

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0335]

Review of Post-Inspection Responses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY:

The Food and Drug Administration (FDA) is announcing a program to support public health protection by facilitating the timely issuance of warning letters. The program establishes a timeframe for the submission and agency review of post-inspection responses to inspectional observations that are communicated to a firm through issuance of a form FDA 483, list of inspectional observations.

DATES:

The program will begin on September 15, 2009.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA issues a form FDA 483, Inspectional Observations, upon completion of an inspection, to notify an inspected establishment's top management of objectionable conditions relating to products and/or processes, or other violations of the Federal Food, Drug, and Cosmetic Act and related acts, that were observed during the inspection.

The FDA 483 form includes this preprinted instruction: This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations; and do not represent a final agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address [on the form].

When FDA determines, based on the inspection, that the establishment is in violation of the Federal Food, Drug, and Cosmetic Act or another statute that we enforce, we may issue a warning letter. Warning letters are issued only for significant violations that may lead to enforcement action if they are not promptly and adequately corrected. The decision to issue a

warning letter is made by senior officials within FDA, often including the product center, after a thorough review of all of the relevant facts.

It is not uncommon for an inspected establishment to respond in writing to observations made on an FDA 483 to describe completed or ongoing corrective actions or to promise future corrections. In fact, some inspected establishments submit multiple responses to FDA, sometimes over many months. Delayed and multiple responses to an FDA 483 have resulted in delays in the issuance of warning letters while these responses are reviewed and addressed. FDA's timely issuance of a warning letter should help to achieve prompt voluntary compliance and is therefore in the public interest.

While FDA considers corrective actions, and other factors, in determining whether to issue a warning letter, ongoing or promised corrective actions generally do not preclude the issuance of a warning letter. A warning letter is an important means of notifying regulated industry of violations and achieving prompt voluntary correction. Warning letters serve to ensure that the seriousness and scope of the violations are understood by top management of the inspected establishment, and that the appropriate resources are allocated to fully correct the violations and to prevent their recurrence. FDA is initiating a program to establish a timeframe for the submission of such post-inspection responses to FDA 483 inspectional observations for FDA's consideration in deciding whether to issue a warning letter. Under the program (described in more detail later in this document), the agency will not ordinarily delay the issuance of a warning letter in order to review a response to an FDA 483 that is received more than 15 business days after the FDA 483 was issued.

The purpose of this program is to optimize resource utilization, facilitate the timely issuance of warning letters, and promote prompt correction of violations. FDA will use the information from the program to determine whether to make the program permanent. FDA will conduct an assessment of the program after approximately 18 months.

II. Program Description

Under the program, before issuing a warning letter, FDA will generally allow firms 15 business days to provide a response to FDA 483 observations. If we receive a response to FDA 483 observations within 15 business days after the FDA 483 was issued, we plan to conduct a detailed review of the response before determining whether to issue a warning letter. If we issue a warning letter after reviewing a firm's timely response, the warning letter will recognize receipt of the response and reply as to the apparent adequacy of the firm's corrective actions set forth in the response. Additional correspondence from FDA may be issued with regard to the response, if needed.

If we receive a response to FDA 483 observations more than 15 business days after the FDA 483 was issued, we do not plan to routinely include a response on the apparent adequacy of the firm's corrective actions in the warning letter. Rather, we plan to evaluate the response along with any other written material provided as the direct response to the warning letter (a firm's response to a warning letter may reference any of the firm's earlier responses).

Note that FDA, at its discretion, may issue Warning Letters at any time, independent of receiving a response; and that firms are expected to implement needed corrections to conform to the requirements of the Federal Food, Drug, and Cosmetic Act and associated regulations regardless of whether they respond in writing to FDA or whether such a response is reviewed by FDA.

After the 18-month time period, FDA will evaluate this program and decide whether to continue it with or without adjustments.

Dated: August 4, 2009.
Jeffrey Shuren,
Associate Commissioner for Policy and Planning

[Note: Ombu Enterprises, LLC has reformatted this notice and deleted some non-essential information. You may view the original at www.regulations.gov by entering Docket Number FDA-2009-N-0335.]

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