the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to INTERNET may request that the draft guidance document be sent by return E-mail by sending a message to ''Character@A1.CBER.FDA.GOV''. The draft guidance document may also be obtained through INTERNET via File Transfer Protocol (FTP). Requestors should connect to the Center for Drug Evaluation and Research (CDER) using the FTP. The Center for Biologics Evaluation and Research (CBER) documents are maintained in a subdirectory called CBER on the server, ''CDVS2.CDER.FDA.GOV'' (150.148.24.202). The ''READ.ME'' file in that subdirectory describes the available documents that may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 document (*.w51), or both. A sample dialogue for obtaining the READ.ME file with a text-based FTP program would be:

FTP CDVS2.CDER.FDA.GOV
LOGIN: CHARACTER
<PASSWORD:CHARACTER><''Your E-mail address''>
BINARY
CD CBER
GET READ.ME
EXIT

The draft guidance document may also be obtained by calling the CBER FAX Information System (FAX-ON-DEMAND) at 301–594–1939 from a touch tone telephone.

FOR FURTHER INFORMATION CONTACT:

Tracey H. Forfa or Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074; or

Yuan Yuan Chiu, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3510.

Dated: January 16, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–1581 Filed 1–25–96; 10:42 am]

BILLING CODE 4160–01–F

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21 CFR Parts 600 and 601

[Docket No. 95D–0052]

Changes To An Approved Application; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Draft Guidance; Changes to An Approved Application.'' The draft guidance is intended to assist applicants in determining how they should report changes to an approved license application under the proposed revision to the biologics regulations issued elsewhere in this issue of the Federal Register. FDA does not intend for this draft guidance to be used at this time. The agency is providing this guidance at this time for public comment only.

DATES: Written comments by April 29, 1996.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Draft Guidance; Changes to An Approved Application'' to the Congressional and Consumer Affairs Branch (HFM–12), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, or call FDA's automated information system at 800–835–4709. Send two self-addressed adhesive labels 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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. 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.

Persons with access to INTERNET may request that the draft guidance document be sent by return E-mail by sending a message to ''Changes@A1.CBER.FDA.GOV''. The draft guidance document may also be obtained through INTERNET via File Transfer Protocol (FTP). Requestors should connect to the Center for Drug Evaluation and Research (CDER) using the FTP. The Center for Biologics Evaluation and Research (CBER) documents are maintained in a subdirectory called CBER on the server, ''CDVS2.CDER.FDA.GOV'' (150.148.24.202). The ''READ.ME'' file in that subdirectory describes the available documents which may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 document (*.w51), or both. A sample dialogue for obtaining the READ.ME file with a text-based FTP program would be:

FTP CDVS2.CDER.FDA.GOV
LOGIN: CHANGES
<PASSWORD:CHANGES> <''Your E-mail address''>
BINARY
CD CBER
GET READ.ME
EXIT

The draft guidance document may also be obtained by calling the CBER FAX Information System (FAX-ON-DEMAND) at 301–594–1939 from a touch tone telephone.

FOR FURTHER INFORMATION CONTACT:

Tracey H. Forfa or Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074; or

Yuan Yuan Chiu, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3510.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 6, 1995 (60 FR 17535), FDA published a guidance document intended to provide guidance to applicants on which changes in manufacturing procedures and establishments may be implemented with and/or without prior approval by the Director, CBER under § 601.12 (21 CFR 601.12). The Federal Register notice and guidance document were intended to reduce the burden of reporting changes on manufacturers and to facilitate the approval process.

In a continuing effort to achieve the reduction in reporting burden and to respond to comments received on the April 6, 1995, guidance document, FDA is proposing a revision to § 601.12 published elsewhere in this edition of the Federal Register. In addition, FDA is announcing the availability of a draft guidance document entitled, ''Changes to An Approved Application.'' The guidance document sets forth CBER's current interpretation of the proposed rule to amend § 601.12 as it applies to biologic products other than those considered to be well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology products. The reporting mechanisms proposed in the rule are based on the potential for the change to affect a product's safety, purity, potency, and effectiveness. In a separate document also published in this issue of the Federal Register, FDA is announcing

the availability of a guidance document to assist applicants in determining how they should report changes to an approved application for a well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology product under the proposed rule.

The guidance document will provide guidance to applicants in determining how a change to a product, production process, equipment, facility, responsible personnel, or labeling should be reported to FDA under the proposed revision to § 601.12.

As stated previously, FDA is providing this draft guidance document for comment only. The document is not intended to be used at this time. FDA intends to review the comments received on the proposed rule and this draft guidance document and issue a final rule prescribing the requirements for the reporting changes to an approved license application. A revised guidance document would also be made available at the time of issuance of the final rule. As with other procedural guidance documents, FDA does not intend that this guidance document would be all-inclusive. Alternative approaches could be warranted in specific situations, and certain aspects might not be applicable to all situations. If an applicant believed the reporting procedure described in this guidance document was inapplicable to a specific change for a particular product, the applicant could provide, for CBER's consideration, information supporting an alternative categorization. An applicant also could discuss proposed changes with the agency to prevent expenditure of money and effort on activities that later might be determined to be unacceptable by FDA. The Center for Biologics Evaluation and Research would continue to review submissions on a case-by-case basis. This document would not bind FDA and would not create or confer any rights, privileges, or benefits on or for any person, but would be intended for guidance.

Interested persons may, on or before April 29. 1996, submit to the Dockets Management Branch (address above) comments on the draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and information are to be identified with the docket number found in brackets in the heading of this document. The draft guidance ''Changes to An Approved Application'' and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FDA plans to hold an open public meeting during the comment period to discuss the proposed revision to § 601.12 and the draft guidance document. The time and location of this meeting will be announced in an upcoming issue of the Federal Register.

FDA will consider any comments received in determining whether revisions to the guidance document are warranted. FDA will announce the availability of any revised guidance document in the Federal Register.

Dated: January 16, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–1583 Filed 1–25–96; 10:43 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 281

RIN 1510–AA48

Foreign Exchange Operations

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes regulations to amend the administration of the purchase, custody, deposit, transfer, sale and reporting of foreign exchange (including credits and currencies) by executive departments and agencies. The specific section being amended addresses the limitation on the purchase of foreign exchange. Currently, foreign exchange acquired by agencies shall be placed with accountable officers. Unless otherwise authorized by the Secretary of the Treasury, no accountable officer shall purchase foreign exchange which, together with the balance on hand at the time of purchase, would exceed estimated requirements for a 30 day period. This proposed revision would restrict accountable officers to estimated requirements for a 5–7 business day period unless they have obtained a specific waiver of this requirement from the Secretary of the Treasury.

DATES: Comments on this proposed rule must be received on or before February 28, 1996.

ADDRESSES: All written comments on this proposed rule should be addressed to Michael C. Salapka, Manager, International Funds Branch, Financial Management Service, Prince George Metro Center II Building, Room 5A19, 3700 East-West Highway, Hyattsville, MD 20782, or by FAX to the attention of Bruce Riedl at (202) 874–8023.

FOR FURTHER INFORMATION CONTACT: Michael C. Salapka, (202) 874–8919, (Manager, International Funds Branch); or Bruce Riedl, (202) 874–8918, (Senior Advisor).

SUPPLEMENTAL INFORMATION:

Background

To protect the Government from risk, 31 CFR § 281.7(c), currently limits accountable officers to purchasing foreign exchange only in an amount which, together with the balance on hand, does not exceed the estimated requirements for a 30 day period. However, risk reduction and improvements in cash management dictate that a shorter time period be established. Specifically, in order to (1) minimize local currency operating balances held in designated depositaries; (2) minimize losses due to rate devaluations; and, (3) avoid premature drawdowns on Treasury's General Account, all accountable officers shall ensure that the amount of foreign exchange purchased with dollars, together with the balance on hand, is commensurate with estimated requirements for a 5–7 business day period. This will result in interest savings to the Government. Further, balances in the local currency operating account held at designated depositaries will be kept as close to zero as possible without incurring overdrafts to the account.

In certain situations, the administrative costs, local banking regulations, or possible volume discounts appear to require maintaining balances in excess of the 5–7 day amount. If circumstances require exceeding this limit, the accountable officer must obtain a specific waiver of this requirement from Treasury.

Rulemaking Analysis

This regulation is not a significant regulatory action as defined in Executive Order 12866. Accordingly, a Regulatory Assessment is not required. It is hereby certified pursuant to the Regulatory Flexibility Act that this revision will not have a significant economic impact on a substantial number of small entities. Accordingly, a Regulatory Flexibility Act analysis is not required. This change primarily affects executive departments and agencies.

List of Subjects in 31 CFR Part 281

Foreign exchange, banks, banking.

Accordingly, part 281 of title 31 is proposed to be amended as follows: