James E. Swauger, Ph.D., DABT
VP - Regulatory Oversight
401 N. Main Street
P.O.Box 2959
Winston-Salem, NC 27102

336-741-6646
Fax: 336-728-8028
swaugej@rjrt.com

August 14, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-N-0920 — *Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products* 78 Fed. Reg. 32,581 (May 31, 2013)

On May 31, 2013, the United States Food and Drug Administration ("FDA" or "the agency") published a proposed rule, *Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products*, 78 Fed. Reg. 32,581 (May 31, 2013). The agency invited interested parties to submit comments on or before August 14, 2013. RAI Services Company ("RAIS")[1] hereby respectfully submits its comments to the proposed rule.

The comments are divided into three discrete parts. The first part provides an executive summary of RAIS's analysis of the proposed rule. The second part describes the statutory scheme governing the assessment of user fees, FDA's proposed rule, and other relevant information. The final part sets forth RAIS's analysis of the proposed rule, highlighting the legal deficiencies and practical problems with FDA's proposed rule. These problems render FDA's proposed rule substantively invalid, contrary to law, and inconsistent with the requirements of

[1] RAIS is a wholly-owned subsidiary of Reynolds American Inc. ("RAI") that bears primary responsibility for coordinating implementation of the Family Smoking Prevention and Tobacco Control Act for RAI's FDA-regulated tobacco operating companies, namely R.J. Reynolds Tobacco Company, American Snuff Company, LLC, and Santa Fe Natural Tobacco Company, Inc.

reasoned decision-making. Accordingly, FDA should withdraw its proposed rule, work to develop a new one that corrects the legal deficiencies and practical problems, and then publish the new rule for public comment.

I. EXECUTIVE SUMMARY

FDA's Proposed Rule Fails to Assess User Fees On "Each" Manufacturer or Importer of Tobacco Products as the Tobacco Control Act Requires

- The Family Smoking Prevention and Tobacco Control Act provides that "the Secretary *shall* in accordance with this section assess user fees on, and collect such fees from, *each* manufacturer and importer of tobacco products subject to this subchapter." 21 U.S.C. § 387s(a) (emphasis added). FDA's proposed rule is substantively invalid because, contrary to the statutory requirements, it unlawfully excludes from user-fee responsibility any tobacco products (except cigars and pipe tobacco) that become "subject to this subchapter" by means of a deeming regulation.

- Under the plain language of this provision, FDA has no discretion to exempt tobacco products from user fees if they are later deemed subject to the Act by regulation. *See* 21 U.S.C. § 387a(b). Other provisions of the Act confirm this interpretation, by clearly contemplating that products "deemed" subject to regulation will be assessed user fees. *See* 21 U.S.C. § 387s(b)(2)(B)(iii) and (iv).

- Thus, whether a tobacco product is subject to the federal excise tax does not affect FDA's obligation to assess user fees on and collect user fees from each manufacturer and importer of tobacco products subject to the Act. *See* 21 U.S.C. § 387s(a).

FDA Must Devise A Rational, Common Metric To Assess User Fees On All Regulated Tobacco Products Including Those Not Subject to Federal Excise Taxes

- Because FDA is required to impose user fees on "deemed" products that may be properly considered "new" classes of tobacco products (*i.e.*, those classes not specifically enumerated in Section 919(b)(2)(B)(i) and subject to the federal excise tax), FDA must formulate a common metric (*i.e.*, a measure that explains how many cigarettes are equal to how much smokeless tobacco or the like) by which to compare new tobacco products to existing classes of tobacco.

- The applicable percentage share of user fees to be paid by different classes of tobacco products is based on the relative volume of different types or classes of products placed in the market. But that cannot be calculated without a common metric.

- Because the Act does not supply that common metric, FDA must fill in the statutory gap. In doing so, FDA must give maximum possible effect to all provisions of the Tobacco Control Act. *See, e.g.*, *Citizens to Save Spencer Cnty. v. EPA*, 600 F.2d 844, 870-71 (D.C. Cir. 1979). Once the agency formulates a proposed common metric, it should publish and receive public comment on its proposal.

- When developing a common metric, FDA should take account of the following considerations. For existing classes of tobacco products, FDA is required to use the same determination of applicable percentage share required by the Fair and Equitable Tobacco Reform Act of 2004 ("FETRA") — a statute currently administered by the Department of Agriculture ("USDA") that will sunset in 2014. Like the Tobacco Control Act, FETRA is silent on what common metric should be used to compare classes of tobacco products. Because FETRA applies only to six enumerated classes of tobacco products, each of which is subject to federal excise taxes, USDA has exercised its discretion to use the federal excise tax rates for 2003 to convert the volume of different classes of tobacco products into the common unit of tax dollars owed.

- FDA could choose to use USDA's methodology for the existing six classes of tobacco products enumerated in both the Tobacco Control Act and FETRA. If FDA deems a new product subject to regulation that is not subject to excise taxes, it must determine a common metric for that product in a way that is reasonable, exercising the same gap-filling power that led USDA to select the excise tax rates.

    - For products substantially similar to existing classes, the most reasonable course may be to borrow the tax rate applicable to the closest analogous class (*e.g.*, a tobacco-derived smokeless product could be assigned the same excise tax rate as smokeless tobacco as both are non-combustible tobacco products).

    - For products not readily comparable to an existing class, FDA could devise some other reasonable metric designed to fairly and objectively measure the product's volume and compare it to existing products. For instance, volume might be measured by the amount of nicotine per product (such as an e-cigarette cartridge) or perhaps by the total percentage of nicotine by mass.

- In the alternative, because FETRA is silent on what common metric should be used, FDA could choose to reject USDA's methodology and establish a different common metric for all tobacco product classes. For example, FDA could devise a common metric based on traditional selling sizes and/or weights of packages (*e.g.*, 20 cigarettes = 1 e-cigarette cartridge = 1 standard container of moist snuff = 4 large cigars).

- While FDA may have other options in selecting a common metric for calculating the applicable percentages of user fees, it may not elect an option that excludes any tobacco products that are subject to the Tobacco Control Act by virtue of a "deeming" regulation.

The Proposed Rule Does Not Comply With The Requirements Of Reasoned Decision-Making

- FDA's proposed rule does not serve the purpose of the user-fee provision. User fees require regulated parties to provide the funding for FDA's new oversight of the tobacco industry. The proposed rule, however, threatens to impose that burden on only some regulated parties, representing an ever-shrinking percentage of the industry as alternative tobacco products grow in market share.

- The proposed rule also fails to include a workable and reasonable mechanism for resolving disputes about user-fee liabilities. For example, it does not provide a route for challenging FDA's initial action in response to a complaint about an erroneous user-fee assessment or enable affected parties to submit all information relevant to the proper assessment of user fees.

II. BACKGROUND

The Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), Pub. L. No. 111-31, 123 Stat. 1777 (2009), amended the Food, Drug and Cosmetic Act ("FDCA") to permit FDA to regulate the manufacture, distribution, and marketing of tobacco products. A tobacco product is "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. § 201(rr)(1).

Not all tobacco products are subject to FDA's regulatory authority. The Tobacco Control Act applies automatically only to certain enumerated products: cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products. In addition, the Act authorizes FDA to bring other tobacco products under its purview by issuing a regulation "deem[ing]" them subject to the Act. 21 U.S.C. § 387a(b) ("This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco *and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter*." (emphasis added)). Indeed, FDA has expressed its intention to "deem" other tobacco products, such as e-cigarettes, subject to the Act.

A. User Fees Under The Tobacco Control Act

To fund FDA's new activities and responsibilities, Congress directed the agency to collect "user fees" from the regulated portion of the industry. Section 919 of the Act provides that FDA "shall" assess and collect user fees from "each manufacturer and importer of tobacco products subject to this subchapter." *Id.* § 387s(a). The statute sets a fixed total amount to be assessed and collected from the industry for each fiscal year (*e.g.*, for fiscal year 2014, $534 million). *Id.* § 387s(b)(1). That total amount is then apportioned among classes of tobacco products using each class's "applicable percentage" of the total tobacco market. *Id.* § 387s(b)(2)(A). Each class's share, in turn, is allocated to manufacturers and importers of that class of products in accordance with their "percentage share" of the market. *Id.* § 387s(b)(3)–(4). "No manufacturer or importer of tobacco products shall be required to pay a user fee in excess of" its percentage share. *Id.* § 387s(b)(3)(B).

A labyrinthine statutory scheme governs the calculation of the "applicable percentage" for classes of tobacco products. The Act enumerates six specific classes of tobacco products and directs the manner in which their applicable percentages must be calculated. Section 919(b)(2)(B) provides in relevant part:

> (i) In general. . . . the applicable percentage for a fiscal year for each of the following classes of tobacco products shall be determined in accordance with clause (ii):
>
> (I) Cigarettes.
> (II) Cigars, including small cigars and cigars other than small cigars.
> (III) Snuff.
> (IV) Chewing tobacco.
> (V) Pipe tobacco.
> (VI) Roll-your-own tobacco.
>
> (ii) Allocations. The applicable percentage of each class of tobacco product described in clause (i) for a fiscal year shall be the percentage determined under [7 U.S.C. § 518d(c)] for each such class of product for such fiscal year.

Id. § 387s(b)(2)(B)(i)-(2). (Only four of the listed classes are currently subject to user fees. A separate statutory provision forbids assessing user fees on tobacco products not subject to regulation. *See* 21 U.S.C. § 387s(a)(2)(B)(iii). Pipe tobacco and cigars are neither listed as subject to regulation in § 387a(b), nor have they been deemed subject to the Act.)

B. The Fair and Equitable Tobacco Reform Act of 2004

The applicable percentage for assessing user fees on the classes of tobacco products enumerated in Section 919 is determined by reference to a provision of the Fair and Equitable Tobacco Reform Act of 2004, Pub. L. 108-357 ("FETRA"). *See* 21 U.S.C. § 387s(b)(2)(B)(ii). FETRA is administered by USDA, not FDA. FETRA imposes quarterly assessments on tobacco manufacturers and importers during fiscal years 2005 through 2014, in order to provide funds for certain annual transitional payments to eligible tobacco quota holders and producers. Those quarterly assessments are apportioned among the same six classes of tobacco products set forth in Section 919.

To facilitate the necessary market share calculations under FETRA, each manufacturer and importer of tobacco products is required to submit to USDA copies of certain tax and customs forms, filed with the Treasury Department and the Department of Homeland Security, that relate to "(A) the removal of tobacco products into domestic commerce ... and (B) the payment of taxes imposed under chapter 52 of the Internal Revenue Code of 1986." 7 U.S.C. § 518d(h); 7 C.F.R. § 1463.7(b); *see also Prime Time Int'l Co. v. Vilsack*, 599 F.3d 678, 681 (D.C. Cir. 2010) (describing statutory process).

FETRA's text, however, does not provide all the information necessary to calculate the applicable percentage for each class. It supplies baseline percentages for fiscal year 2005, the first year FETRA was in force, as follows:

> (1) Initial allocation
> The percentage of the total amount required by subsection (b) to be assessed against, and paid by, the manufacturers and importers of each class of tobacco product in fiscal year 2005 shall be as follows:
>
> (A) For cigarette manufacturers and importers, 96.331 percent.
> (B) For cigar manufacturers and importers, 2.783 percent.
> (C) For snuff manufacturers and importers, 0.539 percent.
> (D) For roll-your-own tobacco manufacturers and importers, 0.171 percent.
> (E) For chewing tobacco manufacturers and importers, 0.111 percent.
> (F) For pipe tobacco manufacturers and importers, 0.066 percent.

7 U.S.C. § 518d(c)(1).

For subsequent fiscal years, FETRA directs USDA to "adjust the percentage of the total amount required under subsection (b) to be assessed against, and paid by, the manufacturers and importers of each class of tobacco product specified in paragraph (1) to reflect *changes* in the share of *gross domestic volume* held by that class of tobacco product." 7 U.S.C. § 518d(c)(2) (emphasis added). "Gross domestic volume" is a defined term in FETRA, meaning:

> the volume of tobacco products —
> (A) removed (as defined by section 5702 of title 26); and
> (B) not exempt from tax under chapter 52 of title 26 at the time of their removal under that chapter or the Harmonized Tariff Schedule of the United States.

7 U.S.C. § 518d(a)(2). The term "removed" is generally "interpreted to mean the placement of the product into the stream of commerce." *Philip Morris USA Inc. v. Vilsack*, 896 F. Supp. 2d 512, 517 n.7 (E.D. Va. 2012), *appeal filed* No. 12-2498 (4th Cir.); *see also* 26 U.S.C. § 5702(j) ("removed" means removed "from the factory or from internal revenue bond . . . [or] customs custody, and shall also include the smuggling or other unlawful importation . . . into the United States."). As a result, "gross domestic volume" refers to the total volume of non-tax-exempt tobacco products placed into the stream of commerce.

The problem for USDA has been that it is impossible to compare changes in the gross domestic volume of different types of tobacco products without a common metric. For instance, how many cigarettes equal one pound of snuff? FETRA does not say, leaving USDA the task of devising a common metric on its own.

Because all the classes of tobacco products subject to FETRA were also subject to the federal excise tax, 26 U.S.C. § 5701, USDA's approach has been to use the excise tax rates to supply that common metric. USDA multiplies the volume of each class of tobacco products by the 2003 excise tax rates, thereby converting incommensurable goods (*e.g.*, sticks of cigarettes and cans of snuff) into the common metric of dollars (*i.e.*, taxes that would be owed under the 2003 rates). USDA then calculates each class's proportionate share of the total amount owed and assigns that share as the applicable percentage. Thus, "although FETRA did not provide an explicit formula or a method for arriving at the initial Step A percentages, USDA ... determined (from 2003 excise tax rates and excise volume tax data) that an algorithm could be used to arrive at those exact percentages." USDA, "Determination of the Administrator of the Farm Service Agency and Executive Vice President of the Commodity Credit Corporation Regarding Current 'Step A' and 'Step B' Assessment Methods in the Tobacco Transition Payment Program." Nov. 16, 2011, page 5, *available at* http://www.fsa.usda.gov/Internet/FSA_File/tobacco_determ_11162011.pdf; *see also* 78 Fed. Reg. at 32,582.

Beginning in fiscal year 2015, as FETRA's mandate sunsets, USDA will stop calculating the applicable percentages for the classes of products enumerated in Section 919. Congress foresaw this and directed that "[b]eginning not later than fiscal year 2015, and for each subsequent fiscal year, the Secretary shall ensure that the Food and Drug Administration is able to determine the applicable percentages described in [§ 387s(b)(2)(B)(2) and (4)]," *i.e.*, the provisions of the Tobacco Control Act that incorporate FETRA calculations. *Id* § 387s(b)(2)(B)(7).

C. FDA's Proposed Rule For Calculating User Fees

On May 31, 2013, FDA issued its proposed rule, which purports to satisfy this requirement by "ensur[ing] that FDA continues to have the information [it] needs to calculate, assess, and collect user fees" pursuant to the Tobacco Control Act. *Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products*, 78 Fed. Reg. 32,581 (May 31, 2013). Beginning in October 2014, FDA's proposed rule requires each domestic manufacturer and importer of tobacco products subject to the Tobacco Control Act to submit the following information to FDA each month: (1) identification information; (2) removal information (the units of product, by

class, removed and not tax exempt[2] for the prior month and the Federal excise tax it paid, by class, for such removal); and (3) certified copies of the returns and forms. 78 Fed. Reg. at 32,593.

The proposed rule explains how FDA plans to calculate each manufacturer's user-fee liability. Like USDA before it, FDA will first calculate the "yearly class allocation" of each product class (except cigars) by multiplying the units of non-tax-exempt product "removed" (*i.e.*, placed into commerce) for the most recent full calendar year by the maximum federal excise tax rate for that class, using the 2003 excise tax rate. *Id.* Each class's yearly allocation will be calculated by dividing the total amount of excise tax thus derived by the particular class's total excise tax liability; that percentage, in turn, will be multiplied by the total user fee assessment prescribed by statute for that fiscal year. *Id.* at 32,593–94. "For any class of tobacco products that is not deemed by FDA to be subject to [the Tobacco Control Act], the amount of user fees that would otherwise be assessed to such class of tobacco products will be reallocated to the classes of tobacco products that are subject to [the Tobacco Control Act] in the same manner and based on the same relative percentages otherwise determined" for that class of tobacco products. *Id.* at 32,594.

FDA will calculate each domestic manufacturer's or importer's individual assessment, which is based on its "percentage share" of the relevant class, on a quarterly basis. "For each class of tobacco products except cigars, FDA will calculate the percentage share for each domestic manufacturer and importer by dividing the Federal excise taxes that it paid for the class for the prior quarter by the total excise taxes that all domestic manufacturers and importers paid for the class for that same quarter." *Id.* If the resulting percentage share is less than 0.0001 percent, the share will be excluded from the assessment for that class of tobacco products. *Id.* "Within each class of tobacco products, the assessment owed by a domestic manufacturer or importer for the quarter is the yearly class allocation . . . divided by four and then multiplied by the domestic manufacturer's or importer's percentage share, truncated to the fourth decimal place, for that class of tobacco products." *Id.*

This proposed calculation is the same as that used by USDA for all classes of tobacco products subject to user fees except for cigars — because Section 919(b)(5) of

---

[2] Under the cross-referenced Tax Code, only limited categories of tobacco products are tax exempt, including (a) "tobacco products furnished for employee use or experimental purposes"; (b) "tobacco products and cigarette papers and tubes transferred or removed in bond from domestic factories and export warehouses"; and (c) "tobacco products and cigarette papers and tubes released in bond from customs custody"; and (d) "tobacco products and cigarette papers and tubes exported and returned." 7 U.S.C. § 518d(a)(2)(B).

the Tobacco Control Act specifies the calculation that should be used for cigars. *Id.* at 32,586; 21 U.S.C. § 387s(b)(5). FDA will make any necessary adjustments to account for any corrections to the manufacturer and importer assessment (*e.g.*, to include a manufacturer or importer that was not included in a relevant assessment calculation) on an annual basis. 78 Fed. Reg. at 32,594.

The proposed rule also includes a proposed dispute mechanism. It would allow a manufacturer or importer to dispute any assessment in writing within 45 days of the date on the assessment notification. *Id.* If FDA determines that an error assessment was too high, FDA will refund the amount erroneously assessed to the manufacturer or importer. *Id.* If FDA determines that there was no error in the assessment, the proposed rule states that "FDA will provide a dated, written response, and its response will provide information about how to submit a request for further Agency review." *Id.*

Significantly, the proposed rule does not apply to "each manufacturer and importer of tobacco products subject to this subchapter," as the statute requires. 21 U.S.C. § 387s(a). Instead, it proposes to apportion the total amount of user fees established for a given fiscal year among only those classes of tobacco products enumerated in Section 919(b)(2)(B)(i): cigarettes, snuff, chewing tobacco, pipe tobacco, cigars, and roll-your-own tobacco. 78 Fed. Reg. at 32,593. The proposed rule reasons that, because only those six classes of tobacco products are (i) defined as "tobacco products" under the Internal Revenue Code; (ii) "removed" within the meaning described above; and (iii) subject to excise tax, FDA will assess a user fee only on those six classes of products. Under the proposed rule, FDA will not assess a user fee on any tobacco product that is not specified in Section 919(b)(2)(B)(i), including any product "deemed" by regulation to be subject to the Tobacco Control Act, such as e-cigarettes. *Id.* at 32,586.

FDA invited comments on these class allocations. *Id.* In particular, FDA asked affected parties to comment on "what additional classes" of tobacco products should be subject to user fees and "how user fee calculations would be made if additional classes were to be added, particularly if added classes were not subject to Federal excise taxes." *Id.*

D. FDA's Intent To "Deem" Products Subject To The Tobacco Control Act

FDA's request for comment is timely because FDA has indicated that it soon intends to issue regulations deeming certain products subject to the Tobacco Control Act. It is therefore important that, before its deeming regulations are published, FDA develop an appropriate user fee regulation that applies to each manufacturer and importer of tobacco products subject to the Act, including those products deemed subject to the Act by regulation.

While cigarettes continue to dominate the tobacco product market, alternative tobacco products may obtain a significant market share in the future. For example, sales of e-cigarettes are predicted to easily exceed one percent of the cigarette market in 2013, and will probably also exceed one percent of the total U.S. tobacco market (assuming cigarettes constitute approximately 90 percent of that market). *See* Yitzchak Jacobovitz (Capstone), Tobacco Policy & Regulation Menthol, E-Cigarettes, ACA Driven-Smoking Cessation (June 7, 2013). One analyst estimates that e-cigarettes will replace about 1.5 billion cigarettes in 2013, up from around 600 million in 2012. *See* Sam Ro, E-Cigarettes Are A Small, But Rapidly Growing Problem For Big Tobacco (Apr. 27, 2013) (citing Morgan Stanley's David Alderman), *available at* http://www.businessinsider.com.au/chart-e-cigarette-growth-2013-4. In addition, differences in tax treatment are already producing shifts in the tobacco product market. Large federal excise-tax disparities among tobacco products are causing significant market shifts from higher to lower-taxed products. *See* GAO, Tobacco Taxes[:] Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes (GAO-12-475) (Apr. 2012); *see also* CDC, Consumption of Cigarettes and Combustible Tobacco — United States, 2000—2011 (Aug. 3, 2012) (stating that sales of other forms of tobacco that are taxed at significantly lower rates than cigarettes have increased in recent years).

As noted above, however, not all tobacco products are automatically subject to the Tobacco Control Act. Instead, the Act's Section 903(b) grants FDA authority to bring other tobacco products under its purview by issuing a regulation "deem[ing]" them subject to the Act. 21 U.S.C. § 387a(b). In *Sottera, Inc. v. Food & Drug Administration*, the U.S. Court of Appeals for the D.C. Circuit held that FDA could not regulate e-cigarettes as medical devices because e-cigarettes are "tobacco products" as defined by the FDCA. 627 F.3d 891 (2010). Since that decision, FDA has stated its intent to extend its authority to regulate this emerging class of products and to issue a regulation "deeming" e-cigarettes as tobacco products subject to the Tobacco Control Act.[3] On July 23, 2013, FDA published its

[3] *See, e.g.*, Letter from Lawrence R. Deyton, M.S.P.H., M.D. and Janet Woodcock, M.D. to Tobacco Industry Stakeholder (Apr. 25, 2011), *available at* http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm; *see also* FDA Center for Tobacco Product Update (January

Semiannual Regulatory Agenda, which included a proposal to "deem" other tobacco products subject to the Tobacco Control Act. *See* 78 Fed. Reg. 44,252, 44,257 (July 23, 2013). The agenda states that FDA intends to publish a Notice of Proposed Rulemaking on that subject in October 2013.

III. ANALYSIS

A. The Proposed Rule is Substantively Invalid Because It Fails to Assess User Fees From "Each" Manufacturer or Importer of Tobacco Products as the Tobacco Control Act Requires.

The proposed rule violates the plain language of the Tobacco Control Act, which provides that the Secretary "shall" impose user fees on "each" manufacturer and importer of tobacco products subject to the Tobacco Control Act. 21 U.S.C. § 387s(a). FDA should withdraw its proposed rule and promulgate a regulation that, consistent with that statutory requirement, assesses user fees on all tobacco products subject to the Act, including those products later "deemed" subject to the Act by FDA. Doing so will require FDA to fashion a reasonable common metric by which to compare new tobacco products to existing classes of tobacco. Once FDA has devised a reasonable common metric, it should re-issue notice of a proposed rule and seek further public comment.

1. FDA Must Assess User Fees on All Tobacco Products Subject to the Tobacco Control Act.

The interpretation of any statute "starts with its text," *Milner v. Department of the Navy*, 131 S. Ct. 1259, 1264 (2011), and where the text is unambiguous, "judicial inquiry is complete," *Rubin v. United States*, 449 U.S. 424, 530 (1981). An agency has no discretion to deviate from plain statutory text. *See generally Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984); *see also EME Homer City Generation, LP v. EPA*, 696 F.3d 7, 23 (D.C. Cir. 2012) (an agency "may not exceed a statute's authorization or violate a statute's limits"). Although an agency enjoys discretion to "choose a reasonable interpretation" of ambiguous statutory language, its "interpretation must still stay within the boundaries of the statutory text." *EME Homer*, 696 F.3d at 23.

Here, Section 919 of the Tobacco Control Act mandates that "the Secretary *shall* in accordance with this section assess user fees on, and collect such fees from, *each* manufacturer and importer of tobacco products subject to this subchapter." 21 U.S.C. § 387s(a) (emphasis added). That congressional command admits of no

---

16 – April 30, 2011), available at http:// www.fda.gov/downloads/TobaccoProducts/NewsEvents/UCM254031.pdf; FDA News & Events, "Electronic Cigarettes (e-cigarettes)," *available at* http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm.

exceptions: If a tobacco product is subject to the Act, its manufacturers and importers "shall" be assessed a user fee.

FDA's proposed rule nonetheless purports to exclude from user-fee assessments those tobacco products (except pipe tobacco and cigars) that are subject to the Act by virtue of a deeming regulation. The Act contains no warrant for such an exclusion. Section 919(a) does not distinguish between products subject to the Act because of deeming regulations and those listed in the original enactment. Rather, FDA must assess user fees on "each" tobacco product that is "subject to this subchapter." 21 U.S.C. § 387s(a). And there is no doubt that a "deemed" product is one "subject to this subchapter." That is the very phrase Congress used to describe the effect of a deeming regulation. *Id.* § 387a(b) ("This subchapter shall apply to . . . any other tobacco products that the Secretary by regulation *deems to be subject to this subchapter*." (emphasis added)). Thus, under Section 919(a)'s plain language, once FDA brings a new tobacco product under its regulatory purview through use of a deeming regulation, it must assess user fees on each manufacturer of that product.

Other provisions of the statute confirm this interpretation. Section 919(b)(2)(B)(iii), for example, states that "[n]otwithstanding clause (ii), no user fees shall be assessed on a class of tobacco products *unless* such class of tobacco products is listed in [§ 387a(b)] *or is deemed by the Secretary in a regulation under [§ 387a(b)] to be subject to this chapter*." *Id.* § 387s(b)(2)(B)(iii) (emphasis added). The italicized language would be impermissibly superfluous if deemed products were excluded from the reach of Section 919(a). *Cf. TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001).

Section 919(b)(2)(B)(iv) reinforces the point. That paragraph governs the reallocation of user fees attributable to tobacco products not yet subject to the Tobacco Control Act. It provides:

> In case of a class of tobacco products that is *not* listed in [§ 387a(b)] or deemed by the Secretary in a regulation under [§ 387a(b)] to be subject to this chapter, the amount of user fees *that would otherwise be assessed* to such class of tobacco products shall be reallocated to the classes of tobacco products that are subject to this chapter. . . .

21 U.S.C. § 387s(b)(2)(B)(iv) (emphasis added). The italicized language makes clear that if a tobacco product has *not* been made subject to the Tobacco Control Act, FDA must calculate the fees "that would otherwise be assessed" to that class of products — *i.e.*, the fees that would be assessed if the product *were* subject to the Act.

The statute as a whole thus demonstrates that Congress contemplated a comprehensive calculation of industry-wide user fees. *See Dolan v. USPS*, 546 U.S.

481, 486 (2006) (courts must "read[] the *whole* statutory text, considering the purpose and context of the statute"). The user fees attributable to all tobacco products — whether or not they have been deemed subject to regulation — must first be calculated. Then, the user fees that would be owed by products not subject to the chapter will be reallocated among those that are. The comprehensive nature of that scheme leaves no room for FDA to permit a product to be (i) deemed subject to the Tobacco Control Act, but yet (ii) not subject to user fees. Not only is that contrary to the text of the statute, but it would create a hole in the legislative scheme. Because the user fees attributable to such a product could not be reallocated (paragraph (iv) permits reallocation only of those products that are "not" subject to the Tobacco Control Act), the fees due on the product would simply vanish.

The legislative history of the Tobacco Control Act supports its plain text. The House Report on Section 919 explains that the Act "limits the imposition of user fees to cigarettes, smokeless, and roll-your-own tobacco *until the Secretary exercises jurisdiction over other tobacco products.*" H.R. Rep. No. 110-762 at 85-86 (2008) (emphasis added). As that language suggests, once the Secretary chooses to exercise jurisdiction over other tobacco products, the initial limitation of user fees to the products enumerated in Section 919(b)(2)(B)(i) will come to an end.

In any case, Congress could not have intended to permit FDA to selectively exclude certain product classes from user fees, since the result would be grossly unfair to existing classes, arbitrary, and unreasonable. The market shares of "alternative" tobacco products, especially e-cigarettes, are growing. If FDA "deems" e-cigarettes subject to the Act by fiscal year 2015 but excludes them from user-fee assessments, that will have a material impact on existing manufacturers and importers. For example, for fiscal year 2014, the user fees assessed among the classes of tobacco products enumerated in Section 919 will be $534 million. 21 U.S.C. § 387s(b)(1)(F). If e-cigarettes represent only 1% of the U.S. tobacco product market in 2014 (a conservative number in light of 2013 estimates), the proportionate share of user fees justly owed by e-cigarette producers would be around $5,340,000; instead, under the proposed rule, that amount must be paid for those producers by their competitors. As the market share of alternative tobacco products grows further, the size of the anti-competitive burden borne by traditional tobacco manufacturers will grow alongside it, even as their aggregate market share diminishes.

Accordingly, for all these reasons, FDA's proposed rule does not comply with the statutory requirement that the Secretary "shall" impose user fees on "each" manufacturer of tobacco products subject to the Tobacco Control Act, including tobacco products deemed subject to the statute. FDA should therefore withdraw its proposed rule. And it should publish a new proposed rule that, consistent with the statutory requirements, makes clear that all tobacco products subject to the Tobacco Control Act are subject to user fee assessments.

2. FDA Must Devise A Rational, Common Metric To Assess User Fees On All Regulated Tobacco Products Including Those Not Subject to Federal Excise Taxes.

The proposed rule solicits comment on "how user fee calculations would be made if additional classes were to be added, particularly if added classes were not subject to Federal excise taxes." 78 Fed. Reg. at 32,586. FDA has a range of plausible options at its disposal, but whether a tobacco product is subject to the federal excise tax does not affect FDA's obligation to assess and collect a user fee. Because the proposed rule fails to set out a proposed approach for assessing fees on tobacco products, however, there is no basis for informed public comment. Accordingly, FDA should develop a proposed approach for assessing user fees and seek public comment to ensure that the approach it selects is workable, reasonable, and consistent with all applicable legal requirements.

In developing an appropriate rule for further public comment, FDA should take account of the following considerations. As explained, above, Section 919(b)(2)(B)(ii) provides that "[t]he applicable percentage of each class of tobacco product described in clause (i) [*i.e.*, the six enumerated classes] for a fiscal year shall be the percentage determined under [FETRA] for each such class of product for such fiscal year." 21 U.S.C. § 387s(b)(2)(B)(ii); *cf.* 7 U.S.C. § 518d(c) (FETRA provision). Because FETRA will sunset in 2014, however, USDA (which administers FETRA) will no longer make the "determin[ation]" incorporated by reference into the Tobacco Control Act. For that reason, beginning with fiscal year 2015, FDA must make that determination itself. 21 U.S.C. § 387s(b)(7).

FETRA's applicable provision, 7 U.S.C. § 518d(c), requires the agency to "adjust" the applicable percentage of tobacco-product classes "to reflect changes in the share of gross domestic volume held by that class of tobacco product." *Id.* § 518d(c)(2). Performing that function requires establishing a common metric by which to measure different kinds of tobacco products; yet FETRA nowhere says what that common metric should be. The "gap left . . . by Congress" in the statute required USDA to "formulat[e] policy" to fill the lacuna and enable it to administer the congressional scheme. *Chevron USA Inc. v. Nat. Res. Defense Council*, 467 U.S. 837, 843 (1984); *see also American Petroleum Institute v. EPA*, 706 F.3d 474, 480 (D.C. Cir. 2013) (agency has discretion to "flesh out the interstices of a technical regime" provided it does not "arrogate to itself purposes outside the statutory provision it is applying").

When it administered FETRA, USDA chose to use the 2003 federal excise tax rates to supply that metric — a choice that was upheld as reasonable but not required by the statutory text. *See Philip Morris USA Inc. v. Vilsack*, 896 F. Supp. 2d 512, 518-24 (E.D. Va. 2012); *cf. also Prime Time Int'l Co. v. Vilsack*, 599 F.3d 678, 681-84 (D.C. Cir. 2010). The excise tax rates presented USDA with a solution to the gap in FETRA (*i.e.*, the missing common metric) because (i) unlike under the

Tobacco Control Act, the classes of tobacco products subject to FETRA were closed and could not be expanded, and (ii) all of those classes were subject to excise taxes. Because those tax rates converted all FETRA-covered tobacco products into a common unit (dollars of tax liability), those rates embed a congressional judgment about the very question confronting USDA: How many cigarettes equal how many pounds of snuff? As a matter of USDA's discretion to engage gap-filling, it was rational to select a common metric that was accepted by Congress in the excise tax rates and appeared to explain the initial percentages established by FETRA for fiscal year 2005. *See* 7 U.S.C. § 518d(c)(1).[4]

Now that FETRA is about to sunset, however, USDA will no longer perform those calculations, meaning FDA must determine the applicable percentages of user fees itself. *See* 21 U.S.C. § 387s(b)(7)(B). That leads to a statutory puzzle. Section 919(a)'s unambiguous text requires FDA to assess and collect user fees from *all* manufacturers and importers of tobacco products deemed subject to regulation, even if those products are not one of the classes enumerated specifically in Section 919(b)(2)(B)(i) and previously part of the USDA's FETRA calculation. Nevertheless, FDA must calculate the applicable percentages of those new classes of tobacco products by reference to FETRA — *i.e.*, to reflect their changing shares of "gross domestic volume," *see* 7 U.S.C. § 518d(c)(2) — even though FETRA itself did not contemplate the possibility of new product classes.

FDA has an obligation to resolve this tension in such a way that gives maximum possible effect to all provisions of the Tobacco Control Act. As the D.C. Circuit has explained, "when statutory provisions are in certain respects inconsistent, . . . it is the task of an agency with the requisite authority to pursue a middle course that vitiates neither provision but implements to the fullest extent possible the directives of each." *Citizens to Save Spencer Cnty. v. EPA*, 600 F.2d 844, 870-71 (1979) (internal footnote omitted). That duty to harmonize the statute reflects the rule that "maximum possible effect should be afforded to all statutory provisions, and, wherever possible, none of those provisions rendered null or void." *Id.* The D.C. Circuit has specifically emphasized the need to "interpret FETRA's provisions consistently and in harmony, with none made superfluous or insignificant." *Vilsack*, 599 F.3d at 683.

The proposed rule fails to satisfy that duty. To comply with the statute, FDA must devise a rational common metric by which to compare new classes of tobacco products with existing classes, such that changes in their volume can be measured in the same units and their applicable percentage shares from year to year adjusted

---

[4] *See also* USDA, "Determination of the Administrator of the Farm Service Agency and Executive Vice President of the Commodity Credit Corporation Regarding Current 'Step A' and 'Step B' Assessment Methods in the Tobacco Transition Payment Program." Nov. 16, 2011. Page 5. Available at http://www.fsa.usda.gov/Internet/FSA_File/tobacco_determ_11162011.pdf.

accordingly. The fact that those new classes may not be subject to excise taxes does not relieve FDA of that obligation. The Tobacco Control Act does not require that a tobacco product be subject to excise taxes before it can be made subject to regulation or user fees. Indeed, Congress knew, when it enacted the Tobacco Control Act, that (i) FETRA would sunset in 2014, and (ii) FDA would one day have to assess user fees on tobacco products not subject to FETRA.

Nor is it impossible to devise a common metric without existing excise tax rates. FETRA did not explicitly require USDA to use the common metric embedded in the excise tax; that metric was simply the best available explanation for the initial percentages for 2005, and provided a reasonable way for USDA to measure changes in gross domestic volume in future years. Because that tax-based metric was not required by the statute, however, USDA had an obligation to fill the statutory gap through a range of reasonable options. *See Vilsack,* 896 F. Supp. 2d at 518-24. FDA's authority to fashion a harmonizing solution — within, of course, the constraints of reasoned decision-making imposed by the Administrative Procedure Act, *see* 5 U.S.C. § 706 — is equally clear.

RAIS believes FDA could permissibly abandon USDA's tax-based methodology and devise a new, reasonable common metric for all new and existing classes of tobacco products. For example, FDA could base its calculations on total sales (in units) of each tobacco product, using traditional selling-sizes or weights of packages (*e.g.,* 20 cigarettes = 1 e-cigarette cartridge = 1 standard container of moist snuff = 4 large cigars) to derive the conversion factor necessary for market share calculations. Of course, the devil is in the details, and FDA would need to ensure that the common metric is reasonable. Nonetheless, RAIS believes that this type of approach could be implemented in a manner consistent with the statute and the requirements of reasoned decision-making.

RAIS also believes that, with certain modifications, FDA could decide to continue USDA's method of calculating applicable percentages for the original six product classes using the common metric supplied by excise tax rates. Because the Tobacco Control Act, unlike FETRA, is perpetual and will not sunset, and because Congress may decide to update the excise tax rates to account for changing market conditions, FDA should ensure that its regulations assessing user fees rely on the most up-to-date federal excise tax rates. With that type of modification, however, continuing USDA's method for calculating applicable percentages would be reasonable. It would also be broadly consistent with, but not required by, Section 919(b)(5)'s instruction that, if cigars are ever deemed subject to the Tobacco Control Act, the *market* share of particular manufacturers (*i.e.*, their allocated portion of the applicable percentage owed by the entire class of cigars) will be "based on the excise taxes paid by such manufacturer or importer during the prior fiscal year." 21 U.S.C. § 387s(b)(5).

In addition, there are at least two methods of calculating the applicable percentage share owed by new, untaxed classes of tobacco products that FDA should consider. *First*, if a new product class is substantially similar to one of the existing categories, FDA could calculate that class's percentage share *as if* it were subject to the same excise tax rate as the existing category. For example, the same excise tax rate for smokeless tobacco products (*e.g.*, snuff) could be used as the excise tax rate for certain tobacco-derived oral products (*e.g.*, Nu-Mark's Verve). *Second*, if there is no existing category sufficiently similar to the new product, FDA could devise some other reasonable metric designed to measure the product's volume and compare it to existing products. For instance, volume might be measured by the amount of nicotine contained in the product (such as an e-cigarette cartridge).

In either case, FDA should then proportionally reduce the applicable percentage shares assigned to the product classes named in FETRA — a move that would not violate the statute's text, for it would be an "adjust[ment] . . . to reflect changes in the share of gross domestic volume held by [the original] class[es] of tobacco product[s]." 7 U.S.C. § 518d(c)(2). The Tobacco Control Act does not say that the applicable percentages of the original six classes must add up to 100%; its structure makes that reading impossible.

B. FDA's Proposed Rule Is Arbitrary And Capricious And Does Not Comply With The Requirements Of Reasoned Decision-Making.

Under the Administrative Procedure Act, the Commission's rules and orders should be set aside if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency violates those requirements if it fails to articulate a "rational connection between the facts found and the choice made," *Florida Gas Transmission Co. v. FERC*, 604 F.3d 636, 639 (D.C. Cir. 2010), or fails "to consider an important aspect of the problem," *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, an agency's implementation of a statutory scheme is invalid if it is not appropriately tied to the statute's purpose. *See Judulang v. Holder*, 132 S. Ct. 476, 485 (2012).

FDA should withdraw its proposed rule because it does not comply with the basic requirements of reasoned decision-making. Among other things, the proposed rule unreasonably discriminates among competitors and includes an unworkable dispute mechanism.

1. The Proposed Rule Fails to Serve the Purpose of User Fees And Imposes Undue Discrimination Among Competitors.

User fees are "available only for the purpose for paying the costs of the activities of [FDA] related to the regulation of tobacco products under the Tobacco Control Act." 21 U.S.C. § 387s(c)(1). As the tobacco-product market changes and adapts to scientific innovation, new types of tobacco products will be introduced into the marketplace. Subject to the restraints of competition and the uncertainty of markets, these new product categories may eventually come to comprise a substantial percentage of the tobacco-product market — that is, a substantial percentage of the market FDA is now in the business of regulating. The basic notion of "user fees" is that regulated parties will provide funding for FDA's oversight. But the proposed rule threatens to ensure that only *some* regulated parties, representing an inevitably shrinking percentage of the industry, must pay for FDA's ever-increasing oversight of other products, whose manufacturers pay nothing.

That policy is arbitrary and capricious. It inflicts a massive financial burden on certain segments of an industry even though, as contemplated by the agency, FDA has determined that a different segment ought to be subject to the same regulatory oversight and has acted by regulation to bring that new segment under its purview. That undue discrimination is unreasonable and, at a minimum, warrants an explanation. Moreover, it inevitably and impermissibly saddles traditional tobacco-product manufacturers with a competitive disadvantage by requiring them to pay a tax from which their competitors are exempted. The effect of that disadvantage, predictably, will be to further reduce their market share and further exacerbate the irrationality of requiring them to pay for the costs of FDA's oversight of other businesses.

FDA's approach to tobacco user fees is also contrary to its user-fee policies in other areas. With very limited exceptions, nearly all pharmaceutical and device companies with a marketed product, or a product under review by FDA, are required to pay user fees under the Prescription Drug User Fee Act or the Medical Device User Fee and Modernization Act. In general, each such company pays an identical amount. The rationale of these policies is that, because user fees fund the general activities of the regulator, all members of the regulated industry should contribute.

2. The Proposed Rule's Dispute Mechanism is Inadequate and Unworkable.

The proposed rule is also arbitrary, capricious, and contrary to law because it includes a mechanism for resolving disputes that is inadequate, unreasonable, and unworkable. The proposed rule simply states that a manufacturer or importer

should notify FDA of any dispute in writing within 45 days of a user-fee assessment. That is insufficient.

A rational dispute mechanism must provide a process by which manufacturers and importers can *challenge* a user-fee assessment. Such challenges should be heard if there is a reasonable basis to conclude that the manufacturer or importer was assessed a user fee in excess of its percentage market share, for example if competitors have been wrongly omitted from the market-share calculation or have underreported the volume of their products sold in the United States. The dispute mechanism in the proposed rule should be altered in several respects.

First, the proposed rule should explicitly permit a manufacturer or importer to use all available information, including third-party data, in support of a challenge to a user-fee assessment. That information should include industry-wide sales volumes or the sales of a particular company. At a minimum, the rule should clarify the type of information and evidence a manufacturer or importer can use in challenging the assessment. And because a challenger may be able to establish that a user-fee assessment is wrong (for example, because a different manufacturer has been wrongly omitted) but yet be unable to establish the correct amount on its own (because it does not know the volume of that omitted manufacturer's sales), it should be FDA's burden to determine the correct amount of an assessment once an error is established.

Second, the proposed rule should set a reasonable period, for example three years, within which to challenge a past user-fee assessment after FDA has collected it. A manufacturer or importer's noncompliance with the Tobacco Control Act, and resulting failure to be assessed a user fee during a quarterly period, may be unknown during the relevant quarter. Indeed, it may take months or years for such noncompliance to become apparent. Therefore, a reasonable three-period period will allow the manufacturer or importer needed time to gather information about the propriety of the assessment.

Third, while the preamble to the proposed rules states that "[i]f FDA determines there was an error in the amount of the assessment, FDA would refund the money that was incorrectly assessed," 72 Fed. Reg. at 32587, the proposed rule does not provide a mechanism to enforce such a refund. But because no manufacturer can be made to pay a user fee in excess of its percentage share, 21 U.S.C. § 387s(b)(3)(B), during the pendency of any challenge to a user-fee assessment, the proposed rule should require the disputed portion of the assessment to be placed in escrow and then refunded if the challenge is successful. To comply with the statute, FDA cannot wait until it collects the amount of the assessment to be paid by the delinquent manufacturer or importer. The proposed rule should set a reasonable period (30 days, for example) in which to refund the escrow account, along with any additional money incorrectly paid, once FDA has

determined the correct amount of the assessment to be paid by the delinquent manufacturer or importer. These provisions would assure that the affected party can obtain a prompt refund of any erroneously assessed user fee.

Fourth, the rule should address the circumstance in which a successful challenge to a particular user-fee assessment also establishes that FDA's assessment was incorrect for *all* manufacturers and importers of a particular class or classes of tobacco products. Specifically, the rule should provide a mechanism for FDA to permit input by other parties potentially affected by a challenge and, in the event the challenge is successful, to correct the assessments on a class-wide basis. Relatedly, the rule should provide a mechanism for FDA to calculate the percentage share of non-reporting manufacturers or importers if a manufacturer or importer fails to provide information (or does not provide accurate information). If FDA does not account for noncompliant manufacturers, the other compliant manufacturers and importers will necessarily "pay a user fee in excess of the percentage share of such manufacturer," in violation of the statute. 21 U.S.C. § 387s(b)(3)(B).

Fifth, as currently drafted, the proposed rule permits FDA to unreasonably delay corrections or adjustments for its errors in assessing user fees, by permitting such corrections to be made on an annual basis. 78 Fed. Reg. at 32594. FDA should instead commit to making adjustments to erroneous user-fee assessments in a more prompt way—for example, upon determining the correct amount of the assessment.

Sixth, the proposed rule lacks a proper procedure to challenge FDA's response. The proposed rule states that "[a] request for further Agency review must be submitted in writing within 30 days from the date on FDA's response," but it does not include a method for further review. The proposed rule should explicitly allow a manufacturer or importer to seek judicial review of the FDA's decision in district court, either in the District of Columbia or in the district where the manufacturer has its principal place of business.

Finally, the proposed rule should impose time requirements on FDA's review and response to the dispute. The proposed rule states that "[t]o ensure finality in FDA's accounts and potential refund obligations," the agency "believe[s] it is necessary to have a time limit on disputes over user fee assessments." 78 Fed. Reg. at 32,587. Yet the only time limits identified in the proposed rule are limits placed *on the manufacturers and importers*; no timeframe is imposed on FDA's review and response, even though that process has no less effect on finality. What suffices for the goose should suffice for the gander: The rule should impose at least presumptive time limits on FDA's response to a challenge, perhaps similar to the time given to manufacturers to notify FDA of a dispute (within 45 days of the date of the assessment notification) or to appeal (within 30 days of the date of FDA's response to the dispute).

3. The FDA Should Withdraw And Substantially Revise Its Proposed Rule Before It Issues A Deeming Regulation.

As noted above, although not all tobacco products are currently subject to regulation under the Tobacco Control Act, Section 901 grants FDA authority to expand its regulatory oversight by promulgating regulations deeming other tobacco products subject to the Act. 21 U.S.C. § 387a(b). To this end, FDA has expressed its intention to publish a Notice of Proposed Rulemaking in October 2013 to deem other tobacco products subject to the Act.

Because the statute requires FDA to assess a user fee on "each manufacturer and importer of tobacco products subject to this subchapter," FDA should not propose any "deeming" regulation until after it has revised and finalized its user fee regulations. Under the statute, there cannot be any gap between when a tobacco product is "deemed" subject to the Act and when the manufacturer or importer of such a product is subject to user fees. 21 U.S.C. § 387s(a). Accordingly, if FDA promulgates a final rule that does not appropriately establish a mechanism for assessing user fees on each manufacturer and importer of any tobacco product subject to the Act, FDA would put itself in the difficult position of having to revise its rule and undertake further rulemaking proceedings each and every time it promulgates a regulation deeming a new product subject to the Act. That would impose unreasonable costs on both the agency and interested parties, and it would result in regulatory uncertainty and unnecessary disputes. FDA can avoid these burdens and concerns by ensuring that an appropriate regulation governing the assessment of user fees is in place before it proposes to deem any product subject to the Act.

More fundamentally, FDA should finalize its user-fee regulation first before proposing any "deeming" regulation, because all interested parties are entitled to a reasonable opportunity to comment. Until FDA's user-fee regulation is finalized, it will be impossible to comment fully on any proposed "deeming" regulation. Whether a product will be subject to user fees is certainly relevant to whether it should be subject to regulation under the Act. Accordingly, to ensure that public comment is meaningful and productive, FDA should finalize its user fee regulation before proposing and seeking comment on any deeming regulation.

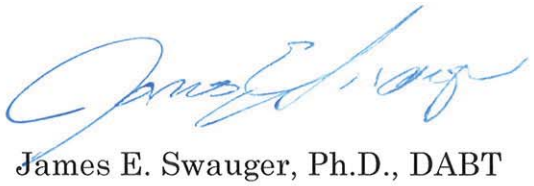
IV. CONCLUSION

For these reasons, FDA's proposed rule is fatally flawed and should be withdrawn. In its place, FDA should publish and seek comment on a proposed rule that implements Congress's mandate that "each" manufacturer or importer of a tobacco product deemed subject to regulation must pay a user fee, 21 U.S.C. § 387s(a). Such a proposed rule should provide a reasonable means of filling the statutory gap left by Congress, namely, devising a common metric by which to

compare the volume of different classes of tobacco products. RAIS believes that FDA must revise this proposed rule before it can promulgate any regulation under Section 901 "deeming" other tobacco products subject to the Tobacco Control Act.

RAIS remains eager to work with FDA to help implement the requirements of the Tobacco Control Act. RAIS hopes these comments will help FDA to publish a revised proposed rule and ultimately to promulgate a final rule that satisfies the statutory requirements and is consistent with the Administrative Procedure Act.

Respectfully submitted,



James E. Swauger, Ph.D., DABT
Vice President – Regulatory Oversight

RAI Services Company