Change Request 2016 National Youth Tobacco Survey (NYTS) (OMB no. 0920-0621, approved 01/16/2015, exp. date 01/31/2018)

Date of Request: December 3, 2015 OMB approval is requested by: 12/11/2015

Summary

The NYTS is the only nationally representative survey of middle and high school students that focuses exclusively on tobacco use patterns and associated factors. The NYTS has been conducted periodically since 1999 and annually starting in 2011. Information collection employs a repeat cross-sectional design to develop national estimates of tobacco use and its correlates, including exposure to pro- and anti-tobacco influences among youth. The survey is administered by CDC's Office on Smoking and Health (OSH) in collaboration with FDA's Center for Tobacco Products (CTP). NYTS data are principally used to generate tobacco-related measures that inform (1) CDC's non-regulatory public health programs and activities, and (2) CTP's regulatory activities. The content of the NYTS questionnaire is largely consistent, however in a given year a subset of questions may be added and others removed to reflect changes in the tobacco product landscape as well as to address emergent data needs.

We request the following:

OMB approval of revised NYTS questionnaire content for 2016. See **Attachment I-1**, National Youth Tobacco Survey 2016 Questionnaire. Changes relative to the 2015 version of the questionnaire are summarized in **Attachment I-8**, Crosswalk of Non-substantive changes to 2016 NYTS.

There are no changes to the sampling plan, recruitment methods, estimated burden per response, or total estimated burden hours.

Background and Justification

The NYTS is a paper and pencil questionnaire administered to U.S. middle and high school students, grades 6-12. A probability based, nationally representative sample is used to select schools; within selected schools, classes are randomly selected and all students in the selected classed are eligible to participate. In order to minimize the burden on the schools and students the NYTS is completed in one class period.

In the fall of 2011, OSH and CTP entered into a collaboration to conduct the NYTS on an annual basis, with each agency funding alternate years. OSH and CTP agreed that in order to minimize unnecessary duplication and redundancy, they would collaborate to leverage the NYTS to meet both agencies' goals. The collaboration agreement between OSH and CTP is that the content of NYTS will be decided collaboratively to meet the needs of both agencies. The agreement was described in the Supporting Statement for the current NYTS clearance (see Section A.4, "Typically, NYTS instrument content in odd years will reflect an emphasis on information needed to inform CDC's non-regulatory public health approaches, and NYTS instrument content in even years will reflect an emphasis on information needed to inform FDA's regulatory activities. Thus, the survey is specifically being designed to avoid duplication while meeting the missions of both agencies.").

To comply with the terms of clearance for the currently approved ICR, CDC is requesting approval for non-substantive changes to the 2015 NYTS that will modify the instrument to maintain relevance with emerging tobacco use behaviors among youth. If approved, the proposed modified instrument will be implemented in 2016 to collect comprehensive information that will inform public health and regulatory activities. The changes proposed mainly reflect incremental improvements to existing wording on the approved instrument in a manner such that the overall content remains consistent with topics already covered. New areas of emphasis for the 2016 NYTS include a standalone section for hookah use, one of the leading types of tobacco products used by youth; modifying previously tested questions to capture data on emerging products (e.g., susceptibility to tobacco product use, curiosity); cycling in questions from previous versions of the NYTS questionnaire to create updated estimates of tobacco use behaviors; a modified section on flavored tobacco products; and a modified section on venues for how youth acquire tobacco products. This request also includes a change to the format of instructions that are used as a prelude to specific questions to improve consistency throughout the instrument. Cognitive testing data was also used to support revising the terminology used for assessment of e-cigarette use among youth. The requested changes, deletions, and additions provide the opportunity for new survey content and incremental improvements to existing wording on the approved instrument in a manner such that the overall content remains consistent with topics covered in previous versions of the instrument. The proposed changes will improve the quality of the survey and relevance with emerging tobacco use behaviors and control policies.

The request includes the addition of 19 questions accompanied by the deletion of 17 questions from the 2015 NYTS to keep respondent burden at the same level as previous administrations of the survey. A portion (n=5) of the added proposed questions have been adapted from previous cycles, 2012, 2013, and 2014, of the NYTS. The remaining portion of added questions (n=12) are modifications of questions that were fielded in the 2015 NYTS to reflect emerging products. Two new questions are proposed to capture better contextual information about the settings in which hookah was used by youth, and more detailed data on the types of flavored tobacco youth are using. This data is essential to inform tobacco control programs and policies as recent data has shown that hookah is a rapidly emerging tobacco product².

The 2016 NYTS questionnaire is provided as Attachment I-1. Changes from the 2015 version of the questionnaire are summarized in Attachment I-8.

Inter-agency Coordination and Agency Points of Contact

HHS established a working group on tobacco to improve the coordination, efficiency, and usability of information collected for surveillance, research, regulatory action, and program management. The working group includes representation from ASPE, CDC, FDA, NIH, and SAMSHA. In 2015, CDC and FDA collaborated on the development of the 2016 NYTS Questionnaire. The draft instrument was circulated for comment to the HHS working group and additional partners including NCHS and the CDC/YRBS program. The 2016 NYTS Questionnaire submitted for OMB approval reflects CDC and FDA priorities and the recommendations and expertise of the HHS working group.

¹ Arrazola RA, Singh T, Corey CG, et al. Tobacco use among middle and high school students—United States, 2011–2014. MMWR 2015;64(14):381–5

² Corey CG, Ambrose BK, Apelberg BJ, King BA. Flavored tobacco product use among middle and high school students — United States, 2014. MMWR 2015;64(38):1066-70

René A. Arrazola, MPH CDC (770) 488-2414 RArrazola@cdc.gov Catherine G. Corey, MSPH FDA (301) 796-7396 <u>Catherine.Corey@fda.hhs.gov</u>

Requested OMB Approval Date and Rationale

OMB approval is requested by 12/11/2015. Approval by this date will support logistical preparations for conducting a paper-and-pencil survey in a school-based setting. High participation rates are important because the sampling frame does not allow for replacement of schools that choose not to participate. Therefore lead time is needed to:

- (a) Finalize, print, and distribute the NYTS questionnaires and supplementary materials (e.g., permission forms). CDC is unable to schedule the print order until questionnaire content is finalized and approved by OMB. In addition, production and distribution may be complicated by end-of-year holidays or inclement weather. Adequate lead time will allow CDC and the data collection contractor to coordinate survey logistics in an efficient and cost-effective manner.
- (b) The production schedule for NYTS materials also impacts school participation, as many schools are unable to confirm their participation without guaranteed survey administration dates.

Estimated Timeline

12/11/2015	Target date for receipt of OMB approval
12/16/2015	Submit print order for NYTS materials to CDC/MASO with print due date of mid- January 2016
Mid-January 2016	Initiate distribution of printed materials to selected schools and survey administrators
Mid-February 2016	Initiate information collection for selected schools
June 2016	Complete information collection