DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

JUN 19 2003

Gary L. Yingling, Esq.
Kirkpatrick & Lockhart, LLP
1800 Massachusetts Avenue, N.W.
Washington, D.C., 20036

Re: FDA Docket No. 99P-1656/CP

Dear Mr. Yingling:

This letter responds to your citizen petition dated May 26, 1999, regarding the Food and Drug Administration's (FDA's) policies with respect to posting warning letters on our website.

Your petition asked us to draft regulatory procedures that would require us to promptly post, to the extent permitted under the Freedom of Information Act (FOIA), agency records related to any previously posted warning letters. You asked that this policy extend to agency memoranda or letters that relate, refer, or pertain to any resolution of any of the issues in the warning letters and, where applicable, updates to the firm profile. Your petition also requested that we post an advisory on our website that would alert website users that warning letters and notices of violation do not constitute final findings of the agency with respect to the matters discussed therein. Finally, your petition requested that we draft a policy or guidance document regarding the posting of information on our website.

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 and denied your petition in part, as discussed 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. Accordingly, we plan to test a modified version of your proposal as a pilot program for six months. Specifically, we intend to give warning letter recipients[1] the option to

[1] 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.

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have their responses posted on our website. 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 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 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. We intend to publish 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.

Regarding your request for the development of guidance on how to post materials relating to warning letters, we decline to do so. As stated above, we will issue a Federal Register notice that describes the pilot discussed herein. If at the end of the six-month pilot we decide to continue this program, we will determine whether additional guidance is necessary.

Finally, in response to your petition, we have already posted an advisory on our website that states the following:

> **NOTE: Matters described in FDA warning letters may have been subject to subsequent interaction between FDA and the recipient of the letter that may have changed the regulatory status of the issues discussed in the letter. If you wish to obtain available additional information on the current status of an issue in a particular warning letter on this website, please contact the agency or the recipient of the letter directly. Inquiries to FDA should be sent to: Food and Drug Administration Freedom of Information Staff (HFI-35),**

35), 5600 Fishers Lane, Rockville, MD 20857. Instructions for how to submit an FOI request can be found at http://www.fda.gov/opacom/backgrounders/foiahand.html.

Our reasoning for adopting the above approach, and for refusing at this time to post all responses and records documenting subsequent actions, 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 1,000 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 decline, at this time, to post all materials relating to warning letters on our website. We further decline to issue new guidance relating to the disclosure of this information. 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. Finally, we have already posted an advisory on our website regarding the status of warning letters.

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