16, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia A. Stewart, 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FDA is announcing the availability of a draft guidance for industry entitled ''Internal Radioactive Contamination—Development of Decorporation Agents.'' This draft guidance is being issued to facilitate the development of new decorporation agents or new uses of previously marketed medical products for the treatment of internal radioactive contamination.

Internal radioactive contamination can arise from accidents involving nuclear reactors, industrial sources, or medical sources. The potential for such accidents has been present for many years. Recent events also have highlighted the potential for nonaccidental radioactive contamination as a result of malicious, criminal, or terrorist actions. Internal contamination occurs when radioactive material is ingested, inhaled, or absorbed from a contaminated wound. As long as these radioactive contaminants remain in the body, they may pose significant health risks. Long-term health concerns include the potential for the development of cancers of the lung, liver, thyroid, stomach, and bone and, when a radioactive contaminant is inhaled, for the development of fibrotic changes in the lung that may lead to restrictive lung disease. The only effective method of reducing these risks is removal of the radioactive contaminants from the body.

''Decorporation agents'' refer to medical products that increase the rate of elimination or excretion of inhaled, ingested, or absorbed radioactive contaminants. The effectiveness of most decorporation agents for the treatment of internal radioactive contamination cannot be tested in humans because the occurrence of accidental or nonaccidental radioactive contamination is rare, and it would be unethical to deliberately contaminate human volunteers with potentially harmful amounts of radioactive materials for investigational purposes.

FDA is issuing this draft guidance to facilitate the development of new decorporation agents or new indications for previously marketed medical products that may be eligible for approval under the Animal Efficacy Rule (21 CFR part 314, subpart I and 21 CFR part 601, subpart H). As set forth in this rule, under certain circumstances animal studies can be relied on to provide substantial evidence of effectiveness of a product. Evaluation of the product for safety in humans is still required, and cannot be addressed by animal studies alone. The adequacy of human safety data will need to be assessed from clinical pharmacology and safety studies conducted in humans. This draft guidance addresses the design and conduct of the requisite CMC, animal efficacy, safety pharmacology, toxicology, clinical pharmacology, biopharmaceutics, and human safety studies needed to support approval of new decorporation agents or new uses of previously marketed medical products for the treatment of internal radioactive contamination.

In addition, approval under the Animal Efficacy Rule is subject to certain postapproval commitments, including submission of a plan for conducting postmarketing studies that would be feasible should an accidental or intentional release of radiation occur, postmarketing restrictions to ensure safe use, if deemed necessary, and product labeling information intended for the patient advising that, among other things, the product's approval was based on effectiveness studies conducted in animals alone. This draft guidance addresses the postapproval commitments that would be needed for approval of a new decorporation agent or for a new indication for a previously approved agent under the Animal Efficacy Rule.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the development of decorporation agents for the treatment of internal radioactive contamination. 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 on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one 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 are available for public examination 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: February 4, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2821 Filed 2–14–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Bureau of Primary Health Care (BPHC) Uniform Data System (OMB No. 0915–0193)—Extension

The Uniform Data System (UDS) contains the annual reporting requirements for the cluster of primary care grantees funded by the Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA). The UDS is a reporting requirement for grantees of the Consolidated Health Center Program (the Program), which provides support to community health centers, migrant health centers, health care for the homeless centers, public housing primary care centers, and other grantees under the Program's authorizing statute (section 330 of the Public Health Service Act, as amended).

The Bureau collects data in the UDS which is used to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, BPHC requires a core set of data collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Universal Report	920	1	920	27	24,840
Grant Report	125	1	125	18	2,250
Total	920		1045		27,090

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Kraemer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 8, 2005.

Steven A. Pelovitz,

Associate Administrator for Administration and Financial Management.

[FR Doc. 05–2818 Filed 2–14–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Disadvantaged Assistance Tracking and Outcome Report (OMB No. 0915–0233)—Extension

The Health Careers Opportunity Program (HCOP) and the Centers of Excellence (COE) Program (sections 740 and 739 of the Public Health Service (PHS) Act, respectively) provide opportunities for under-represented minorities and disadvantaged individuals to enter and graduate from health professions schools. The Disadvantaged Assistance Tracking and Outcome Report (DATOR), is used to track program participants throughout the health professions pipeline into the health care workforce.

The DATOR, to be completed annually by HCOP and COE grantees, includes basic data on student participants (name, social security number, gender, race/ethnicity; targeted health professions, their status in the educational pipeline from pre-professional through professional training; financial assistance received through the grants funded under sections 739 and 740 of the PHS Act in the form of stipends, fellowships or per diem; and their employment or practice setting following their entry into the health care work force).

The proposed reporting instrument does not add significantly to the grantees reporting burden. This reporting instrument complements the grantees internal automated reporting mechanisms of using name and social security number in tracking students. The reporting burden includes the total time, effort, and financial resources expended to maintain, retain and provide the information including: (1) Reviewing instructions; (2) downloading and utilizing technology for the purposes of collecting, validating, and processing the data; and (3) transmitting electronically, or otherwise disclosing the information. Estimates of annualized burden are as follows:

Type of report	Number of respondents	Responses per respondent	Hours per response	Total burden hours
DATOR	150	1	5.5	825