

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.

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

1, 2011, to comment on the draft guidance. FDA received one comment on the draft guidance and that comment was considered as the guidance was finalized. Two of the questions and answers were revised, in addition to a few editorial changes made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated December 2, 2010.

On July 1, 2008, the USP implemented a requirement for the control of residual solvents in drug products marketed in the United States. Once implemented, the requirement, USP General Chapter <467> Residual Solvents, became a statutory requirement under section 501(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351(b)). This document answers questions regarding CVM's implementation of USP <467> Residual Solvents.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Residual Solvents in Animal Drug Products; Questions and Answers." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032; the collections of information in section 512(n)(1) of the FD&C Act (21 U.S.C. 360k) have been approved under OMB control number 0910–0669.

IV. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: March 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than June 8, 2015.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10C–03, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Shortage Designation Management System OMB No. 0906–xxxx–New.

Abstract: HRSA's Bureau of Health Workforce (BHW) is committed to improving the health of the nation's underserved communities and vulnerable populations by developing, implementing, evaluating, and refining programs that strengthen the nation's health workforce. The Department of Health and Human Services relies on two federal shortage designations to identify and dedicate resources to areas and populations in greatest need of providers: Health Professional Shortage Area (HPSA) designations and Medically Underserved Area/Medically Underserved Population (MUA/P) designations. HPSA designations are geographic areas, population groups, and facilities that are experiencing a shortage of health professionals. MUA/P designations are areas, or populations within areas, that are experiencing a shortage of health care services. MUAs are designated for the entire population of a particular geographic area. MUP designations are limited to particular groups of underserved people within an area. These designations are currently used in a number of departmental programs that provide both federal and state government grant/program benefits for communities, health care facilities, and providers. BHW has the responsibility for designating and de-designating HPSAs and MUA/Ps on behalf of the Secretary.

HPSA designations are required to be reviewed and updated regularly to reflect current data. Individual states—through their Primary Care Office (PCO)—have primary responsibility for initiating an application for a new or updated HPSA designation, or withdrawing HPSAs that no longer meet the designation criteria. HRSA reviews the application and makes the final determination on the HPSA designation. Requests come from the PCOs who have access to the online application and review system, Shortage Designation Management System (SDMS). Requests that come from other sources are referred to the PCOs for their review and concurrence. In addition, interested parties, including the Governor, the State Primary Care Association, and state professional associations are notified of each request submitted for their comments and recommendations.

In order to obtain a federal shortage designation for an area, population, or facility, PCOs must submit a shortage designation application through SDMS for review and approval by BHW. Both the HPSA and MUA/P application request local, state, and national data on the population that is experiencing a shortage of health professionals and the number of health professionals relative