



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0073]

Request for Information on Psychosocial Predictors of Uptake of Tobacco and Other Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is opening a docket to obtain data and information related to psychosocial predictors of uptake and continued use of tobacco products, including specific categories of tobacco products and specific individual tobacco products, as well as other products from which predictors may be adapted for or extrapolated to tobacco products. FDA is seeking data and information in the form of reports and manuscripts that are unpublished or not available through indexed bibliographic databases. The purpose of this request for information (RFI) is to gather additional information that could help identify and evaluate predictors of consumer initiation, uptake, and use of tobacco products. FDA has already searched the publicly available scientific literature and is now seeking to supplement that with information that is not included in the published scientific literature.

DATES: Submit either electronic or written comments or information by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-0073 for “Request for Information on Psychosocial Predictors of Uptake of Tobacco and Other Products.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Shireen Ahmad, Office of Science, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 4462, Silver Spring, MD 20993-0002, 1-877-287-1373, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (Tobacco Control Act) into law. The Tobacco Control Act grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. FDA is conducting a systematic review and meta-analysis of the scientific literature in an effort to identify the best psychosocial predictors that longitudinally predict initiation of tobacco product use, uptake of specific types of tobacco products, and uptake of specific individual tobacco products. This information may be used by FDA in future rulemaking and review of industry submissions.

II. Request for Information

FDA seeks information related to psychosocial predictors of uptake of tobacco and other products. FDA has searched the publicly available scientific literature and is now looking to supplement that search with information from other sources, specifically unpublished data or other information. For the purpose of this RFI, FDA considers “psychosocial predictors” to

include constructs that can be measured at the level of the individual, such as beliefs, attitudes, perceptions, intentions, willingness/openness, curiosity, or other measures that have been used in longitudinal research and demonstrated to be associated with product uptake or initiation. In addition to studies reporting on tobacco products, FDA also would accept information on uptake and use of other products from which predictors may be adapted for or extrapolated to tobacco products. If such information is submitted, it should include an explanation of why the predictor and product could be extrapolated to tobacco products.

For this RFI, FDA is requesting unpublished data (summarized); unpublished or prepublication copies of manuscripts, conference presentations, and/or posters; dissertations and/or theses; and white papers or other unpublished reports. FDA is requesting both data that show associations as well as data that fail to show an association (i.e., null findings).

Specifically, FDA is requesting unpublished data from studies on human subjects (including youth, young adults, and older adults) that include:

- A longitudinal design (observational or experimental) in which there is at least one month between assessments and data are reported for at least two time points;
- At least one psychosocial predictor; and
- A quantifiable (continuous or categorical) outcome measure of actual product use (not intentions to use) related to initiation or uptake.

Outcomes may include:

- Initiation;
- Continued use;
- Progression to more frequent use;
- Choice of a specific product; or

- Other similar outcomes.

Data may come from studies outside of the United States; however, we prefer that reports be submitted in English.

For this RFI, FDA is seeking only quantitative scientific data presented in report or manuscript format, and not data from qualitative studies (e.g., interviews, focus groups), anecdotes, or testimonials. FDA is requesting data and information from all interested parties, including, but not limited to, academic and government researchers, industry, and any other sources.

When submitting information, please include details about how the data were collected, including the sample composition, year(s) of data collection, and a detailed summary of the methods and measures used. For data summaries, please include both point estimates and measures of variance, as well as effect sizes (if available).

Please also note that when submitting information and data to the docket, certain compressed file formats (e.g., zip files) are not allowed. Acceptable file formats include: .doc, .docx, .pdf, .ppt, .pptx, .rtf, .txt, .xls, .xlsx, .xlsm, .xlsb, and .wpd.

Dated: January 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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