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As stated previously, FDA is providing this draft guidance document for comment only.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 FDA intends to review the comments received on the proposed rule and this draft guidance document and issue a final rule prescribing the requirements for the reporting changes to an approved license application.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persons may, on or before April 29. 1996, submit to the Dockets Management Branch (address above) comments on the draft guidance document.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 The draft guidance ''Changes to An Approved Application'' and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through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:

PART 281—FOREIGN EXCHANGE OPERATIONS

1. The authority citation for part 281 is revised to read as follows:

Authority: 22 U.S.C. 2363; 31 U.S.C. 3513; E.O. 10488, 18 FR 5699, 3 CFR 1949–1953, Comp., p. 972; E.O. 10900, 26 FR 143, 3 CFR 1959–1963, Comp., p. 429.

2. Section 281.7(c) is revised to read as follows:

§ 281.7 Limitations.

* * * * *

(c) Unless otherwise authorized by the Secretary, 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 5–7 business day period.

* * * * *

Dated: December 4, 1995.

Russell D. Morris,

Commissioner.

[FR Doc. 96–899 Filed 1–26–96; 8:45 am]

BILLING CODE 4810–35–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TX43–1–6275; FRL–5403–7]

Clean Air Act Limited Approval and Limited Disapproval of 15 Percent Rate of Progress and Contingency Plans for Texas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: The EPA proposes a limited approval and limited disapproval of the State Implementation Plan (SIP) revisions submitted by the State of Texas to meet the 15 Percent Rate of Progress Plan requirements of the Clean Air Act. The EPA is proposing a limited approval because the 15 Percent Plans, submitted by Texas, will result in significant emission reductions from the 1990 baseline and thus, will improve air quality. Simultaneously, the EPA is proposing a limited disapproval of the 15 Percent Plans because they fail to demonstrate sufficient reductions of area-wide Volatile Organic Compounds (VOC) to meet the 15 Percent Rate of Progress requirements. Also, the EPA is proposing a limited approval of the contingency plans because these plans, if implemented, will result in emission reductions that will improve air quality. Simultaneously, the EPA is proposing a limited disapproval of the contingency plans because they fail to demonstrate that the required three percent reduction of VOC emissions will be achieved if the plans are implemented.

The EPA is also proposing a limited approval of the specific control measures in the 15 Percent and Contingency Plans because these rules will strengthen the SIP. A final action on these control measures will incorporate these rules into the Federally approved SIP.

DATES: Comments on this proposed action must be post marked by March 29, 1996.

ADDRESSES: Written comments on this action should be addressed to Mr. Thomas H. Diggs, Chief, Air Planning Section, at the EPA Regional Office listed below. Copies of the documents relevant to this action are available for public inspection during normal business hours at the following locations. Persons interested in examining these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

U.S. Environmental Protection Agency, Region 6, Air Planning Section (6PD–L), 1445 Ross Avenue, Suite 700, Dallas, Texas 72202–2733.

Texas Natural Resource Conservation Commission, 12100 Park 35 Circle, Austin, Texas 78711–3087.

FOR FURTHER INFORMATION CONTACT: Mr. Guy R. Donaldson, Air Planning Section (6PD–L), USEPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–7242.

SUPPLEMENTARY INFORMATION:

Background:

Section 182(b)(1) of the Clean Air Act (CAA), as amended in 1990, requires ozone nonattainment areas with classifications of moderate and above to develop plans to reduce area-wide VOC emissions by 15 percent from a 1990 baseline. The plans were to be submitted by November 15, 1993 and the reductions were required to be achieved within 6 years of enactment or November 15, 1996. The Clean Air Act also sets limitations on the creditability of certain types of reductions. Specifically, States cannot take credit for reductions achieved by Federal Motor Vehicle Control Program (FMVCP) measures (new car emissions standards) promulgated prior to 1990 or for reductions resulting from requirements to lower the Reid Vapor Pressure of gasoline promulgated prior to 1990. Furthermore, the CAA does not allow credit for corrections to Vehicle Inspection and Maintenance Programs (I/M) or corrections to Reasonably Available Control Technology (RACT) rules as these programs were required prior to 1990.

In addition, section 172(c)(9) of the Clean Air Act requires that contingency measures be included in the plan revision to be implemented if reasonable further progress is not achieved or if the standard is not attained.

In Texas, four moderate and above ozone nonattainment areas are subject to the 15 Percent Rate of Progress requirements. These are the Beaumont/Port Arthur (serious), Dallas/Fort Worth (moderate), El Paso (serious), and the Houston/Galveston (severe) areas. Texas adopted measures for the 15 Percent Rate of Progress Plans and the required contingency measures in two phases. Phase I was submitted to the EPA on November 13, 1993, and contained measures achieving the bulk of the required reductions in each of the nonattainment areas. Phase II was submitted May 9, 1994. The Phase II submittal was to make up the shortfall in reductions not achieved in the Phase I measures. The combination of the Phase I and Phase II measures was ruled complete by the EPA on May 12, 1994.

On August 3, 1994, Texas submitted rules for the review and processing of Alternate Means of Control (AMOC). These revisions provide for the EPA review and approval of AMOC plans. On November 9, 1994, Texas submitted a narrative explanation and justification of the AMOC process with their plan to reduce emissions an additional 9 percent in the Houston/Galveston and Beaumont/Port Arthur Areas.

The EPA has analyzed the November 13, 1993, submittal; May 9, 1994, submittal; August 3, 1994 submittal; and the AMOC narrative portion of the November 9, 1994, submittal; and believes that these proposed 15 Percent Plans and Contingency Plans can be given limited approval because they overall would strengthen the SIP by achieving reductions in VOC emissions. The 15 Percent Plan and Contingency Plans do not, however, achieve the total required percentage of reductions. Therefore, the EPA is proposing a limited disapproval of the plans. Also, the control measures in the four 15 Percent Plans and Contingency Plans cannot be completely approved, because they do not meet all of the underlying conditions of the Clean Air Act. Therefore, the EPA is only proposing limited approval of the control measures in the 15 Percent Plans and the Contingency Plans as a strengthening of the SIP. The EPA is not taking any action on whether the control measures included in these plans comply with the