

of marketed and investigational human drug products for use in the treatment of cancer.

*G. Science Advisory Board to the National Center for Toxicological Research:* Reviews and advises the Agency on the establishment, implementation and evaluation of the research programs and regulatory responsibilities as it relates to NCTR. The Board will also provide an extra-Agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

*H. Vaccines and Related Biological Products Advisory Committee:* Reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, as well as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

## II. Criteria for Members

Persons nominated for membership as consumer representatives on committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

## III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or resume. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

## IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Nominations should include a cover letter and a current curriculum vitae or resume for each nominee, including a current business and/or home address, telephone number, and email address if available, and a list of consumer or community-based organizations for which the candidate can demonstrate active participation. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore, encourages nominations of appropriately qualified candidates from these groups.

Nominations should also specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations should include confirmation that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest. Members will be invited to serve for terms up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as

voting or nonvoting consumer representatives will not participate in the selection process.

Dated: March 30, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-15-0929]

### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written

comments should be received within 30 days of this notice.

**Proposed Project**

World Trade Center Health Program Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program (OMB No. 0920-0929, expiration 04/30/2015)—Revision—Centers for Disease Control and Prevention (CDC), National Institutes for Occupational Safety and Health (NIOSH).

*Background and Brief Description*

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347), amended the Public Health Service Act (PHS Act) to add Title XXXIII establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were

present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

PHS Act § 3312(a)(3) identifies a list of health conditions for which individuals who are enrolled in the WTC Health Program may be monitored or treated. PHS Act § 3312(a)(6)(B) specifies that interested parties may petition the Administrator of the WTC Health Program to request that a new health condition be added to the List of WTC-Related Health Conditions in 42 CFR 88.1. To aid the petitioner, the WTC Health Program provides a petition form to be completed and then sent to the Administrator for review. However, the petitioner is not required to use the form, and may submit a petition in a different format, provided it contains all of the data elements requested on the form.

Data elements include the interested party's name, contact information, signature, and a statement about the medical basis for the relationship/ association between the 9/11 exposure and the proposed health condition, which the Administrator of the WTC Health Program will use to determine

whether to propose a rule to add the condition, to not to add the condition, or to seek a recommendation from the Scientific/Technical Advisory Committee (STAC).

The petition form is amended slightly to reflect a WTC Health Program policy change. The current form asks respondents to offer reference to “a peer-reviewed, published, epidemiologic study.” The revised form will ask respondents to reference “peer-reviewed, published, epidemiologic and/or direct observational studies.”

The submission of a petition is purely voluntary, and is not required or otherwise compelled by NIOSH or the WTC Health Program.

NIOSH expects to receive no more than 20 submissions annually. Petitioners include prospective and enrolled WTC responders, screening-eligible survivors, certified-eligible survivors, or members of groups who advocate on behalf of responders or survivors, such as physicians. It is estimated that an individual spends an average of 40 hours gathering information to substantiate a request to add a health condition and assembling the petition. The total estimated annualized burden hours are 800.

**ESTIMATED ANNUALIZED BURDEN HOURS**

| Type of respondent                            | Form name                                      | Number of respondents | Number of responses per respondent | Average burden per response (hours) |
|---|--|-----------------------|------------------------------------|-------------------------------------|
| Responder/Survivor/Advocate (physician) ..... | Petition for the addition of health conditions | 20                    | 1                                  | 40                                  |

**Leroy A. 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**

**Food and Drug Administration**

[Docket No. FDA-2010-D-0566]

**Residual Solvents in Animal Drug Products; Questions and Answers; Guidance for Industry; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the

availability of a guidance for industry #211 entitled “Residual Solvents in Animal Drug Products; Questions and Answers.” The questions and answers guidance addresses the United States Pharmacopeia (USP) General Chapter <467> Residual Solvents that applies to both human and veterinary drugs and to compendial and non-compendial drug products. This document answers questions regarding the Center for Veterinary Medicine’s (CVM) implementation of USP <467> Residual Solvents.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See

the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Heather Longstaff, Center for Veterinary Medicine (HFV-145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0651, email: [heather.longstaff@fda.hhs.gov](mailto:heather.longstaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of December 3, 2010 (75 FR 75482), FDA published the notice of availability for a draft guidance entitled “Residual Solvents in Animal Drug Products; Questions and Answers” giving interested persons until February