

enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

**Sharon B. Arnold,**  
Deputy Director.

[FR Doc. 2015-12229 Filed 5-19-15; 8:45 am]

**BILLING CODE 4160-90-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Docket No. CDC-2015-0016]

#### Proposed Revised Vaccine Information Materials for Seasonal Influenza 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 the proposed updated vaccine information statements for inactivated and live attenuated influenza vaccines.

**DATES:** Written comments must be received on or before July 20, 2015.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2015-0016, 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](mailto: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 30329.

*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](mailto: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 are found on the CDC Web site at: <http://www.cdc.gov/vaccines/hcp/vis/index.html>.

HHS/CDC is proposing updated versions of the inactivated and live attenuated seasonal influenza vaccine information statements.

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 "Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know" and "Influenza (Flu) Vaccine (Live, Intranasal): What you need to know." Copies of the proposed vaccine information materials are available at <http://www.regulations.gov> (see Docket Number CDC-2015-0016). 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.

Dated: May 14, 2015.

**Ron A. Otten,**

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

[FR Doc. 2015-12240 Filed 5-19-15; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Docket No. CDC-2015-0014]

#### Proposed Revised Vaccine Information Materials for Pneumococcal Conjugate Vaccine (PCV13)

**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 the proposed updated vaccine information statement for pneumococcal conjugate vaccine (PCV13).

**DATES:** Written comments must be received on or before July 20, 2015.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2015-0014, 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](mailto: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 30329.

*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](mailto: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 are found on the CDC Web site at: <http://www.cdc.gov/vaccines/hcp/vis/index.html>.

HHS/CDC is proposing an updated version of the pneumococcal conjugate vaccine (PCV13) vaccine information statement.

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 "Pneumococcal Conjugate Vaccine (PCV13): What You Need to Know." A copy of the proposed vaccine information materials is available at <http://www.regulations.gov> (see Docket Number CDC-2015-0014). 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.

Dated: May 15, 2015.

**Ron A. Otten,**

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

[FR Doc. 2015-12239 Filed 5-19-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0247]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the guidance for industry on formal meetings with sponsors and applicants for Prescription Drug User Fee Act (PDUFA) products.

**DATES:** Submit either electronic or written comments on the collection of information by July 20, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA, (44 U.S.C. 3501-3520), Federal