

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 1999P-1656]

Posting Warning Letter Responses on FDA's Web Site; Notice of Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) plans to implement a 6-month pilot program in which we (FDA) will post on our Internet Web site certain responses to warning letters. The pilot program is part of our ongoing efforts to keep the public informed regarding agency activities and to make information publicly available. During this pilot, we will post copies of certain responses to warning letters if the recipient requests that the response be posted on our Web site and submits the response in an appropriate electronic format. We will review the responses and redact certain information to ensure that the responses comply with protections available under the Freedom of Information Act (FOIA).

DATES: The pilot program will begin on *[insert date 90 days after date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0587.

SUPPLEMENTARY INFORMATION:

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I. Background

FDA traditionally receives many requests under FOIA (5 U.S.C. 552) for warning letters issued to FDA-regulated entities. In compliance with the Electronic Freedom of Information Act Amendments of 1996 (EFOIA), we post on our Web site warning letters that are, or are likely to be, frequently requested documents under FOIA. Updated information regarding a specific issue discussed in a warning letter, however, may not be available on the Web site. In a citizen petition dated May 26, 1999, we were asked to draft regulatory procedures that would require us to promptly post, to the extent permitted under FOIA, agency records related to any previously posted warning letters. The petition requested 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. We declined to post all materials related to warning letters on our Internet Web site, but decided to initiate a 6-month pilot program in which we will post certain responses to warning letters.

II. Pilot Program Description

The pilot program is part of our ongoing efforts to keep the public informed regarding agency activities and to make information available in a manner that is accessible and fair. Accordingly, we plan to test, for 6 months, a pilot program that provides warning letter recipients the opportunity to have their responses to warning letters posted on our Web site. For purposes of this pilot only, we consider warning letter recipients to be the addressee and any other individuals or entities specifically named in a warning letter.

When the pilot program begins, responses submitted to us: (1) With request that the response be posted, and (2) in the format described in the

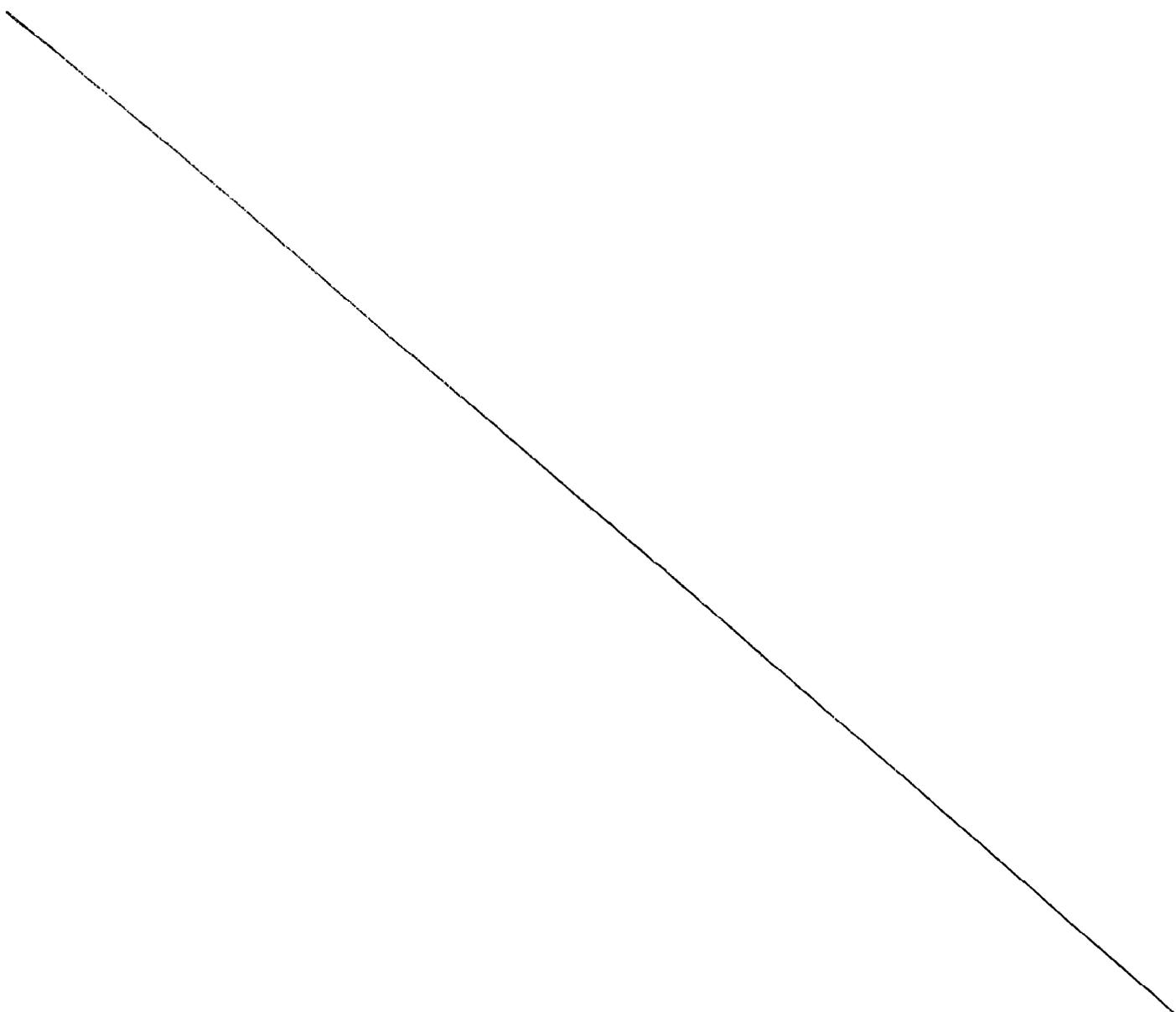
following paragraphs, will be considered for the pilot program. After 180 days, we will evaluate the pilot and determine whether the program should become permanent. However, if we experience undue burden in dealing with the process, find that the process is too resource-intensive, or determine that misleading information is being conveyed to the public as a result of the pilot, we may discontinue the program.

We will post a warning letter recipient's response on our Web site if the recipient: (1) Requests that the response be posted, and (2) submits to us a copy 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 response and redact certain information to ensure that the response complies with protections available under FOIA. For purposes of this pilot program only, we consider a warning letter recipient to be the addressee and any other individual or entity specifically named in a warning letter. If a warning letter recipient wishes to participate in this pilot, the recipient should submit a copy of the response on a computer disk in a word processing format. We will electronically redact and also convert the document to a format that is consistent with 29 U.S.C. 794d. Warning letter recipients submitting a response should clearly identify the warning letter to which they are responding by noting the date of the warning letter and the company(ies) or individual(s) involved.

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(s). During this pilot program, we also intend to place a disclaimer on our Web site stipulating the following:

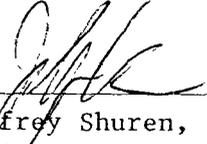
NOTE: The Food and Drug Administration cannot assure the accuracy of information submitted to the agency without a complete review of the submitted materials and resolution of the issues discussed therein. To make certain information available to the public, the agency has undertaken a pilot program 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 about the information contained on our Web site. We reserve the right to change the language in the disclaimer should we consider it appropriate to do so.



Once we have had sufficient opportunity to assess our experience in implementing the pilot program, we will decide whether to make the program permanent.

Dated: 6/16/03
June 16, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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