adjustment provisions with an annual operating reserve adjustment to provide for adequate carryover resources.

J. Impact of PDUFA VI Enhancements on User Fee Revenue

To implement the proposed enhancements for PDUFA VI, funding for a cumulative total of 230 FTE staff is proposed to be phased in over the course of PDUFA VI. The new funding will be phased in as follows:

- $20,077,793 for FY 2018
- $21,317,472 for FY 2019
- $16,953,329 for FY 2020
- $5,426,896 for FY 2021
- $2,769,609 for FY 2022

In addition, $8.73 million will be added in FY 2018 to provide for other additional direct costs associated with the PDUFA VI enhancements. This amount will be included for FYs 2019 through 2022 after being adjusted for inflation.

IV. Purpose and Scope of the Meeting

If you wish to attend this meeting, visit *http://pdufareauthorization.eventbrite.com.* Please register by August 8, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Graham Thompson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

The meeting will include a presentation by FDA and a series of invited panels representing different stakeholder groups identified in the statute (such as patient advocacy groups, consumer advocacy groups, health professionals, and regulated industry). We will also provide an opportunity for other organizations and individuals to make presentations at the meeting or to submit written comments to the docket before the meeting.

FDA will also hold an open public comment period at the meeting to give the public an opportunity to present their comments. Registration for open public comment will occur at the registration desk on the day of the meeting and workshop on a first-come, first-served basis.

Transcripts: As soon as a transcript is available, FDA will post it at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm446608.htm.*

Dated: July 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16916 Filed 7–15–16; 4:15 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0403]

Agency Information Collection Activities; Proposed Collection; Comment Request; Protection of Human Subjects: Informed Consent; Institutional Review Boards

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 the collection of information related to certain regulations that provide protection for human subjects of clinical investigations conducted in support of applications or submissions to FDA for FDA-regulated products. The regulations provide protection of the rights, safety, and welfare of human subjects involved in research activities within FDA's jurisdiction.

DATES: Submit either electronic or written comments on the collection of information by September 19, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0403 for ''Protection of Human Subjects; Informed Consent; Institutional Review Boards.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available

for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20851, *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.

Protection of Human Subjects; Informed Consent; Institutional Review Boards—21 CFR Parts 50 and 56—OMB Control Number 0910–0755—Extension

Part 50 (21 CFR part 50) applies to all clinical investigations regulated by FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i) and 360j(g), respectively), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA, including foods and dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with part 50 is intended to protect the rights and safety of subjects involved in investigations filed with FDA under sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513–516, 518–520, 721, and 801 of the FD&C Act (21 U.S.C. 343, 346, 348, 350a, 350b, 352, 353, 355, 360, 360c–360f, 360h–360j, 379e, and 381, respectively) and sections 351 and 354–360F of the Public Health Service Act.

With few exceptions, no investigator may involve a human being as a subject in FDA-regulated research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (see § 50.20 (21 CFR 50.20)). In seeking informed consent, each subject must be provided with certain elements of informed consent. Those elements are listed in § 50.25. Informed consent shall be documented in writing as described in § 50.27.

An institutional review board (IRB) may approve emergency research without requiring the informed consent of all research subjects provided the IRB finds and documents that certain criteria are met as required in § 50.24. We estimate that about eight times per year an IRB is requested to review emergency research under § 50.24. We estimate, of the eight yearly requests for IRB review under § 50.24, a particular IRB will take about an hour during each of three separate fully convened IRB meetings to review the request under § 50.24 (one meeting occurring after community consultation). The total annual reporting burden for IRB review of emergency research under § 50.24 is estimated at 24 hours (see table 1).

The information requested in the regulations for exception from the general requirements for informed consent for medical devices (21 CFR 812.47), and the information requested in the regulations for exception from the general requirements of informed consent in § 50.23, paragraphs (a) through (c), and (e), is currently approved under OMB control number 0910–0586. The information requested in the investigational new drug (IND) regulations concerning exception from informed consent for emergency research under § 50.24 is currently approved under OMB control number 0910–0014. In addition, the information requested in the regulations for IND safety reporting requirements for human drug and biological products and safety reporting requirements for bioavailability and bioequivalence studies in humans (21 CFR 320.31(d), and 21 CFR 312.32(c)(1)(ii) and (iv)) is currently approved under OMB control number 0910–0672.

Some clinical investigations involving children, although otherwise not approvable, may present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (see § 50.54). Certain clinical investigations involving children may proceed if the IRB finds and documents that the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children and when the Commissioner of Food and Drugs, after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment, makes a determination that certain conditions are met (see § 50.54(b)).

The information requested for clinical investigations in children of FDA-regulated products is covered by the collections of information in the IND regulations (part 312 (21 CFR part 312)), the investigational device exemption (IDE) regulations (part 812 (21 CFR part 812)), the IRB regulations (§ 56.115 (21 CFR 56.115)), the food additive petition and nutrient content claim petition regulations (21 CFR 101.69 and 101.70), and the infant formula regulations (parts 106 and 107 (21 CFR parts 106 and 107)), all of which are approved by OMB. Specifically, the information

collected under the IND regulations is currently approved under OMB control number 0910–0014. The information collected under the IDE regulations is currently approved under OMB control number 0910–0078. The information collected under the IRB regulations is currently approved under OMB control number 0910–0130. The information collected in food additive and nutrient content claim petitions is currently approved under OMB control number 0910–0381 (general requirements) and 0910–0016 (FDA Form 3503). The information collected under the infant formula regulations is currently approved under OMB control number 0910–0256 (general requirements) and 0910–0188 (infant formula recalls).

Part 56 (21 CFR part 56) contains the general standards for the composition, operation, and responsibility of an IRB that reviews clinical investigations regulated by FDA under sections 505(i) and 520(g) of the FD&C Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA, including foods and dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with part 56 is intended to protect the rights and welfare of human subjects involved in such investigations.

The information collected under the IRB regulations ''Protection of Human Subjects—Recordkeeping and Reporting Requirements for Institutional Review Boards (part 56),'' including the information collection activities in the provisions in § 56.108(a)(1) and (b), is currently approved under OMB control number 0910–0130. The information collected under the regulations for the registration of IRBs in § 56.106 is currently approved under OMB control number 0990–0279. The information collected for IRB review and approval for the IDE regulations (part 812) is currently approved under OMB control number 0910–0078. The information collected for premarket approval of medical devices (part 814 (21 CFR part 814)) is currently approved under OMB control number 0910–0231. The information collected under the regulations for IRB requirements for humanitarian use devices (part 814, subpart H) is currently approved under OMB control number 0910–0332. The information collected under the regulations for IRB review and approval of INDs (part 312) is currently approved under OMB control number 0910–0014.

This collection of information is limited to certain provisions in part 50, subpart B (Informed Consent of Human Subjects), and part 56 (Institutional Review Boards), currently approved under OMB control number 0910–0755.

This proposed extension applies to the following collections of information in part 50: §§ 50.24 (*Exception from informed consent requirements for emergency research.*), 50.25 (*Elements of informed consent.*), and 50.27 (*Documentation of informed consent.*).

In part 56, this proposed extension applies to the following collections of information: § 56.109(d) (written statement about research when documentation of informed consent is waived); § 56.109(e) (IRB written notification to approve or disapprove research); § 56.109(f) (continuing review of research); § 56.109(g) (IRB written statements to the sponsor about required public disclosures related to emergency research under § 50.24); § 56.113 (*Suspension or termination of IRB approval of research.*); § 56.120(a) (IRB response to lesser administrative actions for noncompliance); and, § 56.123 (*Reinstatement of an IRB or an institution.*).

In § 56.109(d), if an IRB has waived documentation of consent for research that (1) presents no more than minimal risk of harm to subjects and (2) involves no procedures for which consent is normally required outside of the research context, the IRB may nevertheless require the investigator to provide a written statement about the research to the subjects. We estimate that each IRB will review about two minimal risk FDA-regulated studies each year. Because the studies are minimal risk, the review can be fairly straightforward, and the written statement for the subjects would be brief. We estimate that IRB review of each written statement could be completed in less than 30 minutes (0.5 hours).

In § 56.109(f), the amount of time an IRB spends on the continuing review of a particular study will vary depending on the nature and complexity of the research, the amount and type of new information presented to the IRB, and whether the investigator is seeking approval of substantive changes to the research protocol or informed consent document. For many studies, continuing review can be fairly straightforward, and the IRB should be able to complete its deliberations and approve the research within a brief period of time.

In § 56.109(g), an IRB is required to provide the sponsor of a study involving an exception from informed consent for emergency research under § 50.24 with a written statement of information that has been publicly disclosed to the communities in which the investigation will be conducted and from which the subjects will be drawn. Public disclosure prior to initiation of the investigation would include the plans for the investigation and its risks and expected benefits. There must also be public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results. (See § 50.24(a)(7)(ii) and (iii).) The purpose of the IRB's written statements is to make the sponsor aware that public disclosure has occurred, so that the sponsor can provide copies of the information that has been disclosed to FDA, as required by 21 CFR 312.54(a) and 812.47(a).

We estimate that about eight requests to review emergency research under § 50.24 are submitted each year, and the IRBs that review those studies would prepare two public disclosure reports: One prior to initiation of the research and one following the study's completion. We estimate that it will take an IRB approximately 1 hour to prepare a written statement to the study sponsor describing each public disclosure, for a total of 2 hours per study. The total annual third party disclosure burden for IRBs to fulfill this requirement related to emergency research under § 50.24 is estimated at 16 hours (see table 2).

When an IRB or institution violates the regulations, FDA issues to the IRB or institution a noncompliance letter (see § 56.120(a)). The IRB or institution must respond to the noncompliance letter describing the corrective actions that will be taken by the IRB or institution. FDA estimates about seven IRBs or institutions will be issued a noncompliance letter annually. We estimate that the IRB's or institution's response will take about 10 hours to prepare, with an estimated total annual burden of 70 hours.

In 2016, FDA disqualified one IRB under § 56.121. To date, no IRB or institution has been reinstated or applied for reinstatement under § 56.123. For this reason, we estimate the annual reporting burden for one respondent only. We estimate a 5-hour burden per response, with an estimated total annual burden of 5 hours.

The regulatory provisions in parts 50 and 56 currently approved under this collection of information, OMB control number 0910–0755, and for which this extension is requested, are shown in table 1.

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
56.109(d) Written statement about minimal risk research when documentation of informed consent is waived	2,520	2	5,040	0.5 (30 minutes)	2,520
56.109(e) IRB written notification to approve or disapprove research; 56.109(f) Continuing review; 50.25 Elements of informed consent; and 50.27 Documentation of informed consent	2,520	40	100,800	1	100,800
50.24 Exception from informed consent requirements for emergency research	8	3	24	1	24
56.113 Suspension or termination of IRB approval of research	2,520	1	2,520	0.5 (30 minutes)	1,260
56.120(a) IRB response to lesser administrative actions for noncompliance	7	1	7	10	70
56.123 Reinstatement of an IRB or an institution	1	1	1	5	5
Total					104,679

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
56.109(g) IRB written statement about public disclosures to sponsor of emergency research under 50.24	8	2	16	1	16

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

Dated: July 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17016 Filed 7–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0315]

E2C(R2) Periodic Benefit-Risk Evaluation Report and E2C(R2) Periodic Benefit-Risk Evaluation Report—Questions and Answers; International Council for Harmonisation; Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of guidances for industry entitled ''E2C(R2) Periodic Benefit-Risk Evaluation'' (E2C(R2) guidance) and ''E2C(R2) Periodic Benefit-Risk Evaluation Report—Questions and Answers'' (E2C(R2) Q&A guidance). These guidances were prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The E2C(R2) draft guidance, issued April 11, 2012, updated and combined two ICH guidances, ''E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs'' (E2C guidance) and ''Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs'' (addendum to the E2C guidance). The E2C(R2) guidance is intended to describe the format, content, and timing of a Periodic Benefit-Risk Evaluation Report (PBRER) for an approved drug or biologic, and it finalizes the draft guidance. The E2C(R2) Q&A guidance is a supplementary guidance that is intended to clarify key issues in the E2C(R2) guidance.

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').