or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: June 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12039 Filed 6–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0223]

Draft Guidance for Industry on Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals.'' The purpose of this draft guidance is to provide recommendations to industry for designing nonclinical toxicity studies to determine potential late radiation toxicities (radiation-induced injuries occurring after a latency period of several months to years) of therapeutic radiopharmaceuticals administered systemically. The purpose of such studies is to help minimize the risk of late-occurring irreversible radiation toxicities in clinical studies of therapeutic radiopharmaceuticals.

DATES: Submit written or electronic comments on the draft guidance by September 19, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Adebayo Laniyonu or Renee Tyson, Center for Drug Evaluation and Research (HFD–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7510.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals.'' The objective of this guidance is to provide recommendations to industry for designing nonclinical toxicity studies to determine potential late radiation toxicities of therapeutic radiopharmaceutical agents. This guidance is not intended for diagnostic radiopharmaceuticals or for radiobiologicals (e.g., radiolabeled monoclonal antibodies).

Late radiation toxicity differs from early or acute radiation toxicity. Acute radiation toxicity (e.g., bone marrow failure, nausea, vomiting, diarrhea, and oral mucositis) occurs within days to weeks of an acute dose of radiation and is often self-limiting and reversible. In contrast, late radiation toxicity (e.g., renal failure, pulmonary fibrosis, and chord transection) occurs after a latency period of several months to years, during which relatively normal organ function continues. Late radiation toxicity is usually progressive and irreversible.

Therapeutic radiopharmaceuticals are typically administered systemically to treat cancer. The radiation absorbed doses delivered by therapeutic radiopharmaceuticals may be comparable to those delivered with external beam radiotherapy (XRT). At therapeutic doses of radiation, the late radiation toxicities commonly associated with XRT (e.g., brain necrosis, paralysis, pulmonary fibrosis, liver or kidney failure, and hemorrhagic cystitis) can also be seen with therapeutic radiopharmaceuticals. With XRT, if the total dose given to an organ is less than its tolerance dose, the probability of symptomatic late radiation toxicity to that organ will be minimal. The tolerance doses of most human organs for conventional fractionated XRT are known, and are routinely used to direct the safe administration of XRT. In FDA's experience, however, there are few clinical data from which to estimate organ tolerance doses for therapeutic radiopharmaceuticals. Furthermore, late radiation toxicity has been observed when Medical Internal Radiation Dose (MIRDOSE) estimates of radiation absorbed doses delivered by therapeutic radiopharmaceuticals to target organs were substantially below the published XRT organ tolerance doses.

Therefore, there is a need to gain additional knowledge in this area to support the safe administration of therapeutic radiopharmaceuticals to humans. Because studies in humans would be unethical, the best means to gain insight into this issue is by conducting nonclinical late radiation toxicity studies. These studies will aid in identifying organs at risk and establish a margin of safety for late radiation toxicity. As a result, these studies will help to minimize the risk of late-occurring radiation toxicities in clinical studies of therapeutic radiopharmaceuticals.

This draft guidance focuses solely on late radiation safety concerns that are unique to therapeutic radiopharmaceuticals, and provides recommendations for late radiation toxicity nonclinical study designs including issues regarding good laboratory practices, species selection, dose selection, timing of study, and study parameters.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on nonclinical evaluation of late radiation toxicity of therapeutic radiopharmaceuticals. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the

requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: June 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12040 Filed 6–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4975–N–18]

Notice of Proposed Information Collection: Comment Request; Request for Credit Approval of Substitute Mortgagor

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments Due Date: August 19, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8001, Washington, DC 20410 or *Wayne_Eddins@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Joseph McCloskey, Director, Office of Single Family Asset Management, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–1672 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Request for Credit Approval of Substitute Mortgagor.

OMB Control Number, if applicable: 2502–0036.

Description of the need for the information and proposed use: This information collection is used by HUD to approve the credit of a substitute mortgagor who desires to assume an FHA-insured mortgage. The information is also needed to document the financial stability of the mortgagor.

Agency form numbers, if applicable: HUD–92210 and HUD–92210.1.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The estimated total number of hours needed to prepare the information collection is 2,400. The number of respondents is 600 generating approximately 2,400 annual responses, the frequency of response is on occasion, and the number of hours per response is one.

Status of the proposed information collection: Currently approved.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: June 3, 2005.

Frank L. Davis,

General Deputy Assistant Secretary for Housing-Deputy Federal Housing Commissioner.

[FR Doc. 05–12027 Filed 6–17–05; 8:45 am]

BILLING CODE 4210–27–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of the Draft Comprehensive Conservation Plan and Environmental Assessment for Sand Lake National Wildlife Refuge, Columbia, SD

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Availability.

SUMMARY: The U.S. Fish and Wildlife Service (Service) announces that the Draft Comprehensive Conservation Plan and Environmental Assessment (CCP/EA) for the Sand Lake National Wildlife Refuge (Refuge) is available for public review and comment. This Draft CCP/EA was prepared pursuant to the National Wildlife Refuge System Administration Act, as amended, and the National Environmental Policy Act (NEPA). The Draft CCP/EA describes the Service's proposal for management of the Refuge for 15 years.

DATES: Written comments must be received at the postal or electronic addresses listed below by July 20, 2005. Comments may also be submitted VIA electronic mail to: *kathleen_linder@fws.gov*.

ADDRESSES: To provide written comments or to obtain a copy of the Draft CCP/EA, please write to Linda Kelly, Planning Team Leader, U.S. Fish and Wildlife Service, P.O. Box 25486, Denver Federal Center, Denver, CO 80225–0486; (303) 236–8132; fax (303)236–4792, or Gene Williams, Refuge Manager, Sand Lake National Wildlife Refuge, 39650 Sand Lake Drive, Columbia, South Dakota 57433; (605) 885–6320; fax (605) 885–6401. The Draft CCP/EA will also be available for viewing and downloading online at *http://mountain-prairie.fws.gov/planning.*

FOR FURTHER INFORMATION CONTACT: Linda Kelly, Planning Team Leader at the above address or at (303) 236–8132.

SUPPLEMENTARY INFORMATION: The National Wildlife System Administration Act of 1966, as amended by the National Wildlife Refuge Improvement Act of 1997 (16 U.S.C. 668dd-668ee *et seq*), requires the