DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 10, 2013

Mitchell A. Neuhauser
Managing Counsel - Regulatory
RAI Services Company
401 N. Main Street
P.O. Box 464
Winston-Salem, NC 27102

Re: Docket No. FDA-2013-P-0280

Dear Mr. Neuhauser:

This is our final response to the citizen petition dated March 6, 2013, that you submitted to the Food and Drug Administration (FDA). The citizen petition asks that FDA promulgate a regulation to calculate and assess user fees in such a way that no manufacturer or importer of tobacco products is required to pay such fees in an amount greater than its actual market share-based percentage of a particular class of tobacco products.[1]

Since receiving your citizen petition, FDA has issued a proposed rule on the calculation and assessment of tobacco product user fees (78 Federal Register 32581, May 31, 2013; Docket No. FDA-2012-N-0920). The proposed rule includes provisions designed to help ensure that no manufacturer or importer of tobacco products pays a user fee in excess of the percentage share of that manufacturer or importer (section 919(b)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)(3)(B))). Thus, to the extent your citizen petition seeks to initiate rulemaking, your petition is granted. We invite you to review the proposed rule and submit comments on this rulemaking.

Sincerely,

Leslie Kux
Assistant Commissioner for Policy

[1] We welcome the information you provided regarding alleged cigarette manufacturers who may not have paid user fees that should have been owed and have not registered with FDA as required by section 905 of the FD&C Act (21 U.S.C. 387e). This information has been referred to the appropriate FDA staff and government officials for their review and consideration.