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 These references were superseded under the investigational new drug rewrite (IND Rewrite).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