4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0403]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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-NEW and title "Protection of Human Subjects: Informed Consent; Institutional Review Boards." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7726, Ila.Mizrachi@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.

Protection of Human Subjects: Informed Consent; Institutional Review Boards--(OMB Control Number 0910-NEW)

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 the 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). 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 five times per year an IRB is requested to review emergency research under § 50.24. We estimate, of the five 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 15 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 21 CFR 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 312.32(c)(1)(ii) and (c)(1)(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 (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 (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 0910-0279. 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 OMB control number 0910-0014.

This new collection of information is limited to certain provisions in part 50, subpart B (informed consent of human subjects), and part 56 (IRBs), not currently approved under the OMB control numbers referenced elsewhere in this document. Those new proposed collections of information in part 50 are §§ 50.24 (emergency research), 50.25 (elements of informed consent), and 50.27 (documentation of informed consent).

In part 56, those new proposed collections of information are in § 56.109(e) (IRB written notification to approve or disapprove research); § 56.109(f) (continuing review of research); § 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 institution).

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.

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 five 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 50 hours.

To date, no IRB or institution has been disqualified by FDA under § 56.121. Therefore, no IRB or institution has been reinstated 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.

Those regulatory provisions in parts 50 and 56 not currently approved under certain OMB control numbers are shown in table 1.

In the Federal Register of April 24, 2013 (78 FR 24208), 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	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
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	6,000	40	240,000	1	240,000
50.24 Exception from Informed Consent for Emergency Research	5	3	15	1	15
56.113 Suspension or Termination of IRB Approval of Research	6,000	1	6,000	0.5 (30 minutes)	3,000
56.120(a) IRB Response to Lesser Administrative Actions for Noncompliance	5	1	5	10	50
56.123 Reinstatement of an IRB or Institution	1	1	1	5	5
Total					243,070

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

Dated: July 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-17550 Filed 07/22/2013 at 8:45 am; Publication Date: 07/23/2013]