Guidance for Industry

Timeframe for Submission of Tobacco Health Documents

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

Additional copies are available from:
Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
(Tel) 240-276-1717
http://www.fda.gov/tobaccoguidance

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

December 2009

Table of Contents

Guidance for Industry[1]

Timeframe for Submission of Tobacco Health Documents

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction

This guidance document is intended to assist persons making submissions of certain documents (referred to in this guidance as "tobacco health documents") to FDA under Section 904(a)(4) of the Federal Food, Drug and Cosmetic Act. This document explains:

- The statutory requirement to submit tobacco health documents; and
- The Agency's enforcement policy on the timeframe for submissions of tobacco health documents.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Among its

[1] This guidance has been prepared by the Center for Tobacco Products at the U.S. Food and Drug Administration.

many provisions, the Tobacco Control Act added section 904(a)(4) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 387d(a)(4)), requiring submission of documents related to certain effects of tobacco products.

Section 904(a)(4) of the act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009 "that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives." Information required under section 904(a)(4) of the act must be submitted to FDA beginning December 22, 2009.

III. Discussion

Section 904(a)(4) of the act requires submission of documents beginning on December 22, 2009. FDA recognizes the challenges associated with the collection, review, organization, and production of documents. We also recognize that additional time may be necessary for the production of documents in a digital format, which FDA strongly encourages in order to improve the management and readability of submitted documents. Therefore, FDA does not intend to enforce the December 22, 2009 initial document submission deadline, provided you submit by April 30, 2010 all documents described in section 904(a)(4) developed between June 23, 2009 and March 31, 2010. FDA is in the process of developing a draft guidance document that will explain the requirements of and recommendations for compliance with section 904(a)(4) of the act. We anticipate that the draft guidance document will be issued shortly. .