

investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), abbreviated new drug applications (ANDAs), and supplements to NDAs or BLAs.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidances to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the guidances 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 guidances.

FOR FURTHER INFORMATION CONTACT:

Sally Loewke, Center for Drug Evaluation and Research (HFD-160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7510, or

Kathleen Swisher, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 14, 1998 (63 FR 55067), FDA published a document announcing the availability of a draft guidance for industry entitled "Developing Medical Imaging Drugs and Biologics." In a document published in the **Federal Register** of January 5, 1999 (64 FR 457), FDA reopened the comment period on the draft guidance until February 12, 1999. In a document published in the **Federal Register** of February 16, 1999 (64 FR 7561), FDA extended the comment period until April 14, 1999.

FDA received numerous written comments on the medical imaging draft guidance. In addition, the agency held public meetings on January 25 and March 26, 1999, to discuss various issues concerning the draft guidance. In the **Federal Register** of July 31, 2000 (65 FR 46674), the agency published a document announcing the availability of a revised draft guidance.

After considering the comments that FDA received on the revised draft guidance, the agency decided to revise the draft guidance, divide it into three parts to make it more user-friendly, and issue the three parts as drafts for comment. In the **Federal Register** of May 19, 2003 (68 FR 27008), FDA published a document announcing the availability of the three parts.

Part 1 of "Medical Imaging Drug and Biological Products," entitled "Conducting Safety Assessments," provides recommendations on conducting safety assessments of medical imaging agents. Part 2, "Clinical Indications," provides recommendations on tailoring clinical development programs for medical imaging agents to reflect the use of these agents for diagnosis and monitoring of diseases and conditions. Part 3, "Design, Analysis, and Interpretation of Clinical Studies," provides recommendations on designing a clinical development program for a medical imaging agent, including selecting subjects, and on acquiring, analyzing, and interpreting medical imaging data. Collectively, these guidances provide information and recommendations on how to develop all types of medical imaging agents and how to comply with certain provisions in the final rule, published in the **Federal Register** of May 17, 1999 (64 FR 26657), on the evaluation and approval of in vivo radiopharmaceuticals used in diagnosis and monitoring. Having reviewed the comments that FDA received on each of the three parts, and having made appropriate changes, the agency is issuing final versions of these guidances.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the agency's current thinking on different aspects of the development of medical imaging agents. They do not create or confer any rights for or on any person and do 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 guidances 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 guidances 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 documents at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. The Paperwork Reduction Act of 1995

These guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The guidances would not impose any additional reporting burden because the submission of information on the safety and effectiveness of medical imaging agents in applications for marketing approval and INDs is already required by existing regulations. In fact, clarification by the guidances of FDA's standards for evaluation of medical imaging agents is expected to reduce the overall burden of information collection. FDA received no comments on the analysis of information collection burdens stated in the announcement of availability of the original draft guidance published in the **Federal Register** on October 14, 1998 (63 FR 55067). In the **Federal Register** of July 31, 2000 (65 FR 46674), the agency requested comments on the revised proposed collections of information. No comments were received.

Dated: June 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-14077 Filed 6-21-04; 12:56 pm]

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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, 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: Data Collection Tool for the Black Lung Clinics Program: In Use Without Approval

The Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA), conducts an annual data collection of user information for the Black Lung Clinics Program. The purpose of the Black Lung Clinics Program is to improve the health status of coal workers by providing services to minimize the effects of respiratory and pulmonary impairments

of coal miners. Grantees provide specific diagnostic and treatment procedures required in the management of problems associated with black lung disease which improve the quality of life of miners and reduce economic costs associated with morbidity and mortality arising from pulmonary diseases. The purpose of collecting these data is to provide HRSA with information on how well each grantee is meeting the needs of active and retired miners in the funded communities.

Data from the annual report will provide quantitative information about the programs, specifically: (a) The characteristics of the patients they serve

(gender, age, disability level, occupation type), (b) the characteristics of services provided (medical, non-medical, or counseling), and (c) number of patients served and visits conducted (encounters). This assessment will provide data useful to the program and will enable HRSA to provide data required by Congress under the Government Performance and Results Act of 1993. It will also ensure that the organizations funded have demonstrated a need for services in their communities and that funds are being effectively used to provide services to meet those needs.

The estimated burden is as follows:

Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Database	15	1	15	10	150

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

Dated: June 14, 2004.
Tina M. Cheatham,
Director, Division of Policy Review and Coordination.
 [FR Doc. 04-14079 Filed 6-21-04; 8:45 am]
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DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Retraction of Revocation Notice

AGENCY: Bureau of Customs and Border Protection, U.S. Department of Homeland Security.

ACTION: General notice.

SUMMARY: The below-identified Customs broker license was erroneously included in a list of revoked Customs broker licenses.

Name	License	Port Name
Sherri Boynton	10691	Los Angeles.

Customs broker license No. 10691 remains valid.

Dated: June 10, 2004.

Jayson P. Ahern,

Assistant Commissioner, Office of Field Operations.

[FR Doc. 04-14039 Filed 6-21-04; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4910-N-15]

Notice of Proposed Information Collection for Public Comment; Homeownership Voucher Program Survey

AGENCY: Office of the Assistant Secretary for Public and Indian Housing (PIH), 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:* July 6, 2004.

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: Sherry Fobear-McCown, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4116, Washington, DC 20410-5000. Comments may also be provided to Gerald J. Benoit, Division Director, Office of Housing Voucher Programs, Public and Indian Housing, Department of Housing and Urban Development,