DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Ave.
Silver Spring, MD 20993

September 30, 2015

Cigar Rights of America
Attention: Michael E. Copperman
Director of Legislative and Regulatory Affairs
300 New Jersey Avenue, NW
Suite 900
Washington, DC 20001

Dear Mr. Copperman:

This letter is in response to your Information Quality Act (IQA) Request for Correction dated August 11, 2015. Your Request for Correction concerns the article by Cindy M. Chang, et al., "Systemic Review of Cigar Smoking and All Cause and Smoking Related Mortality," BMC Public Health 15:390, 2015, initially published by the peer-reviewed scientific journal on the BioMed Central website on April 24, 2015 and accessible on FDA's website.[1]

The IQA requires the Office of Management and Budget and federal agencies to develop guidelines to ensure and maximize the quality, objectivity, utility, and integrity of information disseminated by agencies. The guidelines promulgated by HHS and FDA set forth the policies and procedures by which the agency ensures that all the information it disseminates meets the highest standards of quality. However, as these guidelines note, they specifically do not apply to certain types of FDA-disseminated information, including press releases and "Scientific publications that only contain the views of the authors and are not used to support an official agency position."[2]

The peer-reviewed Chang article is accessible on FDA's website in a press release with a link to a database of scientific publications. As stated in the disclaimer on the article, the information contained in the article is the "responsibility of the authors alone" and "does not represent agency position or policy." The use of a disclaimer for the article is consistent with the requirements of the OMB Information Quality Peer Review Bulletin.[3] Therefore, the dissemination referenced in your IQA Request for Corrections falls under the specific exemptions listed in FDA's IQA Guidelines.

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[1] http://www.biomedcentral.com/1471-2458/15/390; http://www.fda.gov/tobaccoproducts/newsevents/ucm452100.htm; and http://www.accessdata.fda.gov/scripts/publications/search_result_record.cfm?id=51907.

[2] http://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public.

[3] 70 FR 2664 (January 14, 2005).

Thank you again for your letter. If you do not agree with this decision on your request, you may send a Request for Reconsideration within 30 days of receipt of this decision. Your Request for Reconsideration should be designated as "Information Quality Appeal" and should include a copy of your original request as well as this decision. Your appeal should state the reasons why you believe this response to your Request for Correction is inadequate. The request may be sent electronically to Ombuds@OC.FDA.gov or by mail to:

FDA Ombudsman
White Oak Building 1, room 4208
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Sincerely,

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director, Office of Science
Center for Tobacco Products