

The burden estimate for this collection of information is based on FDA's experience with petitions for administrative stay of action over the past 3 years. Agency personnel responsible for processing the filing of petitions for administrative stays of action estimate that seven such petitions are received by the agency annually, with each requiring approximately 100 hours of preparation time.

Dated: February 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-3504 Filed 2-11-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0049]

Draft Guidance for Industry on Environmental Assessment of Human Drug and Biologics Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Environmental Assessment of Human Drug and Biologics Applications." This draft guidance is intended to provide information on when an environmental assessment (EA) should be submitted in support of a human drug or biologics application and recommendations on how to prepare EA's.

DATES: Written comments may be submitted on the draft guidance document by April 13, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance for industry entitled "Environmental Assessment of Human Drug and Biologics Applications" to the Drug Information Branch (HFD-210), Center for Drug Evaluation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 two self-addressed labels to assist that office in processing your request. Submit

written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.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 A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. See the **Supplementary Information** section for electronic access to this document.

FOR FURTHER INFORMATION CONTACT:

Nancy B. Sager, Center for Drug Evaluation and Research (HFD-357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5629 or Daniel C. Kearns, Center for Biologics Evaluation and Research (HFM-206), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3031.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Environmental Assessment of Human Drug and Biologics Applications." The National Environmental Policy Act of 1969 (NEPA) requires all Federal agencies to assess the environmental effects of their actions and to ensure that the interested and affected public is informed of environmental analyses. FDA is required under NEPA to consider the environmental effect of approving drug and biologics applications as an integral part of its regulatory process. Under the President's reinventing Government initiatives announced in April 1995, FDA reevaluated and revised its environmental regulations to reduce the number of EA's required to be submitted by industry and, consequently, the number of findings of no significant impact prepared by the agency under NEPA.

In the **Federal Register** of April 3, 1996 (61 FR 14922) (republished May 1, 1996 (61 FR 19476)), FDA issued for public comment a notice of proposed rulemaking that proposed additional categorical exclusions for those actions the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have determined normally do not individually or cumulatively have a significant effect on the quality of the human environment. The final rule was published in the **Federal Register** of July 29, 1997 (62 FR 40570), and became

effective on August 28, 1997. This draft guidance is based on the final rule and is consistent with the Food and Drug Administration Modernization Act of 1997; it is intended to supersede CDER's "Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements," which published in November 1995.

FDA's regulations in part 25 (21 CFR part 25) specify that environmental assessments must be submitted as part of certain new drug applications, abbreviated applications, applications for marketing approval of a biologic product, supplements to such applications, investigational new drug applications, and for various other actions (see § 25.20), unless the action qualifies for a categorical exclusion.

This guidance provides information on when an EA should be submitted and recommendations on how to prepare EA's for submission to CDER and CBER for these drug or biologics applications. Topics covered include: (1) When categorical exclusions apply, (2) when to submit an EA, (3) the content and format of EA's, (4) specific guidance for the environmental issues that are most likely to be associated with human drugs and biologics, (5) test methods, (6) an applicant's treatment of confidential information submitted in support of an EA, and (7) drug master files and master files.

This draft guidance represents the agency's current thinking on the environmental assessment of human drug and biologics applications. 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 requirement of the applicable statute, regulations, or both.

II. Request for Comments

Interested persons may submit written comments on the draft 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 draft guidance 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 this draft guidance is available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/cberftp.html>.

Dated: February 3, 1998.

William K. Hubbard,

*Associate Commissioner for Policy
Coordination.*

[FR Doc. 98-3496 Filed 2-11-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-228]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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.

We are, however, requesting an emergency review of the information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. This collection is necessary to ensure compliance with section 1854 of the Balanced Budget Act. Under Part C of the Social Security Act, a Medicare+Choice (M+C) organization is required to submit an Adjusted Community Rate (ACR) proposal prior to 05/01/98, which is used by M+C organizations to price its benefit packages. Without emergency approval

entities interested in participating in the M+C program will not be afforded enough time to submit the required application prior to the 05/01/98 deadline. As a result, public harm is likely to result because eligible individuals may not receive the M+C health insurance options stipulated by the BBA.

HCFA is requesting OMB review and approval of this collection by 02/20/98, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by 02/19/98. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Request: New collection.

Title of Information Collection: Managed Care Adjusted Community Rate (ACR) Proposal.

Form Number: HCFA-R-228 (OMB approval #: 0938-NEW).

Use: This collection effort will be used to price the benefit package sold to Medicare beneficiaries who will be enrolled in M+C. Organizations submitting the Managed Care Adjusted Community Rate Proposal form would include all M+C organizations plus any organization intending to contract with HCFA as a M+C organization. This would include any eligible organizations with a managed care risk contract, as defined in 42 CFR § 417.401 of federal regulations, in effect on January 1, 1998 with intentions of offering a M+C plan starting January 1, 1999. These current Medicare managed care risk contractors will be required to submit this form no later than May 1, 1998 for the calendar year 1999.

Frequency: Annually.

Affected Public: Businesses or other for profit, not-for-profit institutions.

Number of Respondents: 350.

Total Annual Responses: 350.

Total Annual Hours Requested: 35,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address, phone number, and HCFA form number(s) referenced above, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as

noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by 02/19/98:

Health Care Financing Administration,
Office of Information Services,
Information Technology Investment
Management Group, Division of
HCFA Enterprise Standards, Room
C2-26-17, 7500 Security Boulevard,
Baltimore, MD 21244-1850, Fax
Number: (410) 786-1415, Attn: John
Rudolph HCFA-R-228

and,

Office of Information and Regulatory
Affairs, Office of Management and
Budget, Room 10235, New Executive
Office Building, Washington, DC
20503, Fax Number: (202) 395-6974
or (202) 395-5167 Attn: Allison
Herron Eydt, HCFA Desk Officer.

Dated: February 5, 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. 98-3585 Filed 2-11-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-227]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing
Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA), 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