and must explain why the concerns underlying the request could not reasonably be addressed by other measures. If an exemption is granted, the applicant, manufacturer, or person responsible for the content of labeling of unapproved drugs must distribute the content of labeling in paper form.

(2) For products regulated by the Center for Drug Evaluation and Research, requests for an exemption should be sent to the Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, or for drug products for which there is no reference listed drug, to the Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. For products regulated by the Center for Biologics Evaluation and Research, requests for an exemption should be submitted to the attention of the appropriate Review Division in the relevant Center for Biologics Evaluation and Research Product Office using the following address: Center for Biologics Evaluation and Research, Food and Drug Administration, Document Control Center, 1401 Rockville Pike (HFM–99), Rockville, MD 20852.

■ 3. In § 201.306, revise paragraph (a)(1)(ii) introductory text and paragraph (b)(2) to read as follows:

§ 201.306 Potassium salt preparations intended for oral ingestion by man.

(a) * * *

(1) * * *

(ii) The labeling either on or within the package from which the drug is to be dispensed or accompanying the package from which the drug is to be dispensed under § 201.100(b)(8) bears adequate information for its use by practitioners in accord with the ''full disclosure'' labeling requirements of § 201.100, including the following warning statement: * * *

* * * * *

(b) * * *

(2) The labeling either on or within the package from which the drug is to be dispensed or accompanying the package from which the drug is to be dispensed under § 201.100(b)(8) bears adequate information for its use by practitioners in accord with the ''full disclosure'' labeling requirements of § 201.100, including a recommendation that patients be directed to dissolve any such tablets in an appropriate amount of liquid and to dilute any such liquid preparations adequately to assure against gastrointestinal injury associated with the oral ingestion of concentrated potassium salt preparations.

■ 4. In § 201.310, revise the third sentence of paragraph (a) to read as follows:

§ 201.310 Phenindione; labeling of drug preparations intended for use by man.

(a) * * * In view of the potentially serious effects found to be associated with preparations of this drug intended for use by man, the Commissioner of Food and Drugs will regard such preparations as misbranded within the meaning of section 502(f)(1) and (2) of the Federal Food, Drug, and Cosmetic Act, unless the label and labeling either on or within the package from which the drug is to be dispensed or accompanying the package from which the drug is to be dispensed under § 201.100(b)(8), and any other labeling furnishing or purporting to furnish information for use of the drug, bear a conspicuous warning statement to the following effect: * * *

* * * * *

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

■ 5. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 6. In § 606.121 revise paragraph (c)(8)(ii) to read as follows:

§ 606.121 Container label.

* * * * *

(c) * * *

(8) * * *

(ii) ''See circular of information for indications, contraindications, cautions, and methods of infusion. To obtain the current circular of information, go to *labels.fda.gov,* or call (insert toll-free telephone number) for a faxed, emailed, or mailed copy.'' This statement must be no smaller than 6-point type.

* * * * *

§ 606.122 [Amended]

■ 7. In § 606.122 introductory text, remove the words ''must be available for distribution'' and add in their place ''must be distributed electronically.''

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 8. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

■ 9. In § 610.60, add paragraph (a)(8) to read as follows:

§ 610.60 Container label.

(a) * * *

(8) The container label for biological products must bear the statement: ''To obtain the current prescribing information, go to *labels.fda.gov,* or call (insert the toll-free telephone number) for a faxed, emailed, or mailed copy.'' This statement must be no smaller than 6-point type. If the container label is incapable of bearing the statement due to inadequate space, the statement must be affixed to the container by other means, such as a peel-back label.

* * * * *

■ 10. In § 610.61, revise paragraphs (k) and (n) and add paragraph (t) to read as follows:

§ 610.61 Package label.

* * * * *

(k) The route of administration recommended, or reference to such directions in an enclosed circular or the electronic prescribing information;

* * * * *

(n) The inactive ingredients when a safety factor, or reference to an enclosed circular or the electronic prescribing information;

* * * * *

(t) The package label for products must bear the statement: ''To obtain the current prescribing information, go to *labels.fda.gov* or call (insert the toll-free telephone number) for a faxed, emailed, or mailed copy.'' This statement must be no smaller than 6-point type.

Dated: December 11, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29522 Filed 12–16–14; 11:15 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2014–0661; FRL–9920–46–Region–5]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Ozone and $PM_{2.5}$ Standards

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a submission by the State of Indiana as a revision to the Indiana State Implementation Plan (SIP). The

submitted regulations revise Indiana's ambient air quality standards for ozone and particulate matter to be consistent with EPA's 2008 ozone and 2012 fine particulate matter National Ambient Air Quality Standards. EPA is therefore approving these SIP revisions in accordance with the requirements of the Clean Air Act. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received on or before January 20, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2014–0661, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: aburano.douglas@epa.gov.*
3. *Fax:* (312) 408–2279.
4. *Mail:* Douglas Aburano, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Douglas Aburano, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Eric Svingen, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–4489, *svingen.eric@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: December 5, 2014.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2014–29587 Filed 12–17–14; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

World Trade Center Health Program; Petition 006—Primary Biliary Cirrhosis; Finding of Insufficient Evidence

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Denial of petition for addition of a health condition.

SUMMARY: On October 20, 2014, the Administrator of the World Trade Center (WTC) Health Program received a petition to add primary biliary cirrhosis (Petition 006) to the List of WTC-Related Health Conditions (List). The Administrator has not found sufficient scientific evidence to conduct an analysis of whether to add primary biliary cirrhosis to the List. Accordingly, the Administrator finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

DATES: The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of December 18, 2014.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst, 1090 Tusculum Ave., MS: C–46, Cincinnati, OH 45226; telephone (855)818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov*.

SUPPLEMENTARY INFORMATION:

A. WTC Health Program Statutory Authority

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 [1] 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).

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his or her designee.

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.1. Within 60 calendar days after receipt of a petition to add a condition to the List, the Administrator must take one of the following four actions described in section 3312(a)(6)(B) and 42 CFR 88.17: (i) Request a recommendation of the STAC; (ii) publish a proposed rule in the **Federal Register** to add such health condition; (iii) publish in the **Federal Register** the Administrator's determination not to

[1] Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm–61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111–347 do not pertain to the WTC Health Program and are codified elsewhere.