

At present, the NYTS is the most comprehensive source of nationally representative tobacco data among students in grades 9–12, moreover, the NYTS is the only source of such data for students in grades 6–8. The NYTS has provided national estimates of tobacco use behaviors, information about exposure to pro- and anti-tobacco influences, information about racial and ethnic disparities in tobacco-related topics, and most recently, estimates of use of emerging products such as water pipes (hookahs) and electronic cigarettes (e-cigarettes). Information collected through the NYTS is used to identify trends over time, to inform the development of tobacco cessation programs for youth, and to evaluate the effectiveness of existing interventions and programs.

CDC plans to request OMB approval to conduct additional cycles of the NYTS in 2015, 2016, and 2017. The survey will be conducted among nationally representative samples of students attending public and private

schools in grades 6–12, and will be administered to students as an optically scannable, eight-page booklet of multiple-choice questions. Information supporting the NYTS also will be collected from state-, district-, and school-level administrators and teachers. During the 2015–2017 timeframe, a number of changes will be incorporated that reflect the collaboration between CDC and the Food and Drug Administration that has been ongoing since 2011 to assist the agency with measuring progress toward meeting strategic goals established by the Family Smoking Prevention and Tobacco Control Act. The 2015 survey will examine the following topics: Use of cigarettes, smokeless tobacco, cigars, pipes, bidis, snus, hookahs, electronic vapor products, and dissolvable tobacco products; knowledge and attitudes; media and advertising; access to tobacco products; secondhand smoke exposure; and cessation. Given the dynamic nature of the tobacco control environment, particularly related to

youth, it may be necessary in the future to make additional requests to OMB for changes in the NYTS instruments to reflect the varying landscape.

Results of the NYTS will continue to be used for public health program planning and evaluation. Information collected through the NYTS is expected to provide measures and data for monitoring progress on one of the 20 tobacco-related objectives for Healthy People 2020 and serve as complementary data for five other tobacco-related objectives.

OMB approval will be requested for three years. Changes described in the Revision request include changes to instrument content, a decrease in the average annualized number of respondents, and a decrease in the average annualized burden hours. There are no changes in the estimated burden per response for any type of respondent. Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
State Administrators	State-level Recruitment Script for the NYTS.	35	1	30/60	18
District Administrators	District-level Recruitment Script for the NYTS.	150	1	30/60	75
School Administrators	School-level Recruitment Script for the NYTS.	220	1	30/60	110
Teachers	Data Collection Checklist for the NYTS.	973	1	15/60	243
Students	National Youth Tobacco Survey	20,077	1	45/60	15,058
Total					15,504

Leroy Richardson,

Chief, Information Collection Review Office,
Office of Scientific Integrity, Office of the
Associate Director for Science, Office of the
Director, Centers for Disease Control and
Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2014–0007]

Proposed Revised Vaccine Information Materials for Td, Tdap, Haemophilus influenzae type b, and Rotavirus Vaccines

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. 300aa–26), the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) develops

vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. HHS/CDC seeks written comment on proposed updated vaccine information materials for tetanus/diphtheria vaccine (Td), tetanus/diphtheria and acellular pertussis vaccine (Tdap), *Haemophilus influenzae* type b (Hib) vaccine, and rotavirus vaccine.

DATES: Written comments must be received on or before August 25, 2014.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2014–0007, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Written comments should be addressed to Suzanne Johnson-DeLeon (msj1@cdc.gov), National Center for

Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A-19, 1600 Clifton Road NE., Atlanta, Georgia 30333.

Instructions: All submissions received must include the agency name and docket number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Skip Wolfe (crw4@cdc.gov), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A-19, 1600 Clifton Road NE., Atlanta, Georgia 30329.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program (VICP).

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps,

rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine information materials and copies of the materials can be found on the CDC Web site at: <http://www.cdc.gov/vaccines/hcp/vis/index.html>.

HHS/CDC is proposing updated versions of the Td, Tdap, Hib, and rotavirus vaccine information statements. We also propose to revise the August 26, 2013 Instructions for the Use of Vaccine Information Statements to include a reference to these vaccine information materials.

The vaccine information materials referenced in this notice are being developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and health care provider groups.

We invite written comment on the proposed vaccine information materials entitled “Td Vaccine: What You Need to Know;” “Tdap Vaccine: What You Need to Know;” “*Haemophilus influenzae* type b Vaccine: What You need to Know;” and “Rotavirus Vaccine: What You Need to Know.” Copies of the proposed vaccine information materials are available at <http://www.regulations.gov> (see Docket Number CDC-2014-0007). Comments submitted will be considered in finalizing these materials. When the final materials are published in the **Federal Register**, the notice will include an effective date for their mandatory use.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0120]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Cosmetic Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 25, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0599. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Cosmetic Labeling Regulations—21 CFR Part 701 (OMB Control Number 0910-0599)—Extension

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the Fair Packaging and Labeling Act (the FPLA) require that cosmetic manufacturers, packers, and distributors disclose information about themselves or their products on the labels or labeling of their products. Sections 201, 301, 502, 601, 602, 603, 701, and 704 of the FD&C Act (21 U.S.C. 321, 331, 352, 361, 362, 363, 371, and 374, respectively) and sections 4 and 5 of the FPLA (15 U.S.C. 1453 and 1454) provide authority to FDA to regulate the labeling of cosmetic