

# Guidance for Industry

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## Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product

### *DRAFT GUIDANCE*

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For questions regarding this draft guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.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/GuidanceComplianceRegulatoryInformation/default.htm>.

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

**July 2014**

## **Guidance for Industry<sup>1</sup>**

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# **Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product**

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

This draft guidance provides information to tobacco product manufacturers about the Center for Tobacco Products' (CTP's) policies on manufacturer requests for extensions of time to respond to deficiencies CTP has identified in substantial equivalence (SE) reports, and manufacturer requests to change the predicate tobacco product in submitted SE reports. During its review of an SE report, CTP may issue a scientific advice/information letter or preliminary finding letter to a manufacturer highlighting deficiencies (deficiency letter) of the SE report. In response to those letters, some manufacturers have requested an extension of time to respond to the deficiencies or have indicated they may change the predicate tobacco product identified in the SE report. This guidance provides information on the Agency's current thinking on such requests for extensions of time and change of predicate in submitted SE reports.

FDA's guidance documents, including this draft 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.

**Requests for extensions.** Under section 905(j)(1)(A) of the Federal Food, Drug, and Cosmetic Act, manufacturers that submit an SE report must provide the basis for their determination that the new tobacco product is substantially equivalent to an eligible predicate tobacco product. CTP has found, however, that many of the SE reports submitted to date have deficiencies and, as a result, do not support a determination of substantial equivalence. Recognizing that premarket review requirements are new to this industry, CTP issues letters providing manufacturers an opportunity to address the deficiencies within a certain time period. In response to these

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

## ***Contains Nonbinding Recommendations***

### ***Draft – Not for Implementation***

deficiency letters, many manufacturers have requested an extension of the time period in which to respond, and frequently, the time period requested is several months or more. CTP granted these extension requests for an initial period of the SE program to assist manufacturers as they developed experience in preparing premarket submissions. During this initial period, CTP communicated with manufacturers about common scientific deficiencies found in SE reports through guidance documents, webinars, meetings, issuance of scientific advice/information requests, and preliminary finding letters. As a result, manufacturers should now have enough information to prepare SE reports and amend pending SE reports to address any deficiencies in their SE reports within the time period specified in the deficiency letter. Granting requests for extensions delays CTP's ability to conclude review of pending SE reports. Therefore, CTP now plans to grant extensions in very limited instances.

- Provisional tobacco products<sup>2</sup>- In most instances, CTP intends to review SE reports for provisional products and make determinations based on information provided by the manufacturer as of the date specified in the deficiency letter. CTP does not intend to grant requests for extensions of time for these products except in very limited instances where the manufacturer's rationale for the request demonstrates that the extension is necessary, likely to result in a complete response to all identified deficiencies, and would not significantly delay CTP's continued review of the SE report.
- Non-provisional tobacco products- CTP does not intend to grant extensions of time for these products. Manufacturers of non-provisional tobacco products may withdraw their pending report if they believe they are unable to respond to the requested information within the time specified in the deficiency letter. When these manufacturers obtain sufficient information to respond to the deficiencies, they may submit a new SE report.

***Requests to change the predicate tobacco product.*** In response to a deficiency letter, some manufacturers have also indicated that they plan to amend their SE report to change the predicate tobacco product identified in the SE report. Because the comparison between the new tobacco product and the identified predicate tobacco product is a fundamental aspect of an SE report, changing the predicate tobacco product changes the basis of the analysis. An applicant may change its predicate if scientific review of the application has not yet started. However, once CTP commences scientific review, an applicant should not change its predicate; the application review will be based on the comparison between the predicate in place at the start of scientific review and the new tobacco product. Therefore, if a manufacturer wishes to change the predicate tobacco product after scientific review has commenced, CTP recommends that the manufacturer withdraw the SE report and submit a new report comparing the new tobacco product to that predicate. For "provisional" products, this means the provisional product may no longer remain on the market pending CTP's review.

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<sup>2</sup> The "provisional" tobacco products addressed by this draft guidance are tobacco products that were first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to March 22, 2011, and for which a 905(j) (substantial equivalence) report was submitted no later than March 22, 2011.