Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

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Comments on Draft Guidance for Industry and Food and Drug Administration Staff; Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

Docket No. FDA–2011–D–0125

Ladies and Gentlemen:

The above-designated draft guidance contains two significant policy statements. First, the guidance specifies that a tobacco product is to be considered a new product unless that product was commercially marketed on February 15, 2007. As we noted in our comments on the draft guidance on substantial equivalence, this statement correctly interprets the statutory standard. The clear language of the statute requires this interpretation and excludes any broader definition. Moreover, this interpretation is consistent with the policy of the statute: for products that cause death and disease, exemptions from the premarket approval requirements of Section 910 should be strictly construed.

Moreover, the draft guidance correctly places the burden on the manufacturer to provide proof that the product was commercially marketed on February 15, 2007. As discussed at length in our comments on the draft guidance for substantial equivalence and new product standards, the statute places the burden of proving every element of the statutory standard on the manufacturer. Where, just as here, the consequence of a determination that a product was commercially marketed on February 15, 2007 is to permit that product to be marketed with no further showing that the marketing of the product is appropriate for the protection of the public health and where such product can then become a predicate product that could lead to determinations that other products are substantially equivalent, the need for requiring the manufacturer to bear the burden of proving the necessary factual basis for its claim is strong.

In addition, the guidance correctly states that a product that was only being test marketed on February 15, 2007 was not "commercially" marketed as of that date. The distinction between products that are marketed only for test purposes and products that are "commercially" marketed is well established. The drafters recognized that a product could be "marketed" without being "commercially marketed." Products that are distributed to customers for testing are marketed, but they are not "commercially marketed." Had the drafters of the statute wished to provide grandfathered status to products that were only test marketed on that date, they would not have specified that a product needed to be "commercially" marketed on that date in order to qualify.

Sincerely,

American Cancer Society Cancer Action Network
American Heart Association
Campaign for Tobacco Free Kids
Tobacco Control Legal Consortium

FDA-2011-D-0125

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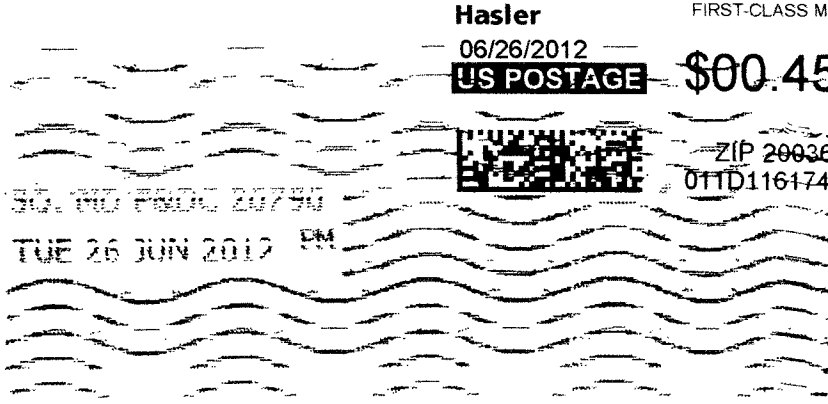
CAMPAIGN for TOBACCO-FREE Kids

1400 EYE STREET, NW • SUITE 1200
WASHINGTON, DC 20005



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