weigh livestock, livestock carcasses, live poultry, or feed for purposes of purchase, sale, acquisition, payment, or settlement of livestock, livestock carcasses or live poultry unless it has been found upon test and inspection, as specified in § 201.72, to be in a condition to give accurate weight. If a scale is inspected or tested and found to be in a condition to give incorrect or inaccurate weights or if any repairs, adjustments or replacements are made to a scale, it shall not be used until it has been inspected and tested and determined to meet all accuracy requirements specified in the regulations.

5. Section 201.72 would be revised to read as follows:

§ 201.72 Scales; testing of.

(a) Each stockyard owner, market agency, dealer, packer, or live poultry dealer who weighs livestock, live poultry, or feed for purposes of purchase, sale, acquisition, payment, or settlement of livestock or live poultry, or who weighs livestock carcasses for the purpose of purchase on a carcass weight basis, or who furnishes scales for such purposes, shall cause such scales to be tested by competent persons in accordance with the regulations at least twice during each calendar year at intervals of approximately 6 months. More frequent testing will be required in cases where the scale does not maintain accuracy between tests.

(b) Each stockyard owner, market agency, dealer, packer, or live poultry dealer who weighs livestock, livestock carcasses, live poultry or feed for purposes of purchase, sale, acquisition, payment, or settlement of livestock, livestock carcasses or live poultry shall furnish reports of such tests and inspections on forms prescribed by the Administrator. The stockyard owner, market agency, dealer, packer or live poultry dealer shall retain one copy of the test and inspection report and shall file one copy with the P&S regional office for the region in which the scale is located.

(c) When scales used for weighing livestock, livestock carcasses, live poultry, or feed are tested and inspected by an agency of a State or municipality or other governmental subdivision, the forms ordinarily used by such agency for reporting test and inspection of scales shall be accepted in lieu of the forms prescribed for this purpose by the Deputy Administrator if such forms contain substantially the same information.

(Approved by the Office of Management and Budget under control number 0580–0015)

6. Section 201.73 would be revised to read as follows:

§ 201.73 Scale operators to be qualified.

Stockyard owners, market agencies, dealers, packers, and live poultry dealers shall employ qualified persons to operate scales for weighing livestock, livestock carcasses, live poultry, or feed for the purposes of purchase, sale, acquisition, payment, or settlement of livestock, livestock carcasses, or live poultry and they shall require such employees to operate the scales in accordance with the regulations.

Done at Washington, DC, this March 26, 1999.

Harold W. Davis,

Acting Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. 99–8068 Filed 4–1–99; 8:45 am]

BILLING CODE 3410–EN–P

SMALL BUSINESS ADMINISTRATION

13 CFR part 120

Business Loan Program

AGENCY: Small Business Administration (SBA).

ACTION: Proposed rule.

SUMMARY: SBA proposes to limit the fees that a Certified Development Company (CDC) can charge a Borrower or Third Party Lender in connection with the processing of a 504 financing to the 1.5 percent processing fee currently authorized by SBA regulations. SBA invites comment on this proposed change and the policies underlying the change.

DATES: Submit comments on or before May 3, 1999.

ADDRESSES: Comments should be mailed to Jane Palsgrove Butler, Associate Administrator for Financial Assistance, Small Business Administration, 409 Third Street, SW, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Michael J. Dowd, 202–205–6660.

SUPPLEMENTARY INFORMATION: SBA proposes to delete § 120.926 (13 CFR 120.926) and amend § 120.971 (13 CFR 120.971) of its regulations. The proposed amendments would clarify SBA's policy prohibiting a CDC from charging a Borrower more than 1.5 percent of the net debenture proceeds for all services related to processing a 504 financing. SBA invites comment on this policy. In addition, SBA proposes to amend its regulations to prohibit a CDC from charging a Third Party Lender for any services related to the processing or packaging of a 504 financing. SBA also invites comment on this proposed policy change.

Before March 1, 1996, the fees that SBA permitted a CDC to charge a Borrower for services related to a 504 financing were contained in SBA's regulations, 13 CFR 108.503–6. In addition to a fee from the Borrower of up to 1.5 percent of the net debenture proceeds to cover CDC costs for loan packaging, processing, and non-legal staff functions, the regulations permitted a CDC to charge the Borrower or Third-Party Lender an additional fee of up to 1.5 percent of the third party financing for services actually rendered by the CDC under a written agreement.

On December 15, 1995, in response to directives from the President for Federal agencies to streamline their regulations, SBA published proposed regulations (60 FR 64356) which consolidated parts 108, 116, 120, 122, and 131 of its regulations into a revised part 120. Former § 108.503–6 (except paragraph (c)) became § 120.971 in the proposed regulations under the heading ''Post-closing fees paid by Borrower.'' Proposed § 120.971 listed the fees that a CDC could charge a Borrower in connection with a 504 financing. Paragraph 108.503–6(c) became paragraph 120.961(b) in the proposed regulations. Proposed paragraph 120.961(b) allowed CDCs to charge a ''finder's fee'' which either the Borrower or Third Party Lender could pay.

On January 31, 1996, SBA published final regulations in the **Federal Register** with an effective date of March 1, 1996 (61 FR 3226) (the ''new regulations''). The heading of § 120.971 was changed to ''Allowable fees paid by Borrower,'' but in all other respects remained as proposed. Proposed paragraph 120.961(b) became § 120.926 in the new regulations. It allowed CDCs to charge only the Third Party Lender, and allowed a CDC to receive that fee from the Third Party Lender if the CDC secured the lender for the Borrower under a written contract. Section 120.926 of the new regulations, specifically prohibited a CDC from obtaining that fee directly from the Borrower.

SBA now proposes to prohibit a CDC from charging a Borrower or a Third Party Lender a referral fee or *any* other fee related to processing or packaging a 504 financing other than the 1.5 percent processing fee a CDC may charge a Borrower pursuant to § 120.971, whatever the CDC may call the fee. Specifically named as prohibited are application fees, finder's fees, referral fees, packaging fees, and additional fees of any kind (''Additional Fees''),

although the proposed rule makes clear that this prohibition applies to any fee the CDC might charge to the Borrower, regardless of what it would be called.

SBA intends that Borrowers not pay Additional Fees either directly or indirectly. SBA believes that Third Party Lenders sometimes pass Additional Fees on to Borrowers in the form of higher interest rates, points, or other charges. SBA considers it good public policy to prohibit a CDC from directly charging a Borrower Additional Fees, or from charging a Third Party Lender Additional Fees which may get passed along to a Borrower, because SBA believes a finder's fee or referral fee is not necessary since there is an established Third Party Lender community readily available to potential 504 borrowers and CDCs.

When the program first began in 1980, it was sometimes difficult for CDCs to locate Third Party Lenders willing to participate in a new program. So, SBA permitted CDCs to charge Additional Fees under former § 108.503–6(c) for services rendered in connection with obtaining a Third Party Loan. Today most CDCs have developed working relationships with one or more lender(s) who regularly participate in 504 financings. In fact, in many instances, the Borrower goes first to a Third Party Lender who refers the Borrower to the CDC. On most other occasions, a CDC refers a Borrower to a Third Party Lender that has participated with the CDC in previous 504 financings; or rarely, a CDC will use a packager to obtain a Third Party Lender. However this Third Party financing is placed, SBA no longer believes that the effort necessary to get a Third Party Lender justifies allowing a CDC to charge a small business Borrower Additional Fees.

SBA believes the compensation for any actions a CDC performs in connection with the origination and processing of a 504 financing is adequately covered by the 1.5 percent processing fee permitted to be paid by a Borrower pursuant to § 120.971(a)(1). A 504 financing includes the CDC loan, Third Party Loan, and Borrower injection (see 13 CFR 120.801). A CDC cannot process a 504 financing unless there is a qualified Third Party Lender. The participation of a Third Party Lender is an integral part of a CDC's processing of a 504 financing. Without it, a 504 financing cannot occur. SBA concludes that a CDC should not receive an Additional Fee of any kind for any actions related to obtaining a Third Party Lender, or processing the Third Party Loan, because the fee a CDC receives under § 120.971(a)(1) covers those actions. Whether a Borrower pays an Additional Fee directly to a CDC or indirectly to a Third Party Lender in the form of higher interest rates, points, or other charges, the Borrower is essentially paying twice for the same services—the processing of its 504 financing. SBA believes that the fee a CDC may charge under § 120.971(a)(1) is the all-inclusive processing fee for a CDC and that this fee covers any services performed by the CDC related to the processing of a 504 financing.

SBA emphasizes that the proposed regulatory amendments would prevent a CDC from charging a Borrower or Third Party Lender *any* fees related to processing or packaging a 504 financing other than the 1.5 percent processing fee a CDC may charge a Borrower pursuant to § 120.971. For example, a CDC would not be able to receive fees from a Borrower or Third Party Lender for (1) referring a Borrower to a Third Party Lender (or the reverse); (2) referring a Borrower to a packager; or (3) helping to process the Third Party Loan.

Since it is proposing to prohibit Additional Fees, SBA proposes to delete § 120.926 in its entirety. As was the case prior to March 1, 1996, all fees which a CDC would be able to charge with respect to a 504 financing would be found in one section of SBA's regulations, § 120.971. SBA proposes to change the heading of § 120.971 to ''Fees Which a CDC May Charge,'' and to add the word ''only'' to § 120.971(a) to make clear that a CDC may charge a Borrower only the fees enumerated in that paragraph.

SBA invites comments on any aspect of these proposed regulations and on the underlying policies as discussed in this preamble. Specifically, SBA invites comment on (but not limited to) the following issues:

1. Whether the fees now permitted to be charged to the borrower, 1.5 percent of the net debenture proceeds, is adequate compensation for processing a 504 financing.

2. Whether a CDC should be able to charge either a Borrower or a Third Party Lender Additional Fees when the fees are clearly itemized and the fees are for special and non-routine work performed in connection with obtaining a Third Party Lender or processing a Third Party Loan.

3. Whether there is any need for a CDC to receive an Additional Fee for its efforts relating to the Third Party Loan in specific situations, such as in urban and rural areas, or with respect to the CDC's efforts to increase the number of loans to New Market small businesses.

4. Whether SBA should establish separate fee limitations depending on whether the CDC is a for-profit or a not-for-profit entity.

Compliance With Executive Orders 12612, 12778, and 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612) and the Paperwork Reduction Act (44 U.S.C. Ch. 35)

SBA certifies that this proposed rule does not constitute a significant rule within the meaning of Executive Order 12866, since it is not likely to have an annual effect on the economy of $100 million or more, result in a major increase in costs or prices, or have a significant adverse effect on competition or the U.S. economy.

SBA certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612. Last year, SBA made approximately four thousand 504 loans. Currently there are approximately 270 CDCs.

SBA certifies that this proposed rule does not impose any additional reporting or recordkeeping requirements under the Paperwork Reduction Act, 44 U.S.C., chapter 35.

For purposes of Executive Order 12778, SBA certifies that this proposed rule is drafted, to the extent practicable, to accord with the standards set forth in paragraph 2 of that Order.

List of Subjects in 13 CFR part 120

Loan programs—business, Small Businesses.

For the reasons stated in the preamble, the Small Business Administration proposes to amend 13 CFR part 120 as follows:

PART 120—BUSINESS LOANS

1. The authority citation for part 120 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6) and 636(a) and (h).

§ 120.926 [Remove]

2. Remove § 120.926.

3. Amend § 120.971 to revise the heading, to revise paragraph (a), to redesignate paragraphs (b), (c), (d), and (e) as paragraphs (c), (d), (e), and (f), respectively, and to add new paragraph (b) as follows:

§ 120.971 Fees a CDC may charge.

(a) *Fees a CDC may charge a Borrower.* A CDC may charge only the following fees to a Borrower:

* * * * *

(b) *Fees a CDC may charge a Third Party Lender.* None.

* * * * *

Dated: March 24, 1999.

Aida Alvarez,

Administrator.

[FR Doc. 99–8148 Filed 4–1–99; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 98N–0583]

RIN 0910–AB16

Exports: Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing new regulations that would establish the notification and recordkeeping requirements for persons exporting human drugs, biologics, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States. These regulations would implement recent changes in the statutory requirements applicable to certain exports, and would also codify recordkeeping requirements for exports of products that cannot be marketed or sold in the United States generally.

DATES: Submit written comments by June 16, 1999. Submit written comments on the information collection requirements by May 3, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20502, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

Enacted and later amended in 1996, the FDA Export Reform and Enhancement Act (Pub. L. 104–134, as amended by Pub. L. 104–180) significantly changed the export requirements for unapproved human drugs, biologics, devices, and animal drugs. For example, before the law was enacted, most exports of unapproved new drug products could only be made to the 21 countries then identified in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382), and these exports were subject to numerous restrictions. The FDA Export Reform and Enhancement Act amended section 802 of the act to allow, among other things, the export of unapproved new human drugs to any country in the world if the drug complies with the laws of the importing country and has valid marketing authorization from any of the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the countries in the European Union (EU) and the European Economic Area (EEA) and certain other requirements are met (see section 802(b)(1)(A) of the act). Currently, the EU countries are Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. The EEA countries are the EU countries, Iceland, Liechtenstein, and Norway. The list of countries will expand automatically if any country accedes to the EU or becomes a member of the EEA. This provision of section 802 of the act also applies to the export of certain devices that cannot be sold or marketed in the United States.

The FDA Export Reform and Enhancement Act also modified the export authority in section 801 of the act (21 U.S.C. 381). Before enactment of the FDA Export Reform and Enhancement Act, section 801(e)(1) of the act applied to the exportation of certain foods, drugs, devices, and cosmetics. Products exported under section 801(e) of the act are not considered adulterated or misbranded if the product intended for export: (1) Meets the foreign purchaser's specifications, (2) is not in conflict with the laws of the country to which it is being exported, (3) is labeled on the outside of the shipping package that the product is intended for export, and (4) is not sold or offered for sale in domestic commerce (see section 801(e)(1) of the act). Additional requirements apply to certain devices (see section 801(e)(2) of the act). The FDA Export Reform and Enhancement Act extended these four basic requirements to all exports under sections 801 and 802 of the act, and to exports of partially processed biologics under section 351(h) of the Public Health Service Act (the PHS Act) (see section 801(e) and (f) of the act); section 802(f)(3) of the act; and section 351(h) of the PHS Act (42 U.S.C. 262(h))), and made section 801(e) of the act the principal export authority for the exportation of unapproved animal drugs other than animal drugs banned in the United States. It also imposed additional labeling requirements on certain exports of approved drugs (see section 801(f) of the act).

The FDA Export Reform and Enhancement Act also established recordkeeping and notification requirements. Products exported under section 802 of the act are subject to certain requirements under section 802(f) and (g) of the act. Section 802(f) of the act prohibits a drug or device from being exported under section 802 of the act if it: (1) Does not conform with current good manufacturing practices, (2) is adulterated under certain provisions in section 501 of the act (21 U.S.C. 351), (3) does not comply with section 801(e)(1) of the act, (4) is the subject of a determination by FDA or the United States Department of Agriculture (with respect to veterinary biologics) that the probability of reimportation of the exported drug or device would present an imminent hazard to the public health and safety of the United States, (5) would present an imminent hazard to the public health of the foreign country, (6) fails to comply with labeling requirements in the country receiving the exported drug or device, or (7) is not promoted in accordance with labeling requirements.

Section 802(g) of the act requires an exporter of a drug or device under section 802(b)(1)(A) of the act to provide a ''simple notification'' to the agency ''identifying the drug or device when the exporter first begins to export such drug or device'' to any of the 25 countries identified in section 802(b)(1)(A) of the act. For exports to other, nonlisted countries, section 802(g) of the act requires the exporter to provide a simple notification ''identifying the drug or device and the country to which such drug or device is being exported.'' This section also requires persons export under any provision of section 802 of the act to ''maintain records of all drugs or devices exported and the countries to which they were exported.''

II. Description of the Proposed Rule

The proposed rule would amend 21 CFR part 1 to create a new § 1.101 entitled ''Notification and recordkeeping.''

Proposed § 1.101(a) would describe the provision's scope as covering notifications and records required for human drug, biologic, device, animal drug, food, and cosmetic exports under