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June 11, 2013

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

RE: Docket No. FDA-2012-N-0920, calculation of user fee assessment

Dear Division of Dockets:

Tantus Tobacco would like to express the following reservations with respect to using excise taxes paid as the basis for calculating market share within the various classifications of tobacco products.

First, using the amount of excise tax paid by a domestic manufacturer or importer to determine market share would clearly favor importers over domestic manufacturers. Taking advantage of lower wages, taxes, regulatory costs and other advantages of off-shore production, importers can typically sell cigars to distributors at a lower price than can domestic manufacturers. Using the excise tax, which is based on the price a domestic manufacturer or importer charges the distributor for the product, to calculate market share would tend to lower an importer's market share liability and increase the liability of a domestic manufacturer. We believe using actual units (sticks for cigarettes, and for cigars when cigars become a regulated product) removed from bonded storage would reflect the true market share. Using excise tax paid to calculate market share would simply be another regulatory hurdle for domestic manufacturers that increases pressures to move production and jobs off-shore.

Second, using excise tax paid to calculate market share would favor companies who do not accurately calculate excise tax (for whatever reason or manner) over companies that do accurately calculate excise tax.

We strongly urge CTP to revisit this aspect of the market share calculation for the FDA user fee.

Sincerely,

Bob Rowland

Director of Government Relations

Tantus Tobacco | 200 Progress Drive

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