DATES: Submit written comments by March 27, 2000. General comments are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance describing OGD's current program entitled ''Preparing Data for Electronic Submission of ANDA's'' are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Additional information can be found on the Internet at http://www.fda.gov/cder/OGD.

FOR FURTHER INFORMATION CONTACT: Jonathan D. Cook, Center for Drug Evaluation and Research (HFA–358), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5683.

SUPPLEMENTARY INFORMATION: As part of the Prescription Drug User Fee Act, as amended by the Food and Drug Administration Modernization Act of 1997, the agency stated its plans to develop and update its information management capabilities to allow electronic submissions by 2002. In the **Federal Register** of January 28, 1999 (63 FR 4433 and 4432), the agency announced the availability of two guidances for industry entitled ''Providing Regulatory Submissions in Electronic Format—General Considerations'' and ''Providing Regulatory Submissions in Electronic Format—NDA's.'' These guidances are the first in a series of guidances for industry on submitting archivable regulatory submissions in electronic format. In the 1999 guidance on general considerations, the agency stated that guidance would be forthcoming on other submission types, including investigational new drug applications, ANDA's, and product licensing applications. As part of that effort, OGD is announcing plans to develop guidance on submitting an archival copy of an ANDA in electronic format. As soon as a draft guidance has been developed, it will be made available for public comment.

OGD has accepted submission of some types of electronic data in ANDA's since 1997. During 1998, OGD received 32 electronic submissions for bioequivalence data and 44 electronic submissions for chemistry, manufacturing, and control data representing 58 distinct ANDA's from 24 different companies. The OGD program has been voluntary with the paper submission serving as the archivable regulatory basis for review decisions. OGD plans to expand its electronic data submission program to include all parts of the ANDA, so that the archivable electronic submission can replace the paper submission as the ANDA of record.

Submission of an ANDA in electronic format is expected to yield many benefits to industry and FDA, including a more consistent submission, a more consistent and rapid review, and, in the future, reduction in archiving and storage space.

Electronic data files described in existing agency guidance and in more detail on the OGD program's Internet site will form the basis for paperless ANDA submissions. ANDA information not contained in the structured data submission (*e.g.,* narratives and graphics) will be submitted in Portable Document Format (PDF), consistent with agency policy recommendations about filing PDF text and other files explained in the 1999 general considerations guidance.

Pending completion of OGD's guidance on submitting archivable ANDA's in electronic format and in the absence of archiving capability, a complete paper ANDA submission is still required.

FDA is seeking input from interested parties on its current program for submitting electronic data to OGD. The agency would like to consider the public's comments as it develops guidance for industry on electronic submission of archivable ANDA's. A guidance for industry entitled ''Preparing Data for Electronic Submission of ANDA's'' describes OGD's current program.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the agency's current program and plans to develop guidance for industry on submitting complete, archivable ANDA's in electronic format. 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997), which provides for early public participation in the guidance development process.

Dated: January 11, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–1869 Filed 1–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–841–853]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

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 summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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.

Type of Information Collection Request: Revision of a currently approved collection;

Title of Information Collection: Durable Medical Equipment Regional Carrier, Certificate of Medical Necessity and Supporting Regulations in 42 CFR, Section 407.18 and 410.1;

Form No.: HCFA–841–853 (OMB# 0938–0679);

Use: A Certificate of Medical Necessity is a standardized format used to communicate information provided by an attending physician and a supplier of medical equipment and supplies. The information is used by carriers to determine the medical necessity of an item or service covered by the Medicare program and being used for the treatment of the Medicare beneficiary's condition. The CMNs being submitted for OMB review are necessary in order for HCFA to

determine the medical necessity of the item or service. The information needed to make this determination requires application of medical judgement that can only be provided by a physician or other clinician who is familiar with the condition of the beneficiary;

Frequency: On occasion;

Affected Public: Business or other for-profit, and Federal Government;

Number of Respondents: 140,000;

Total Annual Responses: 6.8 million;

Total Annual Hours: 1.13 to 1.7 million.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 16, 2000

John Parmigiani,

Manager,

HCFA Office of Information Services Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–1978 Filed 1–26–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–96]

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.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Emergency and Foreign Hospital Services—Beneficiary Statement in Canadian Travel Claims and Supporting Regulations in 42 CFR, Section 424.123;

Form No.: HCFA–R–0096 (OMB# 0938–0484);

Use: Payment may be made for certain Part A inpatient hospital services and Part B outpatient hospital services provided in a nonparticipating U.S. or foreign hospital when services are necessary to prevent the death or serious impairment of the health of the individual. In these situations, the threat to the life or health of the individual necessitates the use of the most accessible hospital available and equipped to furnish such services. Section 3698.4, requires a beneficiary statement indication that after a medical emergency occurred, the beneficiary was traveling between Alaska and another State through Canada by the most direct route without unreasonable delay to acquire medical care;

Frequency: On occasion;

Affected Public: Individuals or Households;

Number of Respondents: 1,100;

Total Annual Responses: 1,100;

Total Annual Hours: 275.

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 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 OMB Desk 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.

Dated: January 3, 2000.

John Parmigiani,

Manager, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–1979 Filed 1–26–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF JUSTICE

Notice of lodging of consent decree pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act

Notice is hereby given that a proposed consent decree in *In re: Cuyahoga Equipment Corporation, et al.,* Case Nos. 86–12206, *et al.* (PCB) (Jointly Administered) (Bkcy. S.D.N.Y.), was lodged on January 11, 2000, with the United States Bankruptcy Court for the Southern District of New York. The proposed consent decree would settle a claim asserted in this Chapter 11 bankruptcy proceeding by the United States on behalf of the United States Environmental Protection Agency (''EPA'') for reimbursement of post-petition administrative expenses in the nature of environmental response costs incurred with respect to the Publicker Industries, Inc. Superfund Site in Philadelphia, Pennsylvania (the ''Publicker Site''). The United States, on behalf of EPA, alleged in a separate federal court action that Cuyahoga Wrecking Corporation and Overland Corporation, two of the debtors involved in the bankruptcy proceeding, were liable as owners and/or operators of the Publicker Site under Section 107(a)(1) and (2) of the Comprehensive Environmental Response Compensation and Liability Act (''CERCLA''), 42 U.S.C. § 9607(a)(1), (2) for, *inter alia,* reimbursement of the United States' response costs incurred in connection with the Publicker Site. *United States and Commonwealth of Pennsylvania* v. *Publicker Industries, Inc., et al.,* Civ. No. 90–7984 (E.D. Pa.). Through that litigation and other cost recovery efforts, the United States previously recovered and expects to recover $16.85 million of the $21.4 million in costs it incurred at the Site, leaving unreimbursed costs, exclusive of prejudgment interest, of approximately $4.55 million.

Under the terms of the proposed consent decree, the United States will recover from the Chapter 11 bankruptcy trustee for the debtors' estate the sum of $1 million, to be paid to the EPA Hazardous Substances Superfund.