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June 12, 2019

Via Electronic Mail and Certified Mail

Hon. Ann Marie Buerkle, Acting Chair
Hon. Robert S. Adler, Commissioner
Hon. Dana Baiocco, Commissioner
Hon. Peter A. Feldman, Commissioner
Hon. Elliot F. Kaye, Commissioner
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, Maryland 20814

Re: Industry Objection to CPSC's Novel Interpretation that the CNPPA Immediately Requires Flow-Restricted Packaging for E-Liquids

Dear Acting Chair and Commissioners:

We write on behalf of the American E-Liquid Manufacturing Standards Association, the American Vaping Association, the New York State Vapor Association, the Smoke-Free Alternatives Trade Association (SFATA), SFATA-California, SFATA-Connecticut, SFATA-Hawaii, SFATA-Louisiana, SFATA-Rhode Island, SFATA-Texas, SFATA-Wisconsin, and the Tennessee Smoke-Free Association (the E-Vapor Coalition), to express industry's strong opposition to the Consumer Product Safety Commission's (CPSC) novel interpretation of the Child Nicotine Poisoning Prevention Act of 2015, PL 11-116 (CNPPA) to immediately require all nicotine-containing e-liquids to be packaged in bottles that comply with the "restricted flow requirement" in 16 C.F.R. § 1700.15(d).

Following CPSC's March 8, 2019 letter to industry on "Nicotine Packaging Test Parameters," which indicated for the first time that CPSC is interpreting the CNPPA to require flow restricted packaging, a number of E-Vapor Coalition association member companies received Notices of Violations from CPSC's Office of Compliance and Field Operations (Notices) alleging that because certain of their e-liquids are not packaged in flow-restricted bottles they are misbranded hazardous substances pursuant to section 2(p) of the Federal Hazardous Substances Act (FHSA). These companies, whose products are intended for adults seeking less harmful alternatives to combustible tobacco, are being ordered to initiate a number of "corrective actions," including to immediately stop sale and distribution, notify all known retailers and consumers, and destroy and dispose of returned units and any remaining inventory.

These actions would force these companies – largely small businesses – out of the market for weeks, if not months, would result in significant costs and lost revenue, and could ultimately drive these small companies out of business.

For the reasons set forth below, we respectfully disagree that the CNPPA requires flow restrictors as part of its special packaging requirements. E-liquids packaged in bottles without flow restrictors (including glass bottles) are not misbranded hazardous substances subject to immediate stop sale orders or any other corrective actions. Rather, flow restrictors can only become part of the special packaging requirements after CPSC completes a notice and comment rulemaking process pursuant to the Administrative Procedures Act (APA). Moreover, CPSC must also consider that its demand that companies change their e-liquid packaging to incorporate flow restrictors potentially conflicts with Food and Drug Administration (FDA) rules prohibiting any changes to components and parts (including packaging) of existing tobacco products without FDA premarket authorization.

Despite the E-Vapor Coalition's strong disagreement with the CPSC's unsupported reading of the CNPPA, the E-Vapor Coalition associations and their members share CPSC's concern regarding the potential hazards of nicotine-containing e-liquids. They do not object to an orderly transition to restricted-flow packaging, in coordination with FDA, and in a manner that will not unduly burden manufacturers, distributors and retailers, or deprive adult consumers of less risky alternatives to combustible tobacco. For these reasons, the E-Vapor Coalition associations and their members request that CPSC either provide the industry with a minimum 12 month period to voluntarily transition to flow-restricted packaging,[1] or issue a notice of proposed rulemaking on flow restrictors, and that CPSC coordinate with FDA to ensure that such transition will not trigger an obligation to obtain pre-market authorization as new tobacco products under FDA's regulations.

[1] Companies' ability to transition to bottles will depend on the timely availability of sufficient volumes of flow-restricted containers, which in turn have to be tested by labs that must develop the capability of testing these containers, and on potential retooling and other changes by affected companies to adapt production. These costs do not include costs of addressing this issue with FDA. To mitigate costs and facilitate broad compliance, CPSC has, on multiple occasions, set effective dates for mandatory standards for 12 months, and even longer, after publication, including for durable nursery products that have been involved in reported deaths and serious injuries. For example, the mandatory standard for booster seats will become effective 18 months after publication. https://cpsc.gov/Newsroom/News-Releases/2018/CPSC-Approves-New-Federal-Safety-Standard-for-Booste-Seats.

We explain our reasoning below and look forward to working with CPSC and FDA during this transition.

I. The Plain Language of the CNPPA Requires Only Child-Resistant Packaging

The plain language of the CNPPA limits the special packaging requirements for nicotine-containing e-liquids to child-resistant closures only. The CNPPA requires certain containers of e-liquids to be "packaged in accordance with the standards provided in Section 1700.15 of title 16, Code of Federal Regulations, *as determined through testing in accordance with the method described in section 1700.20 of title 16, Code of Federal Regulations*, and any subsequent changes to such sections adopted by the Commission." CNPPA, §2(a) (emphasis added). Section 1700.15 includes provisions for both child-resistant closures and the rarely used restricted flow provisions.[2] At the time of enactment, Section 1700.20 included testing procedures for only child resistant closures.[3] Since enactment, no changes to the test procedures described in section 1700.20 have been adopted. Therefore, at the present time, only the use of child-resistant closures can be "determined through testing in accordance with the method described in Section 1700.20." It follows that only child-resistant closures, which the e-liquid industry has adopted and fully supports, are required by the CNPPA, and that Congress intended that any further changes would be addressed through the rulemaking process.

"A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (citing 2A N. Singer, Statutes and Statutory Construction § 46.06 (rev. 6th ed. 2000)). CPSC's new interpretation that the CNPPA requires flow restrictors, disclosed three years after the CNPPA was enacted, fails this test. Had Congress wanted to impose all the specific provisions of Section 1700.15, it would have simply written the statute to read "nicotine provided in a liquid nicotine container . . . shall be packaged in accordance with the standards provided in section 1700.15 of title 16, Code of Federal Regulations." There was simply no need for Congress to reference the testing procedures in 1700.20 to effectuate the requirement of the child-resistant

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[2] Furniture polish is the only substance required to be packaged in flow restricted packaging under CPSC regulations. 16 C.F.R. § 1700.14(a)(2).

[3] The CPSC tacitly acknowledged that Section 1700.20 does not contain testing protocols for flow restrictors in its letters to industry. *See* Letters from Robert S. Kaye, Office of Compliance and Field Operations, to U.S. Consumer Product Safety Commission (February 20, 2019) and (March 8, 2019): *available at*: https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Liquid-Nicotine-Packaging-Business-Guidance. The absence of a testing protocol also necessitated CPSC staff's hasty development of a flawed and unsupported testing protocol to create a performance standard for the provisions of Section 1700.15(d), that was included in the March 8, 2019 letter, and which is not part of the 1700.20 rule.

closure provisions of 1700.15.[4] The clause "as determined through testing in accordance with the method described in section 1700.20 of title 16, Code of Federal Regulations" would therefore be inoperative, superfluous, and insignificant if it was not meant to limit application of Section 1700.15 requirements only to those that can be tested under Section 1700.20, namely, the child-resistant closure provisions.

The CNPPA does, however, empower the Commission to amend the special packaging requirements for e-liquids through notice and comment rulemaking, as required by the APA, 5 U.S.C. §553. Through rulemaking, the Commission could, for example, add testing procedures for flow restrictors to 16 C.F.R. §1700.20. By doing so, compliance with restricted flow could be "determined through testing in accordance with the method described in Section 1700.20," and thus incorporated into the CNPPA requirements. What the Commission may not do, however, is engage in arbitrary and capricious backdoor rulemaking by attempting to impose and enforce these requirements through staff guidance documents, such as the March 8, 2019 letter, and subsequent compliance actions. CPSC is attempting to give its demand for flow restrictors the "force and effect of law," but it may only do so by promulgating a rule after public notice and an opportunity to comment. *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 250 (D.C. Cir. 2014). APA rulemaking would ensure that the Commission's action is lawful by assuring that stakeholders have an opportunity to comment on the data supporting the proposal, and the costs and benefits of the rule. Such an approach would also outline a timeframe for regulated entities to come into compliance, with due consideration to the scope and effect of other applicable regulations that apply to e-liquid producers.[5] Instead, staff has chosen to bypass these established procedures, actions that are in direct conflict with the statutory language.

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[4] The child resistant closure provisions of 1700.15 already reference Section 1700.20 testing procedures and contains a performance standard for percentages of children and adults able to open the packaging.

[5] Notice and comment rulemaking is essential for both the soundness and legitimacy of policy making by unelected officials. *See, e.g.*, *Weyerhaeuser Co. v. Costle*, 590 F.2d 1011, at 1027-8 (D.C. Cir. 1978) ("Our reliance on careful procedural review, moreover, derives from an expectation that if the Agency, in carrying out its essentially legislative task, has infused the administrative process with the degree of openness, explanation, and participatory democracy required by the APA, it will thereby have negate[d] the dangers of arbitrariness and irrationality in the formulation of rules . . . .") (internal quotations omitted). Additionally, rulemaking under the APA generally becomes effective no sooner than 30 days after the publication of the final rule, to allow companies to come into compliance without undue disruption and cost. *See* 5 U.S.C. §553(d). In practice, the CPSC routinely provides significantly longer, as in the recent Mandatory Standard for Highchairs, which became effective a full year after its publications. 83 Fed. Reg. 28358 (June 19, 2018).

II. The Legislative History Confirms that Congress Intended Only to Require Testing for Child-Resistant Packaging, not Testing for Flow Restriction

The CNPPA's legislative history confirms the plain language of the statute, namely, that Congress did not consider restricted flow among the special packaging requirements of the CNPPA. The Senate Committee Report contains no reference to flow restrictors. In describing the impact on manufacturers, the report states "[t]he bill would require those manufacturers to use special packaging for such products to make them *child resistant*." S.R. Rep No. 114-12, at 3 (emphasis added).[6] Similarly, all the comments in the Congressional record from the House of Representatives' debate over the CNPPA discuss only child-resistant packaging and never mention flow restrictors. For example, Congresswoman Sheila Jackson Lee stated: "This bill would save children's lives by allowing the Consumer Product Safety Commission to require the use of child-resistant packaging on liquid nicotine containers sold to consumers. The CPSC currently requires such packaging on many common toxic household substances like bleach, as well as FDA-regulated products like prescription drugs." Child Nicotine Poisoning Prevention Act of 2015, 114 Cong. 229 (2016) (Statement of Ms. Jackson Lee). These referenced products are not required to be packaged in flow restricted packaging. Notably, there is no reference to furniture polish – the only product required to use flow restricted packaging – in the legislative history.[7]

III. CPSC's Novel Reading of the CNPPA is Entirely Inconsistent With its Previous Guidance

For three years following the enactment of the CNPPA, CPSC's guidance on compliance with the law focused *solely* on child-resistant closures. On July 22, 2016, CPSC issued a letter to industry, "Liquid Nicotine Packaging Surveillance Revised Guidance Letter to Industry," that did not mention restricted flow packaging. On August 2, 2018, the agency issued another

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[6] This section of the Committee Report quotes the Congressional Budget Office Cost Estimate, which calculated the costs to business of the CNPPA, on which the Senate Report relied. This estimate took account of only the costs of adopting child resistant closures and did not discuss the costs of flow restrictors. *Congressional Budget Office Cost Estimate*, S. 142, Child Nicotine Poisoning Prevention Act of 2015, Pub. L. No. 114-116. Clearly, imposing restricted flow requirements entails more significant costs, especially in light of CPSC's about-face on this issue, three years later.

[7] All substances required to be in "special packaging" need only come in child-resistant packaging, with the notable exception of furniture polish, which must also be in flow restricted packaging. *See* n. 2 above. By comparing the new requirements on e-liquids to those for other common household products, Congresswoman Jackson Lee's statements support the conclusion that Congress intended the requirements for liquid nicotine to mirror those for the vast majority of substances covered under the Poison Prevention Act, *i.e.*, only child-resistant closures, but not flow restrictors.

Nicotine Packaging Advisory Letter, informing the industry that secondary closures such as dispensing caps, sold along with e-liquid containers and reasonably expected to replace the original child-resistant closures, must also be child-resistant. This guidance is in fact inconsistent with a position that flow restrictors are required. Dispensing caps are generally sold with glass bottles that have not generally incorporated flow restrictors. Had the Commission believed that flow restrictors were required, it would have addressed them in the August 2, 2018 Advisory Letter rather than just provide guidance on child-resistant closures for dispensing caps.

As the agency conceded in its February 20, 2019 letter, it never before gave guidance on the applicability of 16 C.F.R. §1700.15(d). The agency did not even have a test methodology for establishing compliance with this provision at that time. It was not until March 8, 2019 – more than three years after the enactment of the CNPPA – that the CPSC revealed a (hastily drafted) test methodology by which it proposed to measure compliance with the purported requirement to include flow restrictors. The Commission's consistent failure to provide guidance on, or enforce, flow restrictor requirements until early this year can only be because the CPSC itself had never considered these to be required under the CNPPA.

IV. Incident Patterns Do Not Support the Need for Flow Restrictors

While the E-Vapor Coalition associations and their members share the CPSC's concern regarding the potential for child poisoning resulting from exposure to e-liquids, and supports an orderly transition to flow restricted packaging, the available data do not support the need for the immediate stop sale or other corrective actions the Commission is asserting is required. A review of the CPSC's National Electronic Injury Surveillance System (NEISS) data does not suggest that the CPSC should take the extraordinary step of imposing an entirely new flow restrictor requirement, based on a just-developed and untried test method that is suitable only for plastic and not glass containers, with no prior notice and without going through notice and comment rulemaking. The Commission also inexplicably chose not to work with industry to create a protective voluntary standard, as it has consistently done in the past, for example, with the laundry packet industry.[8]

[8] Laundry packets were in the top three products involved in emergency department-treated pediatric poisonings according to CPSC's Unintentional Pediatric Poisoning Injury Estimates for 2016. A new study by the American Academy of Pediatrics has found that laundry packets still cause approximately 40 injuries per day. *See* https://www.techtimes.com/articles/244175/20190605/liquid-laundry-pods-cause-about-40-us-injuries-a-day.htm.

Our review of the 2017 NEISS data for emergency department-treated incidents involving poisoning of children up to age five found 29 incidents[9] involving nicotine poisoning from *all* sources of nicotine. Only eight of these involved e-liquids. Nine incidents involved children ingesting cigarettes, six involved children ingesting chewing tobacco or spit from chewing tobacco, five involved children ingesting new or used nicotine gum or lozenges, and a single incident involved a child using an e-cigarette to inhale vapor containing nicotine.

By way of comparison, there were approximately 200 incidents involving bleach. Bleach is fourth on the list of top-ten products involved in emergency department-treated unintentional pediatric poisoning estimates in 2016, according to CPSC's Unintentional Pediatric Poisoning Injury Estimates for 2016. Nicotine, in any form, is not on the top ten list.[10] Poison Control Center data tell a similar story. The entire category of tobacco, nicotine, and electronic cigarette products accounts for only 1.12% of exposures for children ages 5 and under, whereas cosmetics and personal care products, which is the category most frequently involved in pediatric exposures, account for over ten times more incidents.[11] There were no reported pediatric fatalities in Poison Control Center data that were associated with nicotine products in 2017.[12] Notably, an estimated 60-100 million e-liquid nicotine containers are sold annually in the U.S.[13]

V. The CPSC's Test Method is Arbitrary and Flawed

CPSC's hastily drafted test method for flow restrictors is flawed. More importantly, CPSC must follow procedures for notice and comment rulemaking to impose new requirements, such as restricted flow containers, under the CNPPA. 16 C.F.R. §1700.15(d) describes flow restricted packaging as packaging "from which the flow of liquid is so restricted not more than 2 milliliters of the contents can be obtained when the inverted, opened container is taken or

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[9] None of these reported incidents required more than observation, and none resulted in hospitalization or death. *See* the NEISS website, *available at*: https://www.cpsc.gov/Research--Statistics/NEISS-Injury-Data. Of note, nicotine is only a minor component of overall e-liquid formulations. E-liquids are primarily composed (>99%) of a base carrier (propylene glycol and/or glycerin), flavorants and nicotine. Typical levels of nicotine in e-liquid are 3, 6, 12 and 18 mg/mL of e-liquid.

[10] The rate of emergency department-treated pediatric poisonings from nicotine is so low that it would likely be impossible to make nationwide estimates of incidents attributable to any single source of nicotine.

[11] *See* 2017 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 35th Annual Report, p. 19, table 17C: *available at*: https://piper.filecamp.com/uniq/cwK5Ko3PLwXzfBkk.pdf.

[12] *Id*. at Appendix E, Table 21

[13] ECigIntelligence Snapshot: United States, May 2019: *available at* (subscription only): https://ecigintelligence.com/market-snapshot-usa-may-2019-2/.

squeezed once or when the container is otherwise activated once." CPSC staff's test method does not fully adhere to this regulatory language.

First, the test method contemplates only squeezable bottles, not glass bottles. As the Test Method Overview states, the test fixture that CPSC staff put together "is designed to determine the amount of liquid release from the test container when squeezed once while inverted." However, many bottles of e-liquids are glass and simply cannot be squeezed. Section 1700.15(d) contemplates ways, other than squeezing, in which a container may be "taken … or otherwise activated." CPSC staff ignored this provision and failed to give industry guidance on how to test non-squeezable bottles.

Second, the test method requires squeezing the container for five seconds but provides no support for this arbitrarily selected length of time or an explanation of how this method comports with Section 1700.15(d). Section 1700.15(d) speaks only to a single squeeze or activation. To comply with this regulatory language, staff's test method should simulate a real-life single squeeze or activation. Staff has not provided data showing that a bottle, when squeezed, would be squeezed for a full five seconds, and specifically failed to provide any data supporting the notion that a child accessing such a container would squeeze it for that long. This arbitrarily selected length of time may have a material effect on whether a given container would or would not pass staff's test. Therefore, it must be supported by sufficient evidence. As it stands, it is supported by none.

VI. CPSC's Actions Create a Conflict with FDA's Regulatory Scheme

E-liquids that contain tobacco-derived nicotine are tobacco products subject to FDA's authority pursuant to the Food, Drug and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act (TCA). By way of background, when the TCA was enacted in 2009, it defined "tobacco product" very broadly, in pertinent part, to include anything made or derived from tobacco intended for human consumption, including the components, parts, and accessories of the product. 21 U.S.C. § 321(rr). However, Congress gave FDA immediate authority only over certain tobacco product categories, *e.g.*, cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco. Congress also permitted FDA to "deem" other tobacco products subject to its authority through the rulemaking process. On August 8, 2016, the Agency's "Deeming Rule" went into effect, extending FDA's tobacco product authority over all previously unregulated products that meet the tobacco product definition, including nicotine-containing e-cigarettes and e-liquids. See 81 Fed. Reg. 28973 (May 10, 2016). Now, e-liquids are subject to a host of FDA requirements including, among other things, registration, ingredient listing, harmful constituent testing, warning labels and, most critically, premarket authorization for all new products.

A "new" tobacco product is a tobacco product that was either introduced to the U.S. market after February 15, 2007, or, if it was already on the market as of that date, had *any* modifications made to the product other than to its label. Specifically, a change in any design, component, part, constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient, creates a new tobacco product. 21 U.S.C. § 387j(a)(1). For deemed tobacco products such as e-liquids, FDA established a "compliance policy" in the Deeming Rule whereby non-grandfathered deemed products on the market on the effective date of the rule (*i.e.*, August 8, 2016) are permitted to remain on the market for a certain number of years until premarket applications are due. But products introduced *or modified* after August 8, 2016 would not only be considered new products subject to premarket authorization but would also fall outside of the scope of the compliance policy, and thus could not be legally marketed.

E-liquid bottles are considered components and parts of the e-liquid product. The Deeming Rule defines "components and parts" of deemed tobacco products very broadly as "any software or assembly of materials intended to or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product." 21 C.F.R. § 1143.1. In the preamble of the final Deeming Rule (81 Fed. Reg. at 28975), as well as the FDA's just published Final Guidance on Premarket Tobacco Applications for Electronic Nicotine Delivery Systems (ENDS), FDA has further described the distinctions between components, parts, and accessories of e-cigarettes, and specifically lists "bottles that contain e-liquids" as components and parts.[14]

Moreover, FDA has indicated that modifications to a tobacco product's packaging, and specifically to its "container closure system," could create a new product if the change to the packaging, including a change to the packaging materials used, is intended or reasonably expected to alter or affect the tobacco product's performance, composition, constituents, or characteristics.[15] In other words, if a legally marketed e-liquid product or its components and parts (bottles) are modified today, the manufacturer could be required to entirely remove the e-

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[14] U.S. Food & Drug Admin., Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry (2019); *See* page 6: *available at* https://www.fda.gov/media/127853/download.

See also FDA's webpage on "Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)," *available at*: https://www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends.

[15] Letter from David Ashley, Ph.D., Food and Drug Administration, to Gerard J. Roerty, Jr. Swedish Match North American (January 13, 2017). *See* the letter on the Agency's website: *available at*: http://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM540974.pdf.

liquid from the market and seek FDA marketing authorization – a process expected to cost millions and take years to complete, effectively putting a significant number of companies out of business.

In this case, switching a company's glass bottles to plastic bottles with flow restrictors to comply with CPSC's request would necessitate a change to a component and part of the product that FDA could determine is reasonably expected to alter or affect the product's performance, composition, constituents, or characteristics. Thus, absent clear FDA indication that such a change is not reasonably expected to alter or affect the tobacco product's performance, composition, constituents or characteristics, or a statement from FDA that it will exercise enforcement discretion and not require pre-market authorization in light of CPSC's position, FDA could take the position that a company's modified products are immediately out of compliance with FDA's compliance policy and premarket authorization requirements. Therefore, we respectfully request that CPSC coordinate with FDA on this issue to ensure that small e-vapor companies can continue to remain in business. Specifically, we ask that CPSC refrain from overstepping its authority by pressuring companies to stop sale of and recall e-liquid unless and until FDA formally announces that it will, at a minimum, use its enforcement discretion to permit companies to switch to flow-restricted packaging for e-liquids without fear of FDA enforcement and without the need for pre-market approval from FDA.

VII. Conclusion

For the reasons stated above, the E-Vapor Coalition associations and their members urge CPSC to adhere to the statutory mandate to work with industry to facilitate a voluntary and orderly transition to restricted-flow packaging, or by initiating a notice of proposed rulemaking on flow restrictors. In the meantime, we request that CPSC coordinate with the FDA to address FDA's regulatory obstacles to packaging changes, so that the industry can implement a transition to flow-restricted packaging without risking FDA enforcement actions that could effectively put a significant number of companies out of business.

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We thank you for consideration of these issues and would be glad to arrange a time to meet for further discussions. We look forward to continuing to work together to safeguard children and to protect small businesses.

Cordially yours,

Sheila A. Millar

Azim Chowdhury

cc: Patricia Hanz, General Counsel
Robert Kaye, Director, Office of Compliance and Field Operations
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