

and international officials and scientists to establish and maintain dietary surveillance systems related to maternal and child health, chronic disease nutrition, and risk factors; (3) analyzes, interprets, and disseminates data from surveys, surveillance activities, and epidemiologic studies related to maternal and child nutrition and nutrition factors affecting chronic disease; (4) designs, implements, and evaluates epidemiologic studies and intervention projects for domestic and international application to address micronutrient nutrition; (5) develops and disseminates nutrition guidelines and recommendations for maternal and child health, child growth and development, and prevention/reduction of chronic disease; (6) coordinates and collaborates with appropriate Federal agencies, national and international organizations, and other partners to strengthen and extend nutrition surveillance and epidemiology; and (7) conducts cross-functional nutrition-related activities throughout NCCDPHP.

**Physical Activity and Health Branch (CUCHD).** (1) Plans, coordinates, and conducts surveillance activities in domestic and international settings related to physical activity levels as well as factors associated with physical activity practices; (2) conducts epidemiologic research related to physical activity and its impact on health, obesity, and chronic disease; (3) provides leadership in the development of evidence-based guidelines and recommendations for physical activity; (4) provides technical expertise, consultation and training to state, local, and international officials related to physical activity; (5) disseminates findings from surveillance and epidemiologic research through publications in scientific literature; (6) coordinates and collaborates with appropriate Federal agencies, national and international organizations, and other partners to strengthen and extend surveillance and epidemiology related to physical activity and health and to enhance development of science-based guidelines and recommendations for physical activity; and (7) conducts cross-functional physical activity-related activities throughout NCCDPHP.

**Obesity Prevention and Control Branch (CUCHG).** (1) Plans, coordinates, and conducts surveillance to assess levels of healthy weight, overweight, and obesity and associated factors and behaviors; (2) provides expertise, consultation and training to state, local, and international officials and scientists to establish and maintain surveillance systems related to healthy weight, overweight, and obesity; (3) analyzes,

interprets, and disseminates data from surveys, surveillance activities, and epidemiologic studies related to obesity and overweight; (4) designs, implements, and evaluates epidemiologic studies and intervention projects; (5) develops and disseminates guidelines and recommendations; (6) coordinates and collaborates with appropriate Federal agencies, national and international organizations, and other partners to strengthen and extend surveillance and epidemiology; and (7) conducts cross-functional obesity-related activities throughout NCCDPHP.

**Program Development and Evaluation Branch (CUCHH).** (1) Provides programmatic leadership, technical expertise, and guidance for state-based nutrition, physical activity, and obesity prevention programs; (2) delivers technical assistance and consultation to states, communities, and the public in health promotion and chronic disease prevention; (3) identifies and promotes effective program management approaches and ensures performance-based distribution of public funds; (4) uses research findings, guidelines, and recommendations to develop strategies and interventions that support physical activity, good nutrition, and health weight; (5) conducts behavioral and communications research to understand knowledge, attitudes, and beliefs, and institute health-conscious behavior changes in populations; (6) conducts research to identify effective outreach strategies, particularly for underserved populations and those at highest risk of chronic disease; (7) obtains, analyzes, disseminates, and publishes data from state-based programs to develop operational strategies for translation of results into improved and promising practices; (8) monitors, tracks, and evaluates program interventions and activities for health impact; and (9) establishes and maintains collaborative relationships with external partners and groups, including research institutions, schools of public health, medical schools, state health departments, national and voluntary organizations, and others to ensure that the Division's efforts reflect state-of-the-art practices and methods.

Dated: June 20, 2007.

**William H. Gimson,**

*Chief Operating Officer, Centers for Disease Control and Prevention (CDC).*

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**BILLING CODE 4163-18-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0241]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; 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 recordkeeping requirements for institutional review boards (IRBs).

**DATES:** Submit written or electronic comments on the collection of information by August 27, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. 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:** Elizabeth Berbakos, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**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.

**Institutional Review Boards—21 CFR 56.115 (OMB Control Number 0910-0130)—Extension**

When reviewing clinical research studies regulated by FDA, IRBs are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: Written procedures describing the structure and membership of the IRB and the methods that the IRB will use in performing its functions; the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; minutes of meetings showing attendance, votes and decisions made by the IRB, the number of votes on each

decision for, against, and abstaining, the basis for requiring changes in or disapproving research; records of continuing review activities; copies of all correspondence between investigators and the IRB; statement of significant new findings provided to subjects of the research; and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by FDA in conducting audit inspections of IRBs to determine whether IRBs and clinical investigators are providing adequate protections to human subjects participating in clinical research.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
56.115	5,000	14.6	73,000	100	7,300,000
Total					7,300,000

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The recordkeeping requirement burden is based on the following: The burden for each of the paragraphs under 21 CFR 56.115 has been considered as one estimated burden. FDA estimates that there are approximately 5,000 IRBs. The IRBs meet on an average of 14.6 times annually. The agency estimates that approximately 100 hours of person-time per meeting are required to meet the requirements of the regulation.

Dated: June 21, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2006N-0430]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:**

Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of February 2, 2007 (72 FR 5057), the agency announced that the proposed information collection had been submitted 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 0910-0338. The approval expires on June 30, 2010. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: June 21, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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