DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville MD 20850-3229

March 26, 2012

In Response Refer to File: *2012-1704*

Americans for Limited Government
9900 Main Street, Suite 303
Fairfax, VA 22031

Dear Mr. Mehrens,

This is in response to William Wilson's March 6, 2012 request for records from the Food and Drug Administration pursuant to the Freedom of Information Act regarding copies of any records of the Center for Tobacco Products (CTP) that exist in any of the following categories that were created on or after January 1, 2011 concerning:

1. Records indicating the number of Substantial Equivalence reports submitted to CTP dealing with existing, modified or new tobacco products;
2. Records indicating the number of these submitted Substantial Equivalence reports that CTP has acted upon; and
3. Records regarding the backlog of Substantial Equivalence reports and CTP's plan of action to address the backlog.

Your request was received in the Center for Tobacco Products on March 8, 2012

The documents you have requested for Item 1 and 2 are enclosed. Please note that all substantial equivalence reports have been acknowledged. CTP does not have any records regarding a backlog or a plan of action for a backlog.

Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination with respect to these records and would like FDA to reconsider any particular deletion, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed with respect to these records. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you would have the right to appeal that decision. Any letter of denial will explain how to make this appeal.

The following charges may be included in a monthly invoice:

Reproduction: 0.60 Search: $11.50 Review:11.50 Certification: $0.00 CD: $0.00 TOTAL: $23.60.

DO NOT SEND ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE.

All communications concerning this request should be identified with the reference number above and addressed as follows:

Food and Drug Administration
Division of Freedom of Information
12420 Parklawn Drive, Room 1050
Rockville, MD 20857

This concludes the response for the Center for Tobacco Products. If I can be of further assistance, please let me know by referencing the above file number. You can reach me by phone at 301-796-8880.

Sincerely,

Katherine Uhl

Katherine Uhl
Supervisory FOIA Specialist
Food and Drug Administration
Center for Tobacco Products

Enclosures