availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports.'' This is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. This specific guidance discusses issues related to the electronic submission of postmarketing expedited safety reports for drug products marketed for human use with new drug applications (NDAs) and abbreviated new drug applications (ANDAs), prescription drug products marketed for human use without an approved NDA or ANDA, and therapeutic biological products marketed for human use with biologic license applications (BLAs). This guidance does not apply to vaccines. The submission of these reports in an electronic format will significantly improve the agency's efficiency in processing, archiving, and reviewing the reports.

DATES: Submit written comments on the draft guidance by July 3, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Deborah Yaplee, Center for Drug Evaluation and Research (HFD–400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3237, aersesub@cder.fda.gov; or

Michael Fauntleroy, Center for Biologics Evaluation and Research (HFM–588), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5101, Fauntleroy@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports.'' FDA has cooperated with industry associations and the regulatory authorities of certain other nations to promote international harmonization of regulatory requirements. Much of this effort has been coordinated through the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Under the auspices of the ICH, standards for electronic submission of safety information for human drug and biological products have been developed, including a standard medical terminology for regulatory purposes, ICH M1; electronic standards for the transfer of regulatory information, ICH M2; and standardized data elements for transmission of individual case safety reports, ICH E2B and E2BM formats.

This draft guidance is intended to provide guidance to industry regarding submission of postmarketing expedited safety reports to FDA electronically using the standards established by the ICH. FDA believes the changes recommended by the ICH will result in more effective and efficient safety reporting to regulatory authorities worldwide.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on providing postmarketing expedited safety reports in an electronic format. 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 Dockets Management Branch (address above) written comments on the draft 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 draft 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.

III. Paperwork Reduction Act of 1995

This notice contains no new collections of information. The information requested for marketed human drug and biological products is already covered by the collection of information on postmarketing safety reporting regulations (21 CFR 310.305, 314.80, and 600.80) submitted to the Office of Management and Budget (OMB) for review and clearance. This notice merely provides applicants with an alternative mechanism for submitting postmarketing expedited safety reports to the agency.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB approved the information collection for MedWatch—The FDA Medical Products Reporting Program (Forms FDA 3500 and FDA 3500A) and assigned it OMB control number 0910–0291. The approval for 0910–0291 expires on April 30, 2003.

OMB also approved the information collection for adverse experience reporting for marketed drugs and licensed biological products and assigned them OMB control numbers 0910–0230 and 0910–0308, respectively. The approval for 0910–0230 expires on May 31, 2002, and the approval for 0910–0308 expires on April 30, 2003.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm or at http://www.fda.gov/cber/guidelines.htm.

Dated: April 27, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–11235 Filed 5–3–01; 8:45 am]

BILLING CODE 4160–01–S

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 the 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, Public Law 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 at (301) 443–1129.

Comments are invited on (a) whether the agency needs to collect the proposed information to properly perform its functions and whether the information has any practical utility; (b) whether the agency's estimate of the burden of the proposed collection of information is accurate; (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 for respondents (*e.g.,* by using automated collection techniques or other forms of information technology).

Proposed Project: Ryan White CARE Act Dental Reimbursement Program (OMB No. 0915–0151)—Revision

The Dental Reimbursement Program (DRP) under Part F of the Ryan White CARE Act offers grants to accredited dental schools and programs that provide non-reimbursed oral health care to patients with HIV disease. The Ryan White CARE Act Amendments of 2000 expanded eligibility of this program to accredited schools of dental hygiene, in addition to previously funded schools of dentistry and post-doctoral dental education programs.

HRSA requests a revision to the DRP Application that schools and programs use to apply for funding of non-reimbursed costs incurred in providing oral health care to patients with HIV. Awards are authorized under section 776(b) of the Public Health Service Act (42 U.S.C. 294n). The 2001 DRP Application is intended to collect data in three different areas: program information, patient demographics and services, and reimbursement and funding. It also requests applicants to provide narrative descriptions of their services and facilities, as well as their links and collaboration with community-based providers of oral health services.

The primary purpose of collecting this information annually, as part of the DRP Application, is to verify eligibility and determine the reimbursement amount each applicant should receive. This information also allows HRSA to learn about (1) the extent of the involvement of dental schools and programs in treating patients with HIV, (2) the number and characteristics of clients who receive CARE Act-supported oral health services, (3) the types and frequency of the provision of these services, (4) the non-reimbursed costs of oral health care provided to patients with HIV, and (5) how applicants intend to use DRP funds once they are received. In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected in the DRP Application is critical for HRSA, State and local grantees, and individual providers, to help assess the status of existing HIV-related health service delivery systems.

The reporting burden for reviewing the DRP Application Instructions and completing the Application Form is estimated as:

Collection	Number of responsents	Hours per application	Total burden hours
Reimbursement Request	125	20	2500

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 30, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–11236 Filed 5–3–01; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): Opportunity for Cooperative Research and Development Agreements (CRADAs) To Perform Intervention Studies To Preserve Pancreatic Beta Cell Function and Prevent Type 1 Diabetes

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) is seeking proposals in the form of capability statements from potential collaborators for a Cooperative Research and Development Agreement (CRADA) to perform intervention studies to preserve pancreatic beta cell function and prevent type 1 diabetes. The clinical research will execute pilot and expanded studies of new agents to prevent or ameliorate type 1 diabetes in populations screened for or enrolled in these studies.

Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and Executive Order 12591 of April 10, 1987, as amended by the National Technology Transfer and Advancement Act of 1995), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks a Cooperative Research and Development Agreement (CRADA) with a pharmaceutical or biotechnology company to perform intervention studies to preserve pancreatic beta cell function and prevent type 1 diabetes.

The potential Collaborator(s) capability statement should provide proof of expertise in the design and implementation of new intervention studies of Type 1 Diabetes and should include the scientific rationale for the study proposed, the population to be studied, eligibility and exclusion criteria for the study, possible strategies for patient recruitment and data collection methods, primary and secondary endpoints to be determined, and a discussion of the sample size required given associated assumptions. The scientific rationale should include a discussion of what is the current ''state-of-the-art'', future opportunities, and obstacles in the prevention of type 1 diabetes, and discuss how the field may best be moved forward.

DATES: Only written CRADA capability statements received by the NIDDK on or before July 1, 2001 will be considered; confidential information must be clearly labeled. Potential Collaborators may be invited to meet with the Selection Committee at the Collaborator's expense to provide additional information. The Institute may issue an additional notice of CRADA opportunity. This notice is directed toward companies with resources to support collaborations.