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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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Re: Docket No. FDA-2011-D-0125 (76 Fed. Reg. 22,903 (Apr. 25, 2011)) – Comments on the "Draft Guidance for Industry and FDA Staff: Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007"

Philip Morris USA Inc. ("PM USA") and U.S. Smokeless Tobacco Company LLC ("USSTC") submit these comments on the above-captioned draft guidance document ("Draft Guidance").[1]

I. The Draft Guidance Incorrectly States that Products Only in Test Markets as of February 15, 2007 are not "Grandfathered" and are Subject to Premarket Review.

Without explanation, the Draft Guidance states that products that were only in test markets as of February 15, 2007 are not "grandfathered," but instead are "new tobacco products" subject to premarket review.[2] To the contrary, a product in test market as of February 15, 2007 (if not subsequently modified within the meaning of § 910(a)(1)(B)) is "grandfathered" and not subject to premarket review.

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[1] Philip Morris USA Inc. ("PM USA") and U.S. Smokeless Tobacco Company LLC ("USSTC") are wholly-owned subsidiaries of Altria Group, Inc. Altria Client Services ("ALCS") is making this submission on behalf of PM USA and USSTC. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" is used throughout to refer to PM USA and USSTC.

[2] *See, e.g.*, Draft Guidance at § II ("For the purposes of this guidance document, FDA refers to a tobacco product that was commercially marketed (not in test markets) in the United States as of February 15, 2007, as a 'grandfathered' tobacco product."); Draft Guidance at § III ("In addition, under section 910 of the FD&C Act, a tobacco product that was in only test markets in the United States on February 15, 2007, is a new tobacco product (section 910(a) of the FD&C Act; 21 U.S.C. 387j(a))"); Draft Guidance at § III ("FDA recommends that you provide evidence that the tobacco product was commercially marketed in the United States (not in test markets) on February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.")

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As noted in the Draft Guidance, the term "new tobacco product" is defined in section 910(a)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) as follows:

> (A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or
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> (B) 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.

The Draft Guidance, however, misinterprets the plain meaning of the parenthetical "(including those products in test markets)" in § 910(a)(1)(A). The parenthetical clearly modifies the words before it and explains that "any tobacco product" includes tobacco products only offered in test markets. The parenthetical cannot reasonably be construed to limit the meaning of "commercially marketed." As a general rule of construction, a parenthetical is assumed to explain or modify the word or words that immediately precede it unless the overall context of the statutory provision indicates otherwise.[3] Here, the parenthetical clearly relates to and explains the words that precede it, i.e., "any tobacco product (including those products in test markets)" (emphasis added). This indicates that, as is conventional, the parenthetical is used to modify the words immediately preceding it.[4]

Further confirming Congress's clear intent is a comparison to the language it used to identify an eligible predicate product. An eligible predicate product is

> substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007 . . . .[5]

It is clear that test marketing is considered "commercial marketing," but that test marketing is excluded from the type of commercial marketing that defines an eligible predicate product for substantial equivalence. If Congress intended to exclude test marketed products from "grandfathered" products not subject to premarket review, it would have taken a similar approach in § 910(a)(1)(A).[6] As the statute is actually drafted, however, it is clear that there are different standards for (1) a "grandfathered" product that is exempt from premarket review; and (2) a product that is an eligible

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[3] *See, e.g.,* United States v. Monjaras-Castaneda, 190 F.3d 326, 329 (5th Cir. 1999) ("If the parenthetical referred to 'offense,' it would have been placed directly after that word.").

[4] *Id.* ("Legislators can be presumed to rely on conventional language usage.") (citing Norman J. Singer, 2A Sutherland Statutory Construction § 45.13 at 78 (5th ed. 1992)).

[5] 21 U.S.C. § 387j(a)(2)(A)(i)(I).

[6] Congress could have defined "new tobacco product," for example, to include "any tobacco product that was not commercially marketed (other than for test marketing) in the United States as of February 15, 2007."

predicate product for substantial equivalence. Whereas the former includes products that were only in test markets as of February 15, 2007, the latter does not. Thus, a product in test market as of February 15, 2007 (if not subsequently modified within the meaning of § 910(a)(1)(B)) is indeed "grandfathered" and not subject to premarket review. The Final Guidance should be corrected to reflect Congressional intent.

II. "As of February 15, 2007" Means On or Before that Date.

As noted in previous comments,[7] a plain reading of the phrase "as of February 15, 2007" means on or before the date February 15, 2007. This applies to each of the separate but related questions of (1) whether a tobacco product is a "new tobacco product," and (2) whether a tobacco product is eligible to serve as a predicate for a substantial equivalence evaluation. There is no statutory requirement that a manufacturer provide evidence that a product was marketed (over four years ago) *on* Thursday, February 15, 2007. Such a requirement would not be reasonable or practical, especially given that the Act did not become law until more than 28 months later. If Congress had intended the "new tobacco product" and predicate eligibility provisions to depend on whether a product was marketed *on* February 15, 2007, it would have said so in plain language by using the word "on."[8]

The words "as of" are "used to indicate a time or date at which something begins or ends."[9] Thus, February 15, 2007 is the "end" of the period of eligible predicates and grandfathering as "non-new" tobacco products. The following day is the "beginning" of when tobacco products may be "new" tobacco products and when they are no longer eligible to serve as predicates.[10] Finally, the contrast to the language "after February 15, 2007" (*see* §§ 910(a)(1)(B) and (a)(2)(B)(i)) clearly indicates that "as of" was intended to mean "on or before." The Final Guidance should recognize that a tobacco product marketed on or before February 15, 2007 is "grandfathered," whether or not the manufacturer possesses evidence of marketing efforts on that specific date.

III. The Guidance Should be Limited to Addressing the Question of what is a "New Tobacco Product" under § 910(a)(1)(A), and Should not Address Predicate Eligibility.

The intended scope of the Draft Guidance is not clear. The Federal Register Notice announcing availability of the Draft Guidance states that it "provides recommendations on the information that a manufacturer may use to establish that a tobacco product was commercially marketed in the United States on February 15, 2007, and is, therefore, a grandfathered product not subject to premarket review requirements." The Notice does not mention substantial equivalence or predicate

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[7] *See* Altria Client Services, Inc., Comments dated February 8, 2011, Docket ID No. FDA-2010-D-0635-0008.1.

[8] *See, e.g.,* FDCA § 904(c)(1) (21 U.S.C. § 387d(c)(1)), referencing "a tobacco product not on the market on the date of enactment" as a type of tobacco product requiring pre-market notification of ingredients.

[9] *See* Merriam-Webster Online Dictionary at http://www.merriam-webster.com/dictionary/as%20of.

[10] Except in the case of products previously found to be substantially equivalent; *see* 21 U.S.C. § 387e(j)(1)(A)(i).

eligibility. Nevertheless, the first paragraph of the Draft Guidance mentions predicate eligibility in conjunction with substantial equivalence. Moreover, the title of the Draft Guidance is worded broadly enough to suggest that the Draft Guidance may also apply to determination of predicate eligibility. As discussed above, however, the questions of (1) whether a tobacco product is "grandfathered," i.e. not a "new tobacco product" requiring premarket review; and (2) whether a tobacco product is eligible to serve as a predicate are distinct legal questions with separate analyses.

The Final Guidance should not reference predicate eligibility because (1) the Federal Register Notice did not place the regulated industry on notice that the Draft Guidance, once finalized, may represent FDA's views on predicate eligibility; (2) FDA already has a separate docket and guidance document on substantial equivalence; and (3) non-newness ("grandfathering") and predicate eligibility are distinct legal questions.

IV. The Agency Should Take a Reasonable Approach with Respect to the Evidence Requested to Support a Grandfather Determination.

The Draft Guidance lists nine examples of the types of information that may demonstrate that a tobacco product was marketed as of February 15, 2007. The Draft Guidance also states that "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." Taken literally, this could potentially result in a large volume of documents establishing the marketing pedigree of a tobacco product with unnecessary redundancy. The Final Guidance should clarify that only a reasonable amount of evidence is needed to support a grandfather determination.

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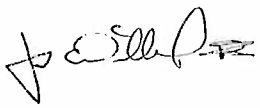
We appreciate the opportunity to submit these comments and urge the Agency to incorporate them in its Final Guidance. We look forward to further opportunities to provide comments to the Agency as its thinking on grandfathered tobacco products evolves.

Sincerely,



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