaimer if we consider it appropriate to do so.

On June 23, 2003, we ssued a Federal Register notice announcing the initiation of the pilot program and describing the appropriate format and procedure to submit warning letter responses during the pilot. Enclosed please find a copy of the Federal Register notice. If at the end of the six-month pilot we decide to continue this program, we will determine whether additional guidance is necessary.

Our reasoning for adopting the above approach is as follows.

1. The EFOIA does not require an agency to post on the Internet records that are not created by the agency; thus, we are not required to post responses to warning letters on our website.

2. We have more than 3,000 warning letters currently posted on our website. Moreover, we issue approximately 750 warning letters each year. In many cases, a response to a warning letter comprises a number of submissions and may be quite voluminous. We receive FOIA requests for records associated with a warning letter in only a small number of cases. In the interest of devoting our scarce resources to areas of greatest public health need, we believe that affirmatively posting, without a request, all documents related to warning letters may not be the best use of our resources. To post these records, we would need to devote a great deal of time and resources to assembling relevant records, scanning paper records into the appropriate electronic format, and other tasks associated with this process. In addition, we would have to review all relevant documents before posting to ensure that they do not contain information that is confidential, trade secret, or otherwise exempt from disclosure

under FOIA. Redaction of such exempt information would be necessary prior to posting.

3. In addition, in many cases, warning letters may raise a variety of regulatory issues, not all of which can be resolved at the same time. Trying to address certain issues, but not others, could lead to confusion for the website user and create uncertainty for us in terms of deciding the timing and extent to which it may be appropriate to post particular records.

4. The decision to grant, in part, your request to post materials related to warning letters allows us to provide updated information to the public, without unduly burdening the agency.

In summary, we intend to test, for six months, a program in which recipient responses to warning letters will be posted on our website. After six months, we will evaluate whether to continue the pilot described above and whether additional guidance is necessary.

We will continue to examine ways in which we can use the Internet to enhance our communications with those outside FDA in a manner that is fair to all parties.

Sincerely,

Jeffrey Shuren, M.D., J.D.
Assistant Commissioner for Policy