ensure compliance with the requirements of the Privacy Act for disclosure of data that contain individually-identifiable information. In addition, the DUA is used to maintain appropriate accounting and tracking of disclosures of records from Privacy Act systems of records. While the burden has not changed, we revised the DUA to The DUA was updated to include language to ensure the agreement is a binding agreement between CMS and the User, to ensure the data is being encrypted and appropriate protections are in place at all times, and to ensure appropriate actions are immediately taken if there is a data breach or incident. *Form Number:* CMS–R–0235 (OMB#: 0938–0734); *Frequency:* Reporting—On occasion; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 1,500; *Total Annual Responses:* 1,500; *Total Annual Hours:* 750.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer:

OMB Human Resources and Housing Branch,

Attention: Carolyn Lovett,

New Executive Office Building, Room 10235,

Washington, DC 20503,

Fax Number: (202) 395–6974.

Dated: September 13, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–18468 Filed 9–20–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10251 and CMS–10232]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* State Plan Pre-print for Integrated Medicare and Medicaid Programs; *Use:* Information submitted via the State Plan Amendment (SPA) pre-print will be used by CMS Central and Regional Offices to analyze a State's proposal to implement integrated Medicare and Medicaid programs. The pre-print is an optional document for use by States to highlight the arrangements between a State and Medicare Advantage Special Needs Plans that are also providing Medicaid services. State Medicaid Agencies will complete the SPA pre-print and submit it to CMS for a comprehensive analysis. The pre-print provides the opportunity for States to confirm that their integrated care model complies with both federal statutory and regulatory requirements. The pre-print contains assurances, check-off items, and areas for States to describe policies and procedures for subjects such as enrollment, marketing and quality assurance. *Form Numbers:* CMS–10251 (OMB#: 0938–NEW); *Frequency:* Reporting—Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 30; *Total Annual Hours:* 600.

2. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* State Plan Template to Implement Section 6062 of the Deficit Reduction Act (DRA) of 2005; *Use:* The DRA provides States with numerous flexibilities in operating their State Medicaid Programs. Section 6062 of the DRA (Opportunity for families of Disabled Children to Purchase Medicaid Coverage for Such Children) allows States the opportunity to provide Medicaid benefits to disabled children who would otherwise be ineligible because of family income that is above the State's highest Medicaid eligibility standards for children. It specifically allows families with disabled children to ''buy-in'' to Medicaid, and prevents them from having to stay impoverished, become impoverished, place their children in out-of-home placements, or simply give up custody of their child in order to access needed health care for their disabled children.

Under the DRA, States must submit a SPA to CMS to effectuate this change to their Medicaid programs. CMS will provide a State Medicaid Director letter providing guidance on this provision and the associated SPA template for use by States to modify their Medicaid State Plans if they choose to implement this provision. Providing the State with this SPA template will reduce State burden significantly. *Form Numbers:* CMS–10232 (OMB#: 0938–NEW); *Frequency:* Reporting—Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 30; *Total Annual Hours:* 600.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on November 20, 2007. CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 13, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–18494 Filed 9–20–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0353]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Pharmaceutical Development Study

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Pharmaceutical Development Study'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 13, 2006 (71 FR 7556), 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 0910–0604. The approval expires on August 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: September 14, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–18641 Filed 9–20–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0337]

Agency Information Collection Activities: Proposed Collection; Comment Request; Radioactive Drug Research Committees

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 information collection contained in regulations governing the use of radioactive drugs for basic informational research.

DATES: Submit written or electronic comments on the collection of information by November 20, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments* or *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: Karen L. Nelson Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20857, 301–827–4816.

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.

Radioactive Drug Research Committees— 21 CFR 361.1 (OMB Control Number 0910–0053)

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic scientific research. Section 361.1 (21 CFR 361.1) sets forth specific regulations regarding the establishment and composition of Radioactive Drug Research Committees and their role in approving and monitoring basic research studies utilizing radiopharmaceuticals. No basic research study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA approved Radioactive Drug Research Committee (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial for safety or efficacy. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

Section 361.1(c)(2) requires that each Radioactive Drug Research Committee shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or