additive petition ranges from $1,600 to $3,000, depending on the intended use of the color and the scope of the requested amendment. A complete schedule of fees is set forth in § 70.19. An average of one Category A and one Category B color additive petition is expected per year. The maximum color additive petition fee for a Category A petition is $2,600 and the maximum color additive petition fee for a Category B petition is $3,000. Because an average of 2 color additive petitions are expected per calendar year, the estimated total annual cost burden to petitioners for this start-up cost would be less than or equal to $5,600 (1 × $2,600 + 1 × $3,000 listing fees = $5,600). There are no capital costs associated with color additive petitions.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for § 70.25 and § 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 179, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: April 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08590 Filed 4–15–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0386]

Agency Information Collection Activities; Proposed Collection; Comment Request; Orphan Drugs Products: 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Orphan Drug Products: Common EMEA/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671).

DATES: Submit written or electronic comments on the collection of information by June 16, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Orphan Drugs—21 CFR Part 316 (OMB Control Number 0910–0167)—Extension

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 (21 U.S.C. 360aa through 360ee) (the FD&C Act). 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 or trader 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 identifies 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 gives 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 and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the FD&C Act and sets 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 non-clinical 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, 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	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
FDA Form 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: April 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08589 Filed 4–15–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Advancing the Development of Pediatric Therapeutics: Pediatric Bone Health; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; rescheduling of public workshop.

The Food and Drug Administration's (FDA) Pediatric and Maternal Health Staff in the Center for Drug Evaluation and Research and the Office of Pediatric Therapeutics are announcing the rescheduling of a 1-day public workshop entitled ''Advancing the Development of Pediatric Therapeutics (ADEPT): Pediatric Bone Health.'' The purpose of this initial workshop is to provide a forum to consider issues related to advancing pediatric regulatory science in the evaluation of bone health in pediatric patients. The workshop scheduled for March 4, 2014, was postponed due to unanticipated weather conditions and rescheduled for June 3, 2014.

Date and Time: The public workshop will be held on June 3, 2014, from 8 a.m. to 5:30 p.m. This workshop is being rescheduled because of a postponed workshop announced in the **Federal Register** of February 6, 2014 (79 FR 7205), originally scheduled for March 4, 2014.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, Rm. 2047, Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security procedures will be performed. Please visit the following Web site for location, parking, security, and travel information: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Denise Pica-Branco, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1732, FAX: 301–796–9858, email: *denise.picabranco@fda.hhs.gov.*

Registration: There is no fee to attend the public workshop, but attendees should register in advance. Space is limited and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at *PediatricBoneHealth@fda.hhs.gov* before May 23, 2014. If you registered for the workshop before March 4, 2014, you *must re-register* for the workshop. For those without Internet access, please contact Denise Pica-Branco (see *Contact Person*) to register. Onsite registration *will not* be available.

If you need special accommodations due to a disability, please contact Denise Pica-Branco (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA has engaged experts to address challenging issues related to the evaluation of effects on bone health for products used to treat pediatric patients. Identification of signals in animal studies and adult clinical trials that warrant further clinical investigation and identification of biomarkers that may be predictive of bone health in children will be discussed. Additionally, strategies and methods to address the challenges of assessing long-term bone health for products used to treat pediatric patients will be discussed.

Information about this meeting is also available at *http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm.*

Dated: April 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08592 Filed 4–15–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0406]

Proposed Strategy and Recommendations for a Risk-Based Framework for Food and Drug Administration Safety and Innovation Act Health Information Technology; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Proposed Strategy and Recommendations for a Risk-Based Framework for Food and Drug Administration Safety and Innovation Act Health Information Technology.'' FDA, the Office of the National Coordinator for Health Information Technology (ONC), and the Federal Communication Commission (FCC) (collectively referred for the purpose of this notice as ''the Agencies'' [1]) seek broad input from stakeholders and experts on the proposed strategy and recommendations for a risk-based framework for the Food and Drug Administration Safety and Innovation Act (FDASIA) Health Information Technology (IT). The topic to be discussed is the FDASIA Health IT report that contains a proposed strategy and recommendations on an appropriate, risk-based framework for health IT that promotes innovation, protects patient safety, and avoids regulatory duplication.

DATES: *Dates and Times:* The public workshop will be held on May 13–15, 2014, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at National Institute of Standards and Technology, 100 Bureau Dr., Building 101, Red Auditorium, Gaithersburg, MD 20899–1070.

Contact Person: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993, 301–796–5528, email: *Bakul.patel@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. on May 2, 2014. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. Onsite registration on the day of the public workshop will not be available.

If you need special accommodations due to a disability, please contact Susan Monahan, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 4321, Silver Spring MD 20993, 301–796–5661, email: *susan.monahan@fda.hhs.gov* no later than April 29, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public

[1] ONC is not an agency, but an office, within the Department of Health and Human Services.