using the World Wide Web (WWW). For WWW access, connect to CBER's site at ''http://www.fda.gov/cber/memo.htm''.

Dated: September 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25181 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0319]

Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection; Guidance Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection,'' dated December 11, 1996. The guidance document, which discusses the appearance in 1996 of two cases of HIV–1 Group O infection in the United States, is intended to provide interim measures to reduce the risk of HIV–1 Group O transmission by blood and blood products pending the licensure of test kits specifically labeled for detection of antibodies to HIV–1 Group O viruses. The guidance document recommends adding three questions to screening questionnaires used to exclude donors at high risk of HIV–1 infection.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 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 guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance document entitled ''Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection.'' It was dated December 11, 1996, and sent to all registered blood and plasma establishments. The guidance document, which discusses the appearance in 1996 of two cases of HIV–1 Group O infection in the United States, recommends adding three questions to screening questionnaires used to exclude donors at high risk for HIV–1 infection. These recommendations are intended to be interim measures to reduce the risk of HIV–1 Group O transmission by blood and blood products pending the licensure of test kits specifically labeled for detection of antibodies to HIV–1 Group O viruses.

As with other guidance documents, FDA does not intend this guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. It is intended to provide recommendations and does not set forth requirements. In response to public comment, development of suitable alternatives or other new information, FDA may revise this guidance document at any time to improve its usefulness. Any revisions to this document will be announced in the **Federal Register**. The recommendations in the document represent the agency's current thinking on screening and deferral of donors at increased risk for HIV–1 Group O infection. 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 to the Dockets Management Branch (address above) written comments on the guidance 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. Any comments previously submitted to the Division of Blood Applications (HFM–370), CBER, FDA, do not have to be resubmitted. Comments previously submitted will be filed with the Dockets Management Branch (address above) under the docket number in the heading of this document. The document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Received comments will be considered in determining whether further revision is warranted.

Persons with access to the Internet may obtain the document by using the World Wide Web (WWW). For WWW access, connect to CBER's site at ''http://www.fda.gov/cber/memo.htm''.

Dated: September 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25128 Filed 9–22–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0381]

Guidance for Industry on Archiving Submissions in Electronic Format—NDA's; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Archiving Submissions in Electronic Format—NDA's.'' This guidance is intended to describe how to submit records and other documents in electronic format to the Center for Drug Evaluation and Research (CDER) for archival purposes. Guidance is provided on submitting case report forms and case report tabulations as part of new drug applications (NDA's). This is the first in a series of guidances for industry that will address archiving NDA submissions in electronic format. Guidance for industry on other submission types will be made available as they are completed. The submission of records in electronic format should reduce the amount of paperwork for applicants and the agency. Submissions in electronic format are voluntary.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance for industry entitled ''Archiving Submissions in Electronic Format—NDA's'' 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. 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.

FOR FURTHER INFORMATION CONTACT: Kenneth Edmunds, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3276, e-mail: ESUB@CDER.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Archiving Submissions in Electronic Format—NDA's.'' Traditionally, FDA has required that regulatory submissions, such as investigational new drug applications and NDA's, be submitted as paper documents. The regulations in part 314 (21 CFR part 314), for example, set forth the requirements and procedures for submitting applications to obtain approval for the marketing of new drugs to FDA. These regulations require the submission of three copies of an application for marketing approval: (1) A complete archival copy, (2) a review copy, and (3) a field copy (§ 314.50(k)).

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the Electronic Records; Electronic Signatures regulation that provides for the voluntary submission of parts or all of an application, as defined in the relevant regulations, in electronic format without an accompanying paper copy (21 CFR part 11). The agency also established public docket number 92S–0251 so the agency can maintain a list of the specific types of records and submissions that can be accepted in electronic format (62 FR 13467, March 20, 1997). The agency unit(s) that are prepared to receive electronic submissions are to identify themselves in that docket. The regulation states that persons should consult with the intended agency receiving unit for details on how to proceed with the electronic submission. The guidance is intended to reduce the need on the part of sponsors to consult CDER for details on archiving electronic submissions. The guidance specifically addresses the NDA and includes subsections on how to submit case report forms and case report tabulations in electronic format to CDER for the archive. Conforming to the guidance in this document will help ensure that submissions provided to CDER in electronic format can be accessed, handled, reviewed, and maintained efficiently.

The guidance is the first in a series that will be issued on archiving electronic submissions to CDER. As a result, it is not all inclusive. CDER anticipates that, as this effort proceeds, sponsors, investigators, and CDER staff may develop alternative and more effective procedures for submitting electronic applications for the archive. For this reason, the guidance will be updated periodically.

The guidance represents the agency's current thinking on electronic submissions for the archive for NDA's. 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.

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 and requests are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of the guidance also is available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''.

Dated: September 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25126 Filed 9–17–97; 4:58 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–304A]

Agency Information Collection Activities: Proposed Collection; 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, is publishing the following summary 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.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice and Prior Quarter Adjustment Statement; *Form No.:* HCFA–304A; *Use:* In response to a need for improved data exchange between drug labelers and States, HCFA, in conjunction with outside consultants, developed the Reconciliation of State Invoice (ROSI), form HCFA–304, and the Prior Quarter Adjustment Statement (PQAS), form HCFA–304A. The ROSI is to be used by Drug Labelers when responding to State invoices of current quarter utilization data only and functions as a reconciliation report to assure accurate rebate payments. The PQAS is used by labelers to report only on prior quarter actions/payments. Prior quarter activity includes changes to utilization data submitted by States, revisions to previously disputed units, and prior period adjustments (URA changes). Both forms assist in reducing disputes by standardizing data exchange and improving communication between Drug labelers and States. *Frequency:* Quarterly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 365; *Total Annual Responses:* 1,460; *Total Annual Hours:* 132,120.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: