

# **“Harmful and Potentially Harmful Constituents” in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act (Revised)\***

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## **Guidance for Industry and FDA Staff**

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-2010-D-0281.

For questions regarding 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](mailto: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 20993-2000.

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

**August 2016**

**This is a revision to this guidance, which originally issued in January 2011. Revisions are noted by date at the end of the guidance.**

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# **“Harmful and Potentially Harmful Constituents” in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act**

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## **Guidance for Industry and FDA Staff<sup>1</sup>**

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**

Section 904(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387d(e)), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act)(Public Law 111-31), requires FDA to establish a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand (the HPHC list). This guidance discusses the meaning of “harmful and potentially harmful constituent” in the context of the HPHC list requirement and is a revision of the guidance of the same title, dated January 2011 (76 FR 5387, January 31, 2011).

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 FDA’s guidances means that something is suggested or recommended, but not required.

### **II. BACKGROUND**

On June 22, 2009, the President signed the Tobacco Control Act 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 many provisions, the Tobacco Control Act added section 904(e) to the FD&C Act, requiring FDA to establish, and periodically revise as appropriate, a list of harmful

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<sup>1</sup> This guidance has been prepared by the Office of Science and the Office of Regulations in the Center for Tobacco Products at FDA.

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and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand.

Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA's tobacco product authorities in Chapter IX of the FD&C Act (21 U.S.C. 387 through 387u) when the Tobacco Control Act went into effect. For other kinds of tobacco products, the statute authorizes FDA to issue regulations "deeming" them to be subject to such authorities. These regulations published on May 10, 2016 (81 FR 28974).<sup>2</sup> We therefore are updating this guidance to better reflect the current range of tobacco products subject to our authority.

### **III. DISCUSSION**

For the purpose of establishing "a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand," as required under section 904(e) of the FD&C Act, FDA believes that the phrase "harmful and potentially harmful constituent" includes any chemical or chemical compound in a tobacco product or in tobacco smoke that:

- a) is, or potentially is, inhaled, ingested, or absorbed into the body, including as an aerosol (vapor) or any other emission; and
- b) causes or has the potential to cause direct or indirect harm to users or non-users of tobacco products. Examples of constituents that have the "potential to cause direct harm" to users or non-users of tobacco products include constituents that are toxicants, carcinogens, and addictive chemicals and chemical compounds. Examples of constituents that have the "potential to cause indirect harm" to users or non-users of tobacco products include constituents that may increase the exposure to the harmful effects of a tobacco product constituent by: 1) potentially facilitating initiation of the use of tobacco products; 2) potentially impeding cessation of the use of tobacco products; or 3) potentially increasing the intensity of tobacco product use (e.g., frequency of use, amount consumed, depth of inhalation). Another example of a constituent that has the "potential to cause indirect harm" is a constituent that may enhance the harmful effects of a tobacco product constituent.

### **Document History**

- January 2011 – First edition of guidance was issued.
- August 2016 – The guidance was updated to reflect the issuance of the deeming rule and the current range of tobacco products now subject to our authority. Note

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<sup>2</sup> 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 (the deeming rule).

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that the phrase “including as an aerosol (vapor) or any other emission” was added to the text under paragraph (a) in section III of this document.