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# Guidance for Industry and FDA Staff

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

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*.

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

**January 2011**

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

**January 2011**

*Contains Nonbinding Recommendations*

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

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

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 number listed on the title page of this guidance.

#### **I. INTRODUCTION**

Section 904(e) of the Federal Food, Drug, and Cosmetic Act (FDCA or the 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 document discusses the meaning of “harmful and potentially harmful constituent” in the context of implementing the HPHC list requirement.

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#### **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 FDCA, requiring FDA to establish, and periodically revise, 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.

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

## *Contains Nonbinding Recommendations*

### **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 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:

- a) that is or potentially is inhaled, ingested, or absorbed into the body; and
- b) that 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.