2001, renewed at appropriate intervals, and will expire on August 3, 2015.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

Matters for Discussion: The agenda for the Subcommittee meeting includes the following dose reconstruction program quality management and assurance activities: Discussion of current findings from NIOSH and Advisory Board dose reconstruction blind reviews; discussion of dose reconstruction cases under review (cases involving Hanford, Mound Plant, Y–12, Oak Ridge National Laboratory, Lawrence Livermore National Laboratory, Pacific Proving Grounds, Hooker Electrochemical, Simonds Saw and Steel, Bethlehem Steel, Weldon Spring, W.R. Grace, Westinghouse, International Minerals and Chemical (IMC) Corporation, Koppers Company, Bridgeport Brass, Uranium Mill in Monticello, General Steel Industries, and DuPont Deepwater Works); and preparation of the Advisory Board's next report to the Secretary, HHS, summarizing the results of completed dose reconstruction reviews.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road NE., Mailstop E–20, Atlanta GA 30333, Telephone (513)533–6800, Toll Free 1(800)CDC–INFO, Email *ocas@cdc.gov.*

The Director, Management Analysis and Services Office, 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.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–23857 Filed 10–6–14; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices (ACIP)

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announce the following meeting of the aforementioned committee.

Times and Dates:

8:00 a.m.–5:45 p.m., EDT, October 29, 2014

8:00 a.m.–1:15 p.m., EDT, October 30, 2014

Place: Centers for Disease Control and Prevention, Tom Harkin Global Communications Center, 1600 Clifton Road NE., Building 19, Kent ''Oz'' Nelson Auditorium, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The committee is charged with advising the Director, CDC, on the appropriate use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. Further, under provisions of the Affordable Care Act, at section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been adopted by the Director of the Centers for Disease Control and Prevention must be covered by applicable health plans.

Matters for Discussion: The agenda will include discussions on: General recommendations; human papillomavirus vaccines; influenza; novel influenza vaccines, tetanus, diphtheria, and acellular pertussis vaccine (Tdap); meningococcal vaccines; child/adolescent immunization schedule; adult immunization schedule; immunization safety; hepatitis vaccines; typhoid vaccines; and vaccine supply. Recommendation votes are scheduled for general recommendations, child/adolescent immunization schedule, adult immunization schedule and typhoid vaccines. Time will be available for public comment.

Agenda items are subject to change as priorities dictate. *Contact Person for More Information:* Stephanie Thomas, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road NE., MS–A27, Atlanta, Georgia 30333, telephone 404/639–8836; Email *ACIP@CDC.GOV*

Meeting is Webcast live via the World Wide Web; for instructions and more information on ACIP please visit the ACIP Web site: *http://www.cdc.gov/vaccines/acip/index.html.*

The Director, Management Analysis and Services Office, 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.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–23856 Filed 10–6–14; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Orphan Drugs; Common European Medicines Agency/Food and Drug Administration Application Form for Orphan Medicinal Product Designation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by November 6, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0167. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Orphan Drugs; Common European Medicines Agency/Food and Drug Administration Application Form for Orphan Medicinal Product Designation—21 CFR Part 316 (OMB Control Number 0910–0167)—Revision

FDA is amending the 1992 Orphan Drug Regulations, part 316 (21 CFR part 316). The 1992 regulations were issued to implement sections 525 through 528 of the Orphan Drug Act Amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360aa through 360ee). The 1992 regulations specify the procedures for sponsors of orphan drugs to use in obtaining the incentives provided for in the FD&C Act and set forth the procedures that FDA will use in administering the FD&C Act.

The amendments are intended to clarify regulatory provisions and make minor improvements to address issues that have arisen since the issuance of the regulations in 1992. They are intended to assist sponsors who are seeking and who have obtained orphan drug designations, as well as FDA in its administration of the orphan drug program. Except with respect to the two revisions addressed further, the revisions in this rule clarify existing language and do not constitute a substantive or material modification to the approved collections of information in current part 316 (see 5 CFR 1320.5(g)). The collections of information in current part 316 have been approved by OMB in accordance with the PRA under OMB control number 0910–0167.

One revision concerns the name of the drug in an orphan-drug designation request. As provided in current § 316.20(b)(2) (*Content and format of a request for orphan-drug designation*), requests for orphan-drug designation must include the generic and trade name, if any, of the drug. For some products, however, neither a generic nor trade name may be available. This can be the case for some large and complicated biological products or for any molecule for which the sponsor has not yet obtained a trade name. Under § 316.20(b)(2) as revised, requests for designation must include a chemical name or a meaningful descriptive name of the drug if neither a generic nor trade name is available. Drug names need to be meaningful to the public because the Orphan Drug Act (Pub. L. 97–414) requires that notice respecting designation of a drug be made available to the public (section 526(c) of the FD&C Act and § 316.28 (*Publication of orphan drug designations*)). Internal business codes or other similar identifiers do not suffice for publication purposes, as they do not provide meaningful notice to the public of a designation. By providing a chemical name or a meaningful descriptive name of a drug in a request for designation, if neither a generic nor trade name is available, sponsors would help ensure that the name of the product that FDA ultimately publishes upon designation is accurate and meaningful.

FDA regulations are currently silent on when sponsors must respond to a deficiency letter from FDA on an orphan-drug designation request. FDA sends such deficiency letters when a request lacks necessary information or contains inaccurate information, i.e., miscalculated prevalence estimate. This rule revises § 316.24(a) (*Deficiency letters and granting orphan-drug designation*) to include a requirement that sponsors respond to deficiency letters from FDA on designation requests within 1 year of issuance of the deficiency letter, unless within that time frame the sponsor requests an extension of time to respond. FDA will grant all reasonable requests for an extension. In the event the sponsor fails to respond to the deficiency or request an extension of time to respond within the 1-year time frame, FDA may consider the designation request voluntarily withdrawn. This proposal is necessary to ensure that designation requests do not become ''stale'' by the time they are granted, such that the basis for the initial request may no longer hold.

Sections 525 through 528 of the FD&C Act give FDA statutory authority to do the following: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316, specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the FD&C Act, and set forth procedures FDA will use in administering the FD&C Act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Section 316.20 specifies the content and format of an orphan drug application, which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.26 allows an applicant to amend the applications under certain circumstances. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

The information requested from respondents, for the most part, is an accounting of information already in the possession of the applicant. It is estimated, based on frequency of requests over the past 3 years, that 275 persons or organizations per year will request orphan-drug designation and none will request formal recommendations on design of preclinical or clinical studies.

In the **Federal Register** of April 16, 2014 (79 FR 21471), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section/FDA Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
316.10, 316.12, and 316.14	2	1	2	100	200
316.20, 316.21, and 316.26	225	2	450	150	67,500
Form FDA 3671	50	3	150	45	6,750
316.22	65	1	65	2	130
316.27	43	1	43	5	215
316.30	450	1	450	3	1,350
316.36	2	3	6	15	90
Total					76,235

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

Dated: October 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23846 Filed 10–6–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0222]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: On July 16, 2014, the Agency submitted a proposed collection of information entitled ''Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0693. The approval expires on August 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: October 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23842 Filed 10–6–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0432]

Pathological Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint To Support Accelerated Approval; 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 entitled ''Pathological Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval.'' This guidance is intended to assist applicants in designing trials to support marketing approval of drugs to treat breast cancer in the neoadjuvant (preoperative) setting using pathological complete response (pCR) as a surrogate endpoint that could support approval under the accelerated approval regulations. Despite advances in systemic therapy of early-stage breast cancer over the past few decades, there remains a significant unmet medical need for certain high-risk or poor prognosis populations of early-stage breast cancer patients. This guidance is intended to encourage industry innovation and expedite the development of breakthrough therapies to treat high-risk early-stage breast cancer. This guidance finalizes the draft guidance issued May 30, 2012.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. 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: Tatiana Prowell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2112, Silver Spring, MD 20993–0002, 301–796–2330.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Pathological Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval.'' Under the accelerated approval regulations (21 CFR part 314, subpart H, and 21 CFR part 601, subpart E), FDA may grant marketing approval for a new drug on the basis of adequate and well-controlled trials establishing