



The Honorable Henry A. Waxman  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives  
Washington, D.C. 20515-6115

OCT 03 2012

Dear Mr. Waxman:

Thank you for your letter of August 27, 2012, citing internal tobacco company documents that indicate some tobacco companies have been deliberately promoting cigars and pipe tobacco to avoid regulatory restrictions and higher federal tax rates. Your letter also urges the Food and Drug Administration (FDA or the Agency) to take enforcement action and to issue deeming regulations pursuant to the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

We share your concern about efforts by certain tobacco companies to evade existing tobacco regulations intended to protect the public health and prevent America's youth from using tobacco products. As you know, the Tobacco Control Act provided FDA with immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. Section 901 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, permits FDA to issue regulations deeming other tobacco products, including cigars, cigarillos, little cigars, pipe tobacco, and novel products like electronic cigarettes (e-cigarettes) to be subject to Chapter IX of the FD&C Act.

On July 7, 2011, in the Department of Health and Human Services' Semiannual Regulatory Agenda (Unified Agenda or Agenda), FDA expressed its intention to exercise its authority to close regulatory gaps by issuing a proposed rule deeming other tobacco products to be subject to Chapter IX of the FD&C Act. As part of the Agenda, FDA stated, "This proposed rule would deem products meeting the statutory definition of 'tobacco product' found at section 201(rr) of the FD&C Act to be subject to FDA's jurisdiction." FDA is working diligently to issue the proposed rule for public comment.

Once FDA finalizes this rulemaking, some provisions in Chapter IX of the FD&C Act would then automatically apply to all "deemed" tobacco products (e.g., industry registration, product listing, ingredient listing, user fees for certain products, and the adulteration and misbranding provisions of the statute), while other provisions, such as the ban on certain characterizing flavors in cigarettes, would not apply to newly deemed tobacco products. Promulgation of the deeming regulation, however, would enable FDA

to take further regulatory action with respect to flavorings in other tobacco products, if FDA concludes that it is appropriate to do so to protect the public health.

The deeming regulation continues to be a priority for the Department of Health and Human Services (HHS) and FDA. This rule presents complex regulatory science issues that require careful analyses, and it has taken the Agency longer than originally anticipated to complete the proposed rule.

It should be noted that FDA is actively enforcing the FD&C Act and its implementing regulations. For example, FDA routinely monitors tobacco marketing and advertising activities of regulated entities, conducts inspections of tobacco product manufacturers and retailers, evaluates regulatory submissions and consumer/public complaints, and takes enforcement action whenever appropriate, including, but not limited to, issuing Warning Letters and civil money penalties. Future enforcement actions may include injunctions and no tobacco sale orders. With respect to the issues raised in your letter, FDA issued a Warning Letter on May 24, 2012, to a firm advertising pipe tobacco for use as cigarette tobacco.

Thank you, again, for contacting us concerning this matter and for your ongoing work to reduce the mortality and morbidity associated with tobacco product use in the United States. If you have further questions, please let us know.

Sincerely,

A handwritten signature in blue ink that reads "Ireland". The signature is written in a cursive style with a large, sweeping initial "I" that loops back under the rest of the name.

Jeanne Ireland  
Associate Commissioner  
for Legislation

