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SUPPLEMENTAL COMMENTS OF THE RETAIL ASSOCIATIONS IN RESPONSE TO EPA'S PROPOSED MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

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I. Introduction

The Retail Industry Leaders Association ("RILA"), the Food Marketing Institute ("FMI"), the National Association of Chain Drug Stores ("NACDS"), the National Retail Federation ("NRF"), the National Grocers Association ("NGA"), and their members (collectively the "Retail Associations") hereby submit supplemental comments in response to EPA's proposed rule, entitled "Management Standards for Hazardous Waste Pharmaceuticals," 80 Fed. Reg. 58,014 (September 25, 2015) ("Pharmaceutical Proposal"). These comments build upon the comments previously submitted by the Retail Associations on December 22, 2015, and provide further input to help ensure that any final rule provides an appropriate regulatory framework for retailers of prescription pharmaceuticals, over-the-counter ("OTC") pharmaceuticals, and dietary supplements.

The Retail Associations realize that the formal period for public comment on the Pharmaceutical Proposal closed on December 24, 2015. However, these supplemental comments are based entirely on a development since that time, namely the recent promulgation of a final rule regarding nicotine-containing products by the Food and Drug Administration ("FDA"). *See* 81 Fed. Reg. 28,973 (May 10, 2016) ("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") (hereinafter referred to as the "Deeming Rule"). The Retail Associations urge EPA to take these comments into account, so as to ensure consistency between the two agencies.

As discussed briefly below, the Deeming Rule and related actions by FDA provide important support for one key aspect of EPA's Pharmaceutical Proposal, *i.e.*, the potential amendment of the hazardous waste listing for nicotine and salts (EPA Hazardous Waste No. P075) as it applies to low-concentration nicotine products. In particular, the FDA rule underscores the dubious nature of the human toxicity data that EPA relied on when it originally classified nicotine as an acutely hazardous waste under the Resource Conservation and Recovery Act ("RCRA"), thereby supporting a change in the RCRA classification of low-concentration nicotine products or an exemption from the RCRA hazardous waste regulations for such products. In addition, the FDA actions establish methods for identifying and controlling the concentration of nicotine in e-cigarette products, which should address EPA's concerns about "unpredictability" in such

concentrations, and therefore should help clear the path for providing regulatory relief for e-cigarette products in the same manner as for other low-concentration nicotine products.

II. The FDA Rule Undercuts the Data EPA Originally Relied on to Classify Nicotine as an Acutely Hazardous Waste

In the Deeming Rule, FDA relies heavily on a 2014 report by the Surgeon General as an authoritative source on the toxicity of nicotine. *See, e.g.*, 81 Fed. Reg. at 28,981, 29,033, and 29,047 (discussing toxicity of nicotine and citing to Reference 9); *id*. at 29,095 (identifying, as Reference 9, a U.S. Department of Health and Human Services report entitled ‘‘The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General” (2014) (hereinafter referred to as the “Surgeon General’s Report”)). The Surgeon General in that report explicitly stated that he could find no support for the commonly cited estimate that the median lethal dose (“LD50”) for nicotine in humans (via oral administration) is only 1 mg per kg of body weight (corresponding roughly to a fatal dose of 50-60 mg). *See* Surgeon General’s Report (attached to the December 22, 2015 comments of the Retail Associations as Exhibit 3) at 112 (“a systematic literature search was performed …; however, no study was located as a source for an estimate of the dose that is fatal to humans, and the figure of 50-60 mg is poorly documented”). FDA notes further that the proper LD50 is a matter of considerable dispute and may be “much greater” (meaning that nicotine may be much less toxic). *See* 81 Fed. Reg. at 29,034, *citing* B. Mayer, Department of Pharmacology and Toxicology, Karl-Franzens University (Graz, Austria), “How much nicotine kills a human?” *Archives of Toxicology* (2014) (attached to the December 22, 2015 comments of the Retail Associations as Exhibit 4) (stating that the 50-60 mg figure is “highly dubious”).

This is important for the current rulemaking because the LD50 estimate of 1 mg/kg was the primary basis upon which EPA originally listed nicotine (and salts) as acutely hazardous wastes under RCRA. *See* EPA Office of Solid Waste, Background Document entitled “Section 261.33 – Hazardous Waste from Discarding of Commercial Chemicals Products and the Containers and Spill Residues Thereof” (January 1981) (“CCP Background Document”), Appendix A (attached to the December 22, 2015 comments of the Retail Associations as Exhibit 2). Clearly, that estimate was erroneous. As that has now been confirmed, it would be arbitrary and capricious for the EPA to continue to use that estimate to justify the continued classification of low-concentration nicotine products as acutely hazardous wastes. Indeed, FDA states throughout the Deeming Rule that “nicotine *at high enough doses* has acute toxicity,” suggesting that nicotine at lower doses, such as those associated with low-concentration nicotine products, does not pose an acute toxicity concern. *See* 81 Fed. Reg. at 28,981, 29,033, and 29,047 (emphasis added).

III. The FDA Actions Will Ensure Against "Unpredictable" Nicotine Concentrations in E-Cigarette Products, Strengthening the Case for Reclassification or Exemption of Such Products

In the Pharmaceutical Proposal, EPA expressed reservations about extending any RCRA regulatory relief for low-concentration nicotine products to e-cigarettes, largely on the ground that "the concentration of nicotine in e-cigarettes is not limited by any regulation or approval process and is therefore unpredictable." *See* 80 Fed. Reg. 58,072. As an initial matter, EPA's concerns may be unwarranted. In the Deeming Rule, FDA cited some recent studies showing that "variations are no longer as significant among the newer e-cigarette products," and that "nicotine levels [are generally] equivalent to or lower than advertised." *See* 81 Fed. Reg. at 29,034.

In any event, the recent FDA actions should put to rest EPA's concerns about unpredictable nicotine concentrations in e-cigarettes. The Deeming Rule will generally require manufacturers of e-cigarettes to apply for and obtain a "marketing order" from FDA prior to distribution of their products. *See, e.g.*, 81 Fed. Reg. 28,978 ("[e-cigarette] products will be subject to enforcement unless they are grandfathered or are the subject of a marketing authorization order"). An application for such an order is required by statute to include a "full statement of the components, ingredients, [and] additives … of [the] tobacco product." *See* 21 U.S.C. § 387(j)(b)(1)(B). FDA has indicated that this would ordinarily require a specification of the nicotine concentrations in the products. *See* FDA, "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry" (May 2016 Draft) ("Premarket Guidance") (issued together with the Deeming Rule) (attached to these Supplemental Comments) at 20; 81 Fed. Reg. 28,781 (May 10, 2016) (announcing the availability of the Premarket Guidance).

In addition, the Deeming Rule subjects e-cigarettes to a statutory provision requiring a "full description of the methods used in, and the facilities and controls used for … [manufacture of] tobacco product[s]." *See* 21 U.S.C. § 387(j)(b)(1)(C). The FDA has indicated that applications for premarket orders should include operating procedures "to ensure the … product matches specifications." *See* Premarket Guidance at 29. Accordingly, manufacturers of e-cigarettes will have to report the concentrations of nicotine in their products and specify safeguards to ensure that any variations are limited. Moreover, if the products are labeled with their nicotine concentrations – which we believe is generally the case, so that customers know the "strength" of the products – any significant departures from the specified concentrations will subject the manufacturers to substantial penalties as a form of "misbranding" of the products. *See* 21 U.S.C. § 387(c).

In these ways, any remaining uncertainties about the nicotine concentrations in e-cigarette products should be eliminated by the Deeming Rule. With this issue having been addressed by

FDA, EPA should move forward with the RCRA reclassification or exemption of e-cigarette products in the same way as other low-concentration nicotine products.

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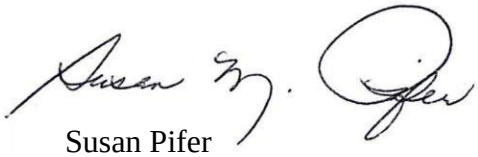
The Retail Associations hope that these supplemental comments will assist EPA in coordinating any final rule on low-concentration nicotine products with the recent actions of FDA. We continue to believe, as set forth in our December 22, 2015 comments, that the current classification of such products as acutely hazardous wastes under RCRA is unjustified. And based upon the FDA's Deeming Rule, it appears arbitrary and capricious. Moreover, this classification is needlessly costing the retail industry well in excess of $40 million per year, since it is the main reason why large numbers of retailers that otherwise would qualify as Conditionally Exempt Small Quantity Generators are subject to full RCRA regulation as Large Quantity Generators.

Based on these supplemental comments and our prior comments, we urge EPA to exempt from RCRA all categories of low-concentration nicotine products currently on the market, and any future categories with comparable nicotine concentrations (*e.g.*, less than 3%). In the alternative, we would also support the reclassification of such products as non-acutely hazardous wastes under RCRA.

We further urge EPA to acknowledge that low concentration nicotine products are not solid wastes (and therefore are not hazardous wastes) if they are destined to be evaluated for potential manufacturer credit or potential use/reuse or reclamation options. Indeed, we believe the same conclusion should apply for all pharmaceutical products. Thus, as discussed in more detail in our December 22, 2015 comments, we urge EPA not to reverse its long-standing guidance that pharmaceuticals destined for evaluation of potential credit are not solid wastes. The Agency should also clearly state that pharmaceuticals sent for evaluation of potential use/reuse or reclamation options are not solid wastes, subject to RCRA, including any new requirements that may be established in this rulemaking.

If you have any questions about our original comments or these supplemental comments, please do not hesitate to contact us.

Sincerely,



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