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April 20, 2012

Matthew Holman, Ph.D.
Director, Division of Product Science
Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: Docket No. FDA-2012-N-0212; Tobacco Product Analysis; Scientific Workshop

Dear Dr. Holman:

Attached please find copies of the studies I cited in my presentation at the FDA's above-captioned science workshop. I am providing the studies to assist the FDA with evaluating and validating analytic methodologies which can be used to help protect public health by:

- 1) Identifying counterfeit cigarettes; and
- 2) Measuring the level of metals in tobacco products including cadmium, lead, arsenic, mercury, and thallium in cigarettes.

As I noted in my presentation, the identification and analysis of counterfeit cigarettes is important since, as documented in the attached studies:

- 1) Counterfeit cigarettes are magnitudes higher in lead, cadmium and other metals than legally-produced products; and
- 2) Counterfeit cigarettes are commonly purchased by underage smokers, our most vulnerable population.

The following are the studies which I cited in my presentation:

1. Swami, Kamal, Judd, Christopher D. and Orsini, John (2009) "[Trace Metals Analysis of Legal and Counterfeit Cigarette Tobacco Samples Using Inductively Coupled Plasma Mass Spectrometry and Cold Vapor Atomic Absorption Spectrometry](#)," Spectroscopy Letters, 42: 8, 479 – 490.

The researchers at the New York State Department of Health's Laboratory of Inorganic and Nuclear Chemistry, concluded that, "The results show that the concentrations of Be, Mn, As, Se, Mo, Cd, Tl, Pb, and Hg were significantly higher in counterfeit cigarette samples than in genuine-brand cigarette samples."

2. Judd, Christopher D. and Swami, Kamal (2010) "[*ICP-MS determination of lead isotope ratios in legal and counterfeit cigarette tobacco samples*](#)," *Isotopes in Environmental and Health Studies* Vol. 46, No. 4, December 2010, 484–494.

Judd and Swami concluded that "The precision of the results was sufficient to distinguish between the counterfeit and genuine USA cigarettes. . . . The technique shows promise as a method for identifying counterfeit cigarettes, possibly determining the source region."

3. Pappas, RS; Polzin, GM, et al. (2007) "[*Cadmium, lead, and thallium in smoke particulate from counterfeit cigarettes compared to authentic US brands*](#)," *Food and Chemical Toxicology*, Vol. 2. Issue 2, February 2007, pp. 202-209.

The researchers at the Centers for Disease Control and Prevention (CDC) explained that:

"We compared mainstream smoke cadmium, thallium, and lead deliveries from counterfeit and authentic brands. Mainstream smoke levels of all three metals were far greater for counterfeit than the authentic brands, in some cases by an order of magnitude. Significant differences still existed even after normalizing mainstream smoke metal levels with nicotine delivery; the counterfeits typically delivered much higher levels of all three analytes. Our findings, based on 21 different counterfeit samples, suggest that counterfeit cigarettes potentially result in a markedly greater exposure to toxic heavy metals than authentic brands, even after correcting for differences in nicotine intake." [Emphasis added]

4. Stephens, W.E., Calder, A., Newton, J., 2005. "[*Source and health implications of high toxic metal levels in illicit tobacco products*](#)," *Environ. Sci. Technol.* 39, 479–488.

The Calder study found that, "A review of the health effects of heavy metal transfer from tobacco via smoke to the lungs indicates that habitual smokers of counterfeits may be risking additional harm from high levels of cadmium and possibly other metals."

Calder (2005) is of particular relevance to FDA/CDP's public health mission since it concludes:

"The purchase of counterfeit cigarettes is often regarded as a victimless crime, with evasion of tax being the only misdemeanor. As well as loss of considerable government revenue,

there are important social implications. Organized criminal gangs manage the manufacture and distribution of counterfeits, and increasing resources are having to be diverted to combating this activity. The main purchasers of counterfeit cigarettes are dominantly those on low incomes, either young people who then become addicted to smoking or the socially disadvantaged for whom so many other factors impact negatively on their state of health that the addition of another factor is potentially very serious. The extent of the U.K. market share now claimed by counterfeits means that an issue once considered marginal is rapidly becoming a major problem. The health risks described above as well as social implications means that early awareness of these issues is important if remedial action is to have significant impact.”

In addition to the above peer-reviewed studies, I am also attaching a copy of CRE’s monograph that I briefly discussed during my presentation, [*An Inquiry into the Nature, Causes and Impacts of Contraband Cigarettes*](#). The CRE paper provides extensive information about the counterfeit cigarette trade with an emphasis on the elevated public health risks associated with illegal products. The paper concluded that:

- ▶ “The increased health hazards from illicit cigarettes disproportionately impact underage and African American smokers.”

Sincerely,

/s/

Bruce Levinson
Senior Vice President,
Regulatory Intervention

Attachments