phases: One in December of 2016 and one in August 2017 and a total of 61 participants were tested: 24 children younger than 6 years, 17 children aged 6–19 years and 20 adult women. One child younger than six years had a BLL greater than five micrograms of lead per deciliter of blood (µg/dL). The child's parents were notified by phone of the results by the ATSDR Medical Officer and follow-up was conducted by the local PEHSU (Pediatric Environmental Health Specialty Unit.

All participants received their results by mail and the EI report was released and presented to the community in a public meeting in August 2018.

Example 3: Private Well Water Sampling in Dimock, PA

Unconventional natural gas drilling activities have been conducted in the Dimock, PA area for approximately 10 years and local residents complain of poor water quality. In 2012, EPA sampled 64 private wells in the area for contaminants that may be present due to natural gas drilling activities. ATSDR assisted in the analysis of the 2012 data set and the following recommendations were made:

○ People with elevated levels of inorganic analytes in their well water should install a home treatment system, and

○ people with high levels of methane in their well water should vent their well and home and treat their water to eliminate potential buildup of explosive gases.

Additional water sampling was recommended and an EI was conducted in August 2017. For the EI, the 64 residents previously sampled were invited to have their private wells retested: 25 residences agreed participate in the EI sampling. Residents were provided the results of their sampling and an EI report is currently being prepared. It will be presented to the community in a public meeting when completed.

Example 4: Follow-Up Arsenic Urine Testing in Hayden, Arizona

ATSDR completed an EI in 2015 at the ASARCO Hayden Smelter Site in Hayden, AZ. The EI included blood lead and urine arsenic testing. Air monitoring determined that the smelter was not operating during the sample collection period and that, given the short half-life of arsenic in the body, the arsenic results may not be valid.

In 2017, ATSDR retested the participants from the 2015 EI to evaluate their urinary arsenic levels. It was determined that all urinary arsenic levels were below the follow-up level and air data indicate that air arsenic levels in the two weeks prior to testing were consistent with usual levels seen in the community. The EI report is being prepared and a community meeting will be held when the document is released.

All of ATSDR's targeted biological assessments (*e.g.,* urine, blood) and some of the environmental investigations (*e.g.,* air, water, soil, or food sampling) involve participants to determine whether they are or have been exposed to unusual levels of pollutants at specific locations (*e.g.,* where people live, spend leisure time, or anywhere they might come into contact with contaminants under investigation).

Questionnaires, appropriate to the specific contaminant, are generally needed in about half of the EIs (at most approximately 12 per year) to assist in interpreting the biological or environmental sampling results. ATSDR collects contact information (*e.g.,* name, address, phone number) to provide the participant with their individual results. ATSDR also collects information on other possible confounding sources of chemical(s) exposure such as medicines taken, foods eaten, hobbies, jobs, etc. In addition, ATSDR asks questions on recreational or occupational activities that could increase a participant's exposure potential. That information represents an individual's exposure history.

The number of questions can vary depending on the number of chemicals being investigated, the route of exposure (*e.g.,* breathing, eating, touching), and number of other sources of the chemical(s) (*e.g.,* products used, jobs). We use approximately 12–20 questions about the pertinent environmental exposures per investigation. Typically, the number of participants in an individual EI ranges from 10 to 100. Participation is completely voluntary, and there are no costs to participants other than their time. Based on a maximum of 12 EIs per year and 100 participants each, the estimated annualized burden hours are 600.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Exposure Investigation Participants	Chemical Exposure Questions	1,200	1	30/60

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–01993 Filed 2–11–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2019–0002]

Advisory Committee on Immunization Practices (ACIP); Correction

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting with comment period; correction.

SUMMARY: On January 28, 2019, the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) published a notice announcing the next meeting of the Advisory Committee on Immunization Practices on February 27–28, 2019 in Atlanta, GA. The notice did not include the docket number for public comment or instructions for submitting public comment. This notice provides that information for the public.

DATES: The meeting will be held on February 27–28, 2019 at the CDC Tom Harkin Global Communication Center, Centers for Disease Control and

Prevention Headquarters (Building 19), Room 232, 1600 Clifton Road NE, Atlanta, GA 30329. Written comments must be received on or before March 2, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0002 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, 1600 Clifton Rd. NE, Mailstop A–27, Atlanta, GA 30329–4027.

Instructions: All submissions received must include the agency name and Docket Number.

Instructions: 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: Stephanie Thomas, ACIP Committee Management Specialist, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, telephone 404–639–8836, email *ACIP@cdc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public, limited only by room seating. The meeting room accommodates 216 for public seating. Rooms 245, 246, and 247, adjacent to the meeting room, will be available once the meeting room reaches capacity, providing up to 120 additional seats. Time will be available for public comment. The meeting will be webcast live via the World Wide Web; for instructions and more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.* Written public comments submitted by 72 hours prior to the ACIP meeting will be provided to the ACIP members before the meeting.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully review and consider all comments submitted to the docket.

Matters To Be Considered

The agenda will include discussions on human papillomavirus vaccines, pneumococcal vaccines, Japanese encephalitis vaccines, influenza vaccines, anthrax vaccine, hepatitis vaccines, Pertussis vaccine, herpes zoster vaccine, and meningococcal vaccines. A recommendation vote is scheduled for anthrax vaccine and Japanese encephalitis vaccines. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit *https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html.*

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 30, 2019.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–01958 Filed 2–11–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–E–6728 and FDA–2017–E–6727]

Determination of Regulatory Review Period for Purposes of Patent Extension; XADAGO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for XADAGO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 15, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 12, 2019. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 15, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 15, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the