effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Manufacturers submitting a formal reclassification petition may wish to request two petitions as examples of successful reclassification petitions.

Magnetic resonance imaging devices, Docket Nos. 87P–0214/CP1 through CP13, and Nd:YAG Laser for posterior capsulotomy devices, Docket No. 86P–0083, were both reclassified from class III to class II following the submission of reclassification petitions. Both petitions are available upon submission of a Freedom of Information request to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857.

V. Submission of Required Information

The summary of and citation to, any information required by the act must be submitted by August 14, 1998, to the Document Mail Center (address above).

Dated: May 28, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–14599 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0189]

Recovery of Investigational New Drugs From Clinical Investigators; Revised Compliance Policy Guide; Availability

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of revised compliance policy guide (CPG) 7132c.05 entitled, ''Recovery of Investigational New Drugs from Clinical Investigators.'' Revised CPG 7132c.05 deletes obsolete drug citations in the Code of Federal Regulations. These references were superseded under the investigational new drug rewrite (IND Rewrite). Revised CPG 7132c.05 clarifies the terminology used to classify the recovery of investigational new drugs from clinical investigators consistent with existing regulations. In addition, consistent with the current CPG, this policy continues to apply to new animal drugs being studied under investigational new animal drug applications.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of revised CPG 7132c.05 ''Recovery of Investigational New Drugs from Clinical Investigators '' (CPG 7132c.05) to the Director, Division of Compliance Policy (HFC–230), Office of Enforcement, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance. Submit written comments on revised CPG 7132c.05 to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: JoAnne C. Marrone, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–1242.

SUPPLEMENTARY INFORMATION:

I. Background

FDA extensively revised its regulations governing the submission and review of IND's on March 19, 1987. These new regulations, called the IND Rewrite, were part of FDA's ongoing efforts to improve and streamline the new drug approval process. There are several provisions in the regulations that refer to the return of unused supplies to the sponsor of the IND. This revised CPG is intended to clarify the terminology to be used when it is necessary to recover investigational drugs from clinical investigators, consistent with the regulations.

This guidance document represents the agency's current thinking on the recovery of investigational drugs from clinical investigators. 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 statute, regulations, or both.

II. Request for Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. Two copies of any comment are to be submitted, except that individuals may submit one copy. Comments and requests for copies are to be identified with the docket number found in brackets in the heading of this document. A copy of revised CPG 7132c.05 and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of the revised CPG (Chapter 4, Sec. 444.100) is also available via Internet using the World Wide Web (www) (connect to the ORA home page at http://www.fda.gov/ora/compliance_ref/cpg).

Dated: May 27, 1997.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 97–14471 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2540 and HCFA-R–48]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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:* Revision of a currently approved collection; *Title of Information Collection:* Skilled Nursing Facility (SNF) and Skilled Nursing Facility Health Care Complex Cost Report, and supporting regulations 42 CFR 413.13, 413.20, 413.24 and 413.157; *Form No.:* HCFA–2540; *Use:* The Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report is the cost report to be used by freestanding SNFs to submit annual information to achieve a settlement of

costs for health care services rendered to Medicare beneficiaries. The 2540 now includes the reporting requirements to submit data electronically. *Frequency:* Annually; *Affected Public:* Business or other for profit, Not for profit institutions, and State, local, or tribal government; *Number of Respondents:* 7,000; *Total Annual Responses:* 7,000; *Total Annual Hours Requested:* 1,372,000.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital Conditions of Participation, and supporting regulations 42 CFR 482.12, 482.22, 482.27, 482.30, 482.41, 482.43, 482.53, 482.56, 482.57, 482.60, 482.61, 482.62 and 482.66; *Document No.:* HCFA-R–48; *Use:* Hospitals seeking to participate in the Medicare and Medicaid programs must meet the Conditions of Participation (COP) for Hospitals, 42 CFR Part 482. The information collection requirements contained in this package are needed to implement the Medicare and Medicaid COP for hospitals. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 1,500; *Total Annual Responses:* 1,500; *Total Annual Hours Requested:* 53,522.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's web site address at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Date: May 27, 1997.

Edwin J. Glatzel

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–14500 Filed 6–2–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[ORD–100–N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: April 1997

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: No new proposals for Medicaid demonstration project were submitted to the Department of Health and Human Services during the month of April under the authority of section 1115 of the Social Security Act. One proposal was withdrawn and no proposals were approved or disapproved during that time period. (This notice can be accessed on the Internet at http://www.hcfa.gov/ord/sect1115.htm.)

COMMENTS: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: *Mail correspondence to:* Susan Anderson, Office of Research and Demonstrations, Health Care Financing Administration, Mail Stop C3–11–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Susan Anderson, (410) 786–3996.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1115 of the Social Security Act (the Act), the Department of Health and Human Services (HHS) may consider and approve research and demonstration proposals with a broad range of policy objectives. These demonstrations can lead to improvements in achieving the purposes of the Act.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the **Federal Register** (59 FR 49249) that specified: (1) The principles that we ordinarily will consider when approving or disapproving demonstration projects under the authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

As part of our procedures, we publish a notice in the **Federal Register** with a monthly listing of all new submissions, pending proposals, approvals, disapprovals, and withdrawn proposals. Proposals submitted in response to a grant solicitation or other competitive process are reported as received during the month that grant or bid is awarded, so as to prevent interference with the awards process.

II. Listing of New, Pending, Approved, Disapproved, and Withdrawn Proposals for the Month of April 1997

A. Comprehensive Health Reform Programs

1. New Proposals

No new proposals were received during the month of April.

2. Pending Proposals

Pending proposals for the month of March 1997 found in the **Federal Register** of May 12, 1997 (62 FR 25957) remain unchanged, except for the deletion of the Community Care of Kansas, which was withdrawn on April 23, 1997, and the addition of the New Jersey Managed Charity Care Demonstration, which was received in March.

3. Approved Conceptual Proposals (Award of Waivers Pending)

No conceptual proposals were approved during the month of April.

4. Approved Proposals

No proposals were approved during the month of April.

5. Disapproved Proposals

No proposals were disapproved during the month of April.

6. Withdrawn Proposals

The following comprehensive health reform proposal was withdrawn voluntarily by the State during the month of April.

Demonstration Title/State: Community Care of Kansas—Kansas.

Description: Kansas proposed to implement a ''managed cooperation demonstration project'' in four predominantly rural counties, and to assess the success of a non-competitive