Investigational Use of Deemed, Finished Tobacco Products That Were on the U.S. Market on August 8, 2016, During the Deeming Compliance Periods

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Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with Docket No. FDA-2016-D-3276.

For questions on the content of this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m.-4 p.m. EDT.

Additional copies are available online at
http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm
You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, 10903 New Hampshire Ave., Silver Spring, MD 20993.

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

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Table of Contents

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Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

FDA published a final rule entitled *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*[2] (the deeming rule) that became effective on August 8, 2016. Newly deemed tobacco products are now required to obtain premarket authorization before a new tobacco product may be legally marketed. This requirement also applies to tobacco products intended for investigational use because, as yet, FDA has not issued regulations that exempt them from the premarket authorization requirement (as provided in section 910(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387j(g))).

In the preamble to the deeming rule, FDA established a compliance policy providing additional time during which FDA does not intend to enforce the premarket authorization requirements for

[1] This guidance was prepared by the Office of Science and Office of Regulations in the Center for Tobacco Products at FDA.

[2] These regulations published on May 10, 2016 (81 FR 28974).

newly deemed, finished tobacco products that were on the U.S. market on August 8, 2016.[3] FDA has received questions regarding the investigational use of such tobacco products during the compliance period. In this guidance, FDA is clarifying that the compliance policy described in the preamble to the deeming final rule applies to these products even if they are used in a scientific investigation.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the FDA'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 FDA's guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), enacted on June 22, 2009, amends the FD&C Act (21 U.S.C. 387 through 387u) ("FD&C Act") and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health (Pub. L. 111– 31, 123 Stat. 1776).

FDA's deeming rule became effective on August 8, 2016. Newly deemed tobacco products are now subject to provisions of the Tobacco Control Act that apply automatically to all products that meet the statutory definition of a tobacco product in section 201(rr) of the FD&C Act. One of these automatic provisions is the requirement in section 910 of the FD&C Act that manufacturers of new tobacco products obtain premarket authorization from FDA under one of three premarket pathways (substantial equivalence (SE) exemption requests, SE Reports, or premarket tobacco product applications (PMTAs)) before they may legally market their products.

In the preamble to the deeming rule, FDA established a compliance policy providing additional time during which FDA does not intend to enforce the premarket authorization requirements for newly deemed, finished products that were on the U.S. market on August 8, 2016, but that were not on the market on February 15, 2007.[4]

FDA provided two compliance periods for newly deemed, finished products that were on the market on August 8, 2016, but that were not on the market on February 15, 2007: One for submission and FDA receipt of applications and one for obtaining premarket authorization. The compliance periods for submission and FDA receipt of applications for newly deemed tobacco products under the three premarket pathways are as follows:

- SE exemption requests — August 8, 2017 (12 months from the effective date of the deeming rule)
- SE reports — February 8, 2018 (18 months from the effective date of the deeming rule)

[3] FDA has defined "finished tobacco product" as a tobacco product, including all components and parts, sealed in final packaging intended for consumer use.

[4] Tobacco products that were on the market on February 15, 2007, are grandfathered and do not require premarket authorization.

- PMTAs — August 8, 2018 (24 months from the effective date of the deeming rule)

Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been made will be subject to a continued compliance period for 12 months after the initial compliance period described previously. For such products, FDA does not intend to initiate enforcement for failure to have premarket authorization during this continued compliance period, which is as follows:

- SE exemption requests — August 8, 2018 (12 months after the compliance period for submission of the requests)
- SE reports — February 8, 2019 (12 months after the compliance period for submission of the reports)
- PMTAs — August 8, 2019 (12 months after the compliance period for submission of the requests)

III. DISCUSSION

Since publication of the deeming rule, FDA has received inquiries about the investigational use of newly deemed, finished tobacco products that were on the market on August 8, 2016, but that were not on the market on February 15, 2007, during the compliance periods announced in the preamble of the deeming rule. In this guidance document, FDA is clarifying that the compliance periods apply to those products even if they are used in a scientific investigation. That is, the Agency does not intend to take enforcement actions against such products remaining on the market for failure to have a premarket authorization order during the compliance periods described in the preamble to the deeming rule, even if they are being used in a scientific investigation as well as being marketed to consumers.