Draft Guidance for Industry and FDA Staff

Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.
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You should submit comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft guidance, contact the Center for Tobacco Products (CTP) at 1-877-CTP-1373.

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

Preface

Additional Copies

Additional copies are available from the Internet at http://www.fda.gov/TobaccoProducts. You may also send an e-mail request to annette.marthaler@fda.hhs.gov to receive an electronic copy of the guidance.

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 number listed on the title page of this guidance.

I. Introduction

This draft guidance provides information on how a manufacturer (you) may establish that your tobacco product was commercially marketed in the United States as of February 15, 2007. A tobacco product that was commercially marketed in the United States as of February 15, 2007, is not subject to the premarket requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and may serve as the predicate tobacco product in a 905(j) report (demonstrating substantial equivalence) for a new tobacco product (section 905(j)(1)(A)(i) of the FD&C Act, 21 U.S.C. 387e(j)(1)(A)(i); 910(a)(2)(A)(i)(I) of the FD&C Act, 21 U.S.C. 387j(a)(2)(A)(i)(I)). We interpret the phrase "as of February 15, 2007," as meaning that the tobacco product was commercially marketed in the United States *on* February 15, 2007.

Section 201(rr) of the FD&C Act defines a tobacco product as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." (21 U.S.C. 321(rr)). Section 910 of the FD&C Act sets out premarket requirements for new tobacco products (21 U.S.C. 387j). The term "new tobacco product" is defined as "(1) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke

constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007" (section 910(a)(1) of the FD&C Act, 21 U.S.C. 387j(a)(1)).

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. When You May Want to Consider these Recommendations

For the purposes of this guidance document, FDA refers to a tobacco product that was commercially marketed (not in test markets) in the United States as of February 15, 2007, as a "grandfathered" tobacco product. If you believe that your tobacco product should be considered a grandfathered product because the tobacco product was commercially marketed in the United States as of February 15, 2007, and would like an agency determination on the status of your product, you may submit a request for review of your product's status to: CTP, Grandfathered Tobacco Product Team, Office of Compliance and Enforcement at 9200 Corporate Blvd., Rockville, MD 20850. You should include any information that supports your request. This guidance provides examples of documents that may be submitted to demonstrate that a tobacco product was commercially marketed as of February 15, 2007.

III. How You May Establish that Your Tobacco Product was Commercially Marketed in the United States on February 15, 2007

In requesting a review of your product's status, you should provide evidence that demonstrates that the product was commercially marketed in the United States on February 15, 2007 (section 910(a) of the FD&C Act). If your tobacco product had been commercially marketed in the United States before February 15, 2007, but was not commercially marketed on that date, it is not a grandfathered product and may not be commercially marketed unless you comply with the premarket requirements of section 910 of the FD&C Act and obtain a marketing order. In addition, under section 910 of the FD&C Act, a tobacco product that was in only test markets in the United States on February 15, 2007, is a new tobacco product (section 910(a) of the FD&C Act; 21 U.S.C. 387j(a)).

FDA recommends that you provide evidence that the tobacco product was commercially marketed in the United States (not in test markets) on February 15, 2007. This information should demonstrate that the tobacco product was not distributed for test marketing only. Examples of such information may include, but are not limited to, the following:

- dated copies of advertisements;
- dated catalog pages;
- dated promotional material;
- dated trade publications;
- dated manufacturing documents;
- dated bills of lading;
- dated freight bills;
- dated waybills; and/or
- complete copies of any supporting information that demonstrate (individually or collectively) that the tobacco product was commercially marketed in the United States on February 15, 2007.

FDA recommends that you submit as much evidence as possible to demonstrate that your tobacco product was commercially marketed in the United States as of February 15, 2007. FDA will inform you as to whether your product is a grandfathered product once it has reviewed the information you have submitted. If FDA is unable to determine the status of your product, the agency may contact you requesting further information.

You should address any questions relating to this guidance or to the grandfathered status of a tobacco product to the Grandfathered Tobacco Product Team, Office of Compliance and Enforcement at 1-877-CTP-1373.