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Harold P. Wimmer

September 30, 2015

Leslie Kux

Associate Commissioner for Policy  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Re: Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products; Docket No. FDA-2015-N-1514

Dear Ms. Kux:

The American Lung Association appreciates the opportunity to submit comments and information regarding the advanced notice of proposed rulemaking (ANPRM), "Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products; Request for Comments," published on July 1, 2015 (docket no. FDA-2015-N-1514). The following comments are intended to supplement the longer set of comments submitted with our public health partners.

Liquid nicotine poisoning is a public health problem requiring the Food and Drug Administration (FDA) to take urgent action. Nicotine is extremely toxic and ingestion can be lethal, especially to young children. Poison control centers have seen a dramatic increase in the number of calls regarding children – particularly children under the age of five – ingesting or being exposed to liquid nicotine.<sup>1</sup> This is extremely concerning, especially considering that e-cigarette use is increasing<sup>2</sup> and liquid nicotine continues to be sold in candy flavors and packaging appealing to children.

The American Lung Association continues to be gravely concerned about the unregulated status of e-cigarettes, along with cigars and other unregulated tobacco products. It has been over one year since FDA proposed its rule deeming authority over e-cigarettes and other unregulated products. The delay in finalizing the deeming regulation not only jeopardizes the public health through the continued and increased dangers of tobacco product use, but also through the risks posed to children through liquid nicotine poisonings. The children being poisoned by liquid nicotine meant for e-cigarettes may be the "canaries in the coal

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mine” signifying the first of greater health consequences from this delay in regulating deadly products. While FDA must take steps now to prevent nicotine poisoning from e-cigarettes, which is well within its current authority, the American Lung Association strongly urges FDA to publish a final deeming rule as soon as possible.

The FDA has clear authority currently under the Tobacco Control Act to regulate tobacco products to prevent child poisoning, because these poisonings represent a significant public health hazard. The American Lung Association urges FDA to take the following actions to respond to this public health crisis:

1. Quickly publish a final rule to deem all tobacco products subject to FDA’s authority under the Tobacco Control Act
2. Publish a proposed rule as soon as possible requiring child-resistant packaging, similar or identical to existing standards governed by the Consumer Product Safety Commission, on liquid nicotine containers
3. Publish a proposed rule requiring nicotine exposure warnings on liquid nicotine containers
4. Utilize FDA’s premarket review authorities to ensure that products that pose a poisoning risk carry child-resistant packaging and nicotine exposure warnings
5. Avoid granting a lengthy compliance grace period to any newly deemed liquid nicotine products not sold in child-resistant packaging

Please note that while all are important actions, the Lung Association considers numbers one and two to be top priorities, and urges FDA to not delay these actions because of potential complications with other actions, such as requiring warning labels.

The American Lung Association looks forward to continuing to work with FDA on these important issues.

Sincerely,



Harold P. Wimmer  
National President and CEO

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<sup>1</sup> There were 1,543 calls to poison control centers in 2013.

<sup>2</sup> King BA, Patel R, and SR Dube. Trend in awareness and use of electronic cigarettes among U.S. adults, 2010-2013. *Nicotine & Tobacco Research*. 19 Sept. 2014. <http://ntr.oxfordjournals.org/content/early/2014/09/19/ntr.ntu191.full.pdf+html>.

