

Board of Governors of the Federal Reserve System, March 10, 2016.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2016-05777 Filed 3-14-16; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2016-0029]

Proposed Revised Vaccine Information Materials for Polio and Varicella 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 polio and varicella vaccines.

DATES: Written comments must be received on or before May 16, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0029, 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, 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), 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 polio and varicella 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 "Polio Vaccine: What You Need to Know" and "Varicella Vaccine: What You Need to Know." Copies of the proposed vaccine information materials are available at <http://www.regulations.gov> (see Docket Number CDC-2016-0029). 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: March 9, 2016.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0736]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tracking Network for PETNet, LivestockNet, and SampleNet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we) 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 our use of a tracking network to collect and share

safety information about animal food from Federal, State, and Territorial Agencies.

DATES: Submit either electronic or written comments on the collection of information by May 16, 2016.

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-0736 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Tracking Network for PETNet, LivestockNet, and SampleNet." 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: 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: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or

provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Tracking Network for PETNet, LivestockNet, and SampleNet—OMB Control Number 0910-0680—Revision

The Center for Veterinary Medicine and the Partnership for Food Protection developed a web-based tracking network (the tracking network) to allow Federal, State, and Territorial regulatory and public health agencies to share safety information about animal food. Information is submitted to the tracking network by regulatory and public health agency employees with membership rights. The efficient exchange of safety information is necessary because it improves early identification and evaluation of a risk associated with an animal food product. We use the information to assist regulatory agencies to quickly identify and evaluate a risk and take whatever action is necessary to mitigate or eliminate exposure to the risk. The tracking network was developed under the requirements set forth under section 1002(b) of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-085). Section 1002(b) of FDAAA required FDA, in relevant part, to establish a pet food early warning alert system.

Currently we receive two types of reports via the tracking network: (1) Reports of pet food related illness and product defects associated with dog food, cat food, and food for other pets,

which are submitted via the Pet Event Tracking Network (PETNet); and (2) reports of animal food-related illness and product defects associated with animal food for livestock animals, aquaculture species, and horses, which are submitted via LivestockNet. We are revising the collection to include a third type of report that would be submitted via "SampleNet." SampleNet will collect reports about animal food laboratory samples considered adulterated by State or FDA regulators. SampleNet will allow Federal, State, and Territorial regulatory and public health agencies to share laboratory data related to adulterated samples for purposes of surveillance, mitigation, work planning, and supporting the animal food standard requirements.

PETNet and LivestockNet reports share the following common data elements, the majority of which are drop down menu choices: Product details (product name, lot code, product form,

and the manufacturer or distributor/packer (if known)), the species affected, number of animals exposed to the product, number of animals affected, body systems affected, product problem/defect, date of onset or the date product problem was detected, the State where the incident occurred, the origin of the information, whether there are supporting laboratory results, and contact information for the reporting member (*i.e.*, name, telephone number will be captured automatically when member logs in to the system). For the LivestockNet report, additional data elements specific to livestock animals will be captured: Product details (indication of whether the product is a medicated feed under 21 CFR 558.3(b)(8), product packaging, and intended purpose of the product), class of the animal species affected, and production loss. For PETNet reports, the only additional data field is the animal life stage. The proposed SampleNet

reports will have the following data elements, many of which are drop down menu choices: Product information (product name, lot code, guarantor information, date and location of sample collection, and product description); laboratory information (sample identification number, the reason for testing, whether the food was reported to the Reportable Food Registry, who performed the analysis); and results information (analyte, test method, analytical results, whether the results contradict a label claim or guarantee, and whether action was taken as a result of the sample analysis).

Description of Respondents: Respondents to the collection of information are Federal, State, and Territorial regulatory and public health agency employees with membership access to the Animal Feed Network.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
PETNet	20	5	100	0.25 (15 minutes)	25
LivestockNet	20	5	100	0.25 (15 minutes)	25
SampleNet	20	5	100	0.25 (15 minutes)	25
Total					75

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate is based on our experience with the tracking network over the past 3 years. We estimate that we will receive an average of 5 submissions from 20 respondents for each type of report, and that it will take 15 minutes (0.25 hour) per response.

Dated: March 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committees: Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 5, 2016, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Stephanie L. Begansky, Center for Drug Evaluation

and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: AADPAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committees will be asked to discuss new drug application (NDA) 208653, benzhydrocodone/acetaminophen oral tablets, submitted by KemPharm, Inc., with the proposed indication of short-term (up to 14 days)