with access to the Web. Updated on a regular basis, the CDRH home page includes ''New Medical Device Development Process'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 1–800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

III. Comments

Interested persons may, on or before October 19, 1998, submit to the Dockets Management Branch (address above) written comments regarding this document. 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 document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 10, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–19318 Filed 7–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0133]

Revised Guidance for Industry on Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997— Elimination of Certain Labeling Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled ''Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997— Elimination of Certain Labeling Requirements.'' Section 126 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act) amends the Federal Food, Drug, and Cosmetic Act (the act) to require, at a minimum, that prior to dispensing, the label of prescription products contain the symbol ''Rx only'' instead of the ''Caution: Federal law prohibits dispensing without prescription'' statement. In addition, the requirement that the labels of certain habit-forming drugs bear the statement ''Warning-May be habit forming'' has been repealed. The revised guidance changes the implementation schedule provided in the original guidance dated February 1998, and answers certain questions concerning implementation of these amendments.

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance for industry can be obtained on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm. Submit written requests for single copies of this 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 to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 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 guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Jerry Phillips, Center for Drug Evaluation and Research (HFD–610), Food and Drug Administration, Office of Generic Drugs, 7500 Standish Pl., Rockville, MD 20855, 301–827–5846, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a revised guidance for industry entitled ''Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997— Elimination of Certain Labeling Requirements.'' Section 126 of Title I of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), signed into law by President Clinton on November 21, 1997, amends section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(b)(4)) to require, at a minimum, that prior to dispensing, the label of prescription products contain the symbol ''Rx only'' instead of the ''Caution: Federal law prohibits dispensing without prescription'' statement. In addition, section 502(d) of the act (21 U.S.C. 352(d)), that required the labels of certain habit-forming drugs to bear the statement ''Warning–May be habit forming'' is repealed. The amendments to section 503(b)(4) and the repeal of section 502(d) of the act became effective February 19, 1998.

FDA published a notice in the **Federal Register** of March 13, 1998, announcing the availability of the original guidance (63 FR 12473) and soliciting comments. Three comments on the guidance were submitted to the docket. In response to the comments, and to questions that were asked concerning the implementation of section 126 of the Modernization Act, FDA is issuing a revised guidance.

The revised guidance: (1) Describes the new prescription drug labeling requirements of the act as amended by the Modernization Act, (2) changes the implementation schedule previously described in the February 1998 guidance, and (3) answers certain frequently asked questions about the provision. The revised guidance advises that FDA does not intend to object if a sponsor of a currently approved product implements section 126 of the Modernization Act at the time of the next revision of its labels, or by February 19, 2003, whichever comes first, and reports these minor changes in the next annual report. For pending

(unapproved) full or abbreviated applications received by the agency prior to February 19, 1998, sponsors have until the time of next revision of their labels or by February 19, 2003, whichever comes first, to comply with the amendments and they must report these minor changes in their next annual report. The guidance also advises that full or abbreviated applications received by FDA after February 19, 1998, should provide labels and labeling in compliance with the amendments.

This revised guidance document represents the agency's current thinking on implementation of the elimination of certain labeling requirements. 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.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 10, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19317 7–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–193]

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: '' An Important Message form Medicare.''and Supporting Regulations 42 CFR 466.78, 489.27, .20; *Form No.*: HCFA–R–193, OMB # 0938–0692; *Use:* Hospitals participating in the Medicare program have agreed to distribute '' An Important Message from Medicare'' to beneficiaries during each admission. Receiving this information will provide the beneficiary with some ability to participate and/ or initiate discussions concerning discussions affecting Medicare coverage or payment and about his or her appeal rights in response to any hospitals notice to the effect that Medicare will no longer cover continued care in the hospital. *Frequency:* Other, as needed; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit, Federal Government, State, Local, or Tribal Government; *Number of Respondents:* 6,700; *Total Annual Responses:* 11,000,000.; *Total Annual Hours:* 183,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, 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: July 9, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–19386 Filed 7–20–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Privacy Act of 1974; Report of New System

AGENCY: Department of Health and Human Services (HHS), Health Care Financing Administration (HCFA).

ACTION: Notice of new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system of records, called ''End-Stage Renal Disease (ESRD) Managed Care Demonstration System,'' HHS/HCFA/ OSP No. 09–70–0067. We have provided background information about the proposed new system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that the ''routine uses'' portion of the system be published for comment, HCFA invites comments on all portions of this notice.

DATES: HCFA filed a new system report with the Chairman of the Committee on Government Reform and Oversight of the House of Representatives, the Chairman of the Committee on Governmental Affairs of the Senate, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), on July 9, 1998. The new system of records, including routine uses, will become effective 40 days from the date submitted to OMB and the Congress, unless HCFA receives comments which require alteration to this notice.

ADDRESSES: The public should address comments to the HCFA Privacy Act Officer, Division of Freedom of Information & Privacy, Office of Information Services, Health Care Financing Administration, 7500 Security Boulevard, C2–01–11, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location by appointment, Monday through Friday 9 a.m.–3 p.m., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Paul Eggers, Office of Strategic Planning, Health Care Financing Administration, 7500 Security Boulevard, C3–24–07, Baltimore, Maryland 21244–1850. His telephone number is (410) 786–6691.

SUPPLEMENTARY INFORMATION: The ESRD Managed Care Demonstration System data file contains information on beneficiaries enrolled in the ESRD Managed Care Demonstration. This information will be used by HCFA and its evaluation contractor to monitor and evaluate the demonstration. The system