Requires no special expertise to use, so that workers or their local health professionals can use the device.

Be immunoassay-based, in order to get sufficient sensitivity and selectivity.

Be self-contained, i.e., does not require any instrumentation for analysis.

Be produced easily and inexpensively and be readily available to workers.

Applicants will be judged according to the following criteria:

1. Adequacy and technical capabilities to develop the desired technologies and product;

2. Ability to develop, produce, market, and support the device; and

3. Ability to complete the CRADA in a timely fashion.

This CRADA is proposed and implemented under the 1986 Federal Technology Transfer Act: Public Law 99–502.

The response must be made to: Theodore F. Schoenborn, Technology Transfer Coordinator, National Institute for Occupational Safety and Health, CDC, 4676 Columbia Parkway, Mailstop R–2, Cincinnati, Ohio 45226 Telephone 513–841–4305, Fax 513–841–4500.

Dated: January 17, 1996.

Linda Rosenstock,

Director, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–950 Filed 1–23–96; 8:45 am]

BILLING CODE 4163–19–P

Food and Drug Administration

[Docket No. 95D–0166]

Quality Assurance Program Audits and Inspections; Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised Compliance Policy Guide (CPG) 7151.02 entitled ''FDA Access to Results of Quality Assurance Program Audits and Inspections.'' This revised CPG provides general policy and guidance to FDA field and headquarters staff (engaged in the inspection and investigation of any regulated entity) regarding routine access to review reports or copying of records that result from the entity's audits and inspections of a written quality assurance program.

ADDRESSES: CPG 7151.02 is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Tom M. Chin, Office of Enforcement (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0410.

SUPPLEMENTARY INFORMATION: FDA has revised CPG 7151.02 entitled ''FDA Access to Results of Quality Assurance Program Audits and Inspections.'' This CPG was revised to provide general policy and clearer guidance to FDA field and headquarters staff (engaged in the inspection and investigation of any regulated entity) regarding routine access to review reports or copying of records that result from the entity's audits and inspections of a written quality assurance program.

The statements made in CPG 7151.02 are not intended to bind the courts, the public, or FDA, or to create or confer any rights, privileges, immunities, or benefits on or for any private person, but are intended merely for internal FDA guidance.

Dated: January 3, 1996.

Gary Dykstra

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 96–940 Filed 1–23–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0386]

Guidance for Industry; Content and Format of Investigational New Drug Applications (IND's) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Industry; Content and Format of Investigational New Drug Applications (IND's) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products.'' The guidance clarifies data requirement issues related to the initial entry of an unapproved drug into human studies in the United States. The guidance is intended to expedite the entry of new drugs into clinical studies by eliminating ambiguities in IND requirements and by decreasing inconsistencies in IND reviews.

DATES: Written comments on the guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry; Content and Format of Investigational New Drug Applications (IND's) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products'' to the Consumer Affairs Branch (formerly the CDER Executive Secretariat Staff), Center for Drug Evaluation and Research (HFD–210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, or the Congressional and Consumer Affairs Branch, Center for Biologics Evaluation and Research (HFM–12), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–1800 or 800–835–4709. Send two self-addressed adhesive labels to assist the offices in processing your requests. A copy of the guidance document is also available from CDER's FAX On Demand. To obtain a copy from FAX On Demand, call 1–800–342–2722 or locally 301–827–0577. An electronic version of the guidance document is also available via Internet. Requesting persons should connect to the CDER file transfer protocol (FTP) server (CDVS2.CDER.FDA.GOV) using the FTP protocol. The guidance is available in WordPerfect versions 5.2 and 6.0. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–6740, or Rebecca Devine, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance entitled ''Guidance for Industry; Content and Format of Investigational New Drug Applications (IND's) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products.'' Any use in humans in the United States of a drug product not

previously authorized for marketing in the United States first requires the submission of an IND to FDA. FDA regulations in §§ 312.22 and 312.23 (21 CFR 312.22 and 312.23) contain the general principles underlying the IND submission and the general requirements for an IND's content and format. This guidance clarifies these requirements related to the initial entry of an unapproved drug, including well-characterized, therapeutic, biotechnology-derived products.

Because of the manufacturing and toxicologic differences between well-characterized, therapeutic, biotechnology-derived products and other biologic products, the guidance only applies to drugs that are not also biologics and to well-characterized, therapeutic, biotechnology-derived biologic products. For products not covered by the guidance the center responsible for the product should be contacted for guidance.

The requirements in §§ 312.22 and 312.23 permit a great deal of flexibility in the amount and depth of data to be submitted in an IND, depending in large part on the phase of the investigation and the specific human testing proposed. In some cases, the extent of that flexibility and the limited data needed has not been appreciated. FDA believes that clarification of these requirements will decrease the submission of unnecessary data and help expedite the entry of new drugs into clinical testing by increasing transparency and reducing ambiguity and inconsistencies. These clarifications will reduce the amount of information ordinarily submitted in an IND, yet continue to provide the agency with the data it needs to assess the safety of the proposed Phase 1 study.

The most significant clarifications contained in the guidance are FDA's willingness to accept an integrated summary report of toxicology findings as initial support for human studies based upon unaudited, draft, toxicological reports of completed animal studies, as well as specific manufacturing data that FDA will accept as appropriate for a Phase 1 study. This guidance applies equally to both commercial and individual investigator sponsors of IND's.

As part of the President's Reinventing Government Initiative, FDA has been reviewing its regulatory processes to determine which requirements could be reduced or eliminated without lowering health and safety standards. These clarifications of the IND requirements have been identified during this review and should significantly reduce the burden on industry regarding data submitted in Phase 1 IND's without sacrificing the quality of FDA's review of the IND.

In addition to this guidance, FDA is preparing an advance notice of proposed rulemaking (ANPR) that will describe proposed revisions to the IND regulations that FDA is contemplating to facilitate further the entry of drugs into clinical studies so that safe and effective drugs can be made available in the United States more quickly. The ANPR is expected to be published in the first quarter of 1996 and will address the possibility of: (1) A specific single dose IND with limited data requirements and (2) reducing or eliminating the IND submission requirements for individual investigators who would like to use products already in Phase 2 of commercial development.

Although this guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the industry, it does represent the agency's current thinking on data requirement issues related to the initial entry of an unapproved drug into human studies in the United States.

Although the guidance is being implemented immediately because it merely clarifies existing regulations and is expected to reduce the data submission burden on the industry, FDA is soliciting comments on the guidance that will be taken into account in making further revisions or clarifications to the IND process. FDA is particularly interested in comments on how the guidance could be extended to cover biological products other than well-characterized, therapeutic, biotechnology-derived products or whether a separate guidance should be developed for those products.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. Two copies of any 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 guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 8, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–943 Filed 1–23–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Public Information Collection Requirements Submitted for Public Comment and Recommendations

AGENCY: Health Care Financing Administration, HHS.

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, is publishing the following summaries of proposed collections for public comment. 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: Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration; *Form No.:* HCFA–2728; *Use:* This form captures the necessary medical information required to determine Medicare eligibility of an end stage renal disease claimant. It also captures the specific medical data required for research and policy decisions on this population as required by law. *Frequency:* Annually; *Affected Public:* Individuals or households, business or other for-profit, not-for-profit institutions; *Number of Respondents:* 60,000; *Total Annual Hours Requested:* 25,200.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.