4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2013-N-0227]

Tobacco Product Manufacturing Practice; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to obtain input on recommendations for regulations on good manufacturing practice for tobacco products that were submitted to FDA by a group of 13 tobacco companies (tobacco companies' recommendations). FDA is establishing this docket to provide an opportunity for all interested parties to comment on the tobacco companies' recommendations and to share information that will improve FDA's understanding of the tobacco industry and its manufacturing operations.

DATES: Submit electronic or written comments on the tobacco companies' recommendations by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Public Law 111-31; 123 Stat. 1776) was signed into law, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing. The new provisions include, among other things, the authority to issue regulations related to tobacco product manufacturing practice in order to protect the public health and to assure that tobacco products are in compliance with the FD&C Act. Specifically, section 906(e) of the FD&C Act (21 U.S.C. 387f(e)) provides that "in applying manufacturing restrictions to tobacco, the Secretary shall * * * prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology."

On January 10, 2012, a group of 13 tobacco companies submitted to FDA: (1) Recommendations for good manufacturing practice regulations, (2) a preamble to the recommended regulations, and (3) a cover letter with a meeting request (Ref. 1). The preamble, as noted in the cover letter, provides the participating tobacco companies' common perspective

and interpretation of the recommended regulations. On May 2, 2012, representatives of the tobacco companies met with FDA to present an overview of their recommendations and their approach to developing them.

FDA is establishing a docket to provide an opportunity for all interested parties to comment on the tobacco companies' recommendations and to share information that will improve FDA's understanding of the tobacco industry and its manufacturing operations.

II. Comments

Interested persons may submit either electronic comments regarding the tobacco companies' recommendations to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at http://www.regulations.gov.

1. Recommendations for Tobacco Product Good Manufacturing Practices Regulation and Request for Meeting, submitted to FDA, January 10, 2012.

Dated: March 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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