

If a penetration percentage is used in the study analysis, explain how that particular percentage was chosen.

RECOMMENDED NUMBER BY UNIT

Size	One	Two	Three	Four

Names and positions of individuals in the community who provided information for the study:

Dated: August 31, 1994.

Bob J. Nash,

Under Secretary for Small Community and Rural Development.

[FR Doc. 94-23925 Filed 9-27-94; 8:45 am]

BILLING CODE 3410-07-U

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 286

[INS No. 1392-93]

RIN 1115-AA-30

Immigration User Fee; Remittance Requirements

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This rule publishes changes to requirements related to the Immigration User Fee Account (IUFA). The rule amends existing regulations to comply with the 1991 and 1994 Department of Justice Appropriations Acts. In addition, this rule changes where remittances shall be sent; requires additional information in the remittance and statement procedures for fees; clarifies how remittances shall be paid; and makes a nomenclature change. Two minor technical corrections are also being made to correct errors in the text of the regulations.

EFFECTIVE DATE: October 28, 1994.

FOR FURTHER INFORMATION CONTACT: Michael Natchuras, Budget Analyst, Fee Analysis and Operations Branch, Office of Finance, Office of Budget, Immigration and Naturalization Service (INS), 425 I Street NW., Room 6307, Washington, DC 0536-0002, telephone (0) (202) 616-2754.

SUPPLEMENTARY INFORMATION:

I. Introduction

The INS published a proposed rule on February 15, 1994, at 59 FR 7227,

making changes to requirements related to the Immigration User Fee Account. The proposed rule was published with a 60-day comment period. The public had the opportunity to comment on the proposed rule through April 18, 1994.

Changes in current regulations are needed to make the regulations consistent with current law, and establish requirements for fee collection data and remittance information. In addition, the final rule implements a nomenclature change throughout 8 CFR 86 to remove the word "Comptroller" and to put in its place the words "Associate Commissioner, Finance," and makes two other technical corrections.

Comments were received from seven commenters, including three industry associations. All the comments were carefully considered before preparing this final rule. Following is a discussion of the comments.

II. Summary of Comments

A. Monthly Summary Statement Requirement

Five commenters expressed dissatisfaction with this reporting requirement. One commenter expressed agreement in principal with the proposed submission of monthly information related to the Immigration User Fees collected.

The commenters who expressed dissatisfaction with the reporting requirement indicated that the monthly requirement would add an additional and costly reporting burden which would duplicate a quarterly remittance statement, and would require carrier-ticketing information which is considered to be "commercially confidential." One commenter indicated that there would be timing difficulty in reporting information as required in the proposed rule, given the dates airlines receive domestic and international sales reports. Along these same lines, another commenter suggested that carriers be given at least 1 month to submit a report. Further, two commenters noted that the universal scope of the requirement should be limited if the reporting requirement is published as a final rule. One of these suggested that the requirement apply to high-volume carriers; the other suggested that it be applicable to carriers who consistently fail to remit fees. Another of the comments suggested that, should the monthly reporting requirement be implemented, it should include a "sunset" provision to discontinue the requirement after 2 years subject to evaluation of the benefits in relation to the costs.

The commenter that supported the requirement believed that the monthly submission of a summary report for each month's collections would assist the INS in developing more accurate budgets and in allocating funds for staff and equipment as traffic patterns change.

The INS continues to believe that, in order to improve its financial management of the IUFA, it must have some indication of fee remittances in advance of their receipt. Therefore, a report of net monthly collections will be required. As a result of the type and timing of remittance data available, there has been difficulty in making resource estimates. Remittances to INS represent passengers who purchased tickets during the remittance period, which is not necessarily the same period in which the passenger will travel. The INS data are limited to the number of persons inspected and actual remittances. Since the remittances are made on a quarterly basis, there is not timely information with which to make accurate collection projections. For example, even though the fiscal year starts on October 1, the first remittances for the fiscal year are not due until January 31 of each year. Historically, the bulk of these collections are received in February and accounting records report them in March. Hence, it is mid-March before any picture of actual collections comes into focus. The mid-point of the year is very late in the fiscal year to be making program and budget changes.

Concerning the comment which suggested that the monthly reporting requirement and the statement which accompanies remittances are duplicative, INS believes that there is a misunderstanding concerning the purpose of each document. The monthly report is to serve as a predictor of the amount of funds to be received, while the remittance statement provides detailed information pertaining to a specific actual remittance. Each document has a separate, unique, and identifiable purpose.

However, in response to the public's comments, INS is making the following changes. The INS will not require a reporting of the number of ticket sales, given issues related to commercial confidentiality. In addition, in order to ease the reporting burden, a report of remittances will be required only for carriers or ticket-selling agents whose fee collections exceed \$50,000 a month. Further, in response to the issue of duplication of reporting requirements, INS is making an additional change. Since the quarterly remittance statement includes information for the last month in a given quarter, a separate monthly

report will not be required for those months. This means that monthly reporting will be required for the months of October, November, January, February, April, May, July, and September. In order to allow more reporting time, the report will be due to INS on the last business day of the following month.

Finally, with regard to the suggestion to "sunset" the monthly reporting requirement, INS seriously considered this comment. However, INS believes this to be an ongoing requirement which is needed to adequately manage the account. Should the information become available from other sources, or should some other matters arise, INS will reevaluate the requirement and modify the regulations as appropriate.

B. Record Retention Period

Three commenters addressed the proposed 5-year record-retention period. Each commenter indicated the extended retention period was burdensome and costly, and that it exceeded the requirements of other Federal agencies. In view of the comments received, the current 2-year retention period will remain in effect.

One commenter noted that the proposed rule did not specify the type of records and documents which must be kept. In response to this comment, INS provides the following guidance. Each collector and remitter should maintain records necessary for the carrier to demonstrate to the INS the accuracy of fees collected and remitted, and to otherwise determine compliance with applicable statutes and regulations. Modern technology available to achieve this result may be utilized.

C. Fourth Quarter Remittance of Fees

Two commenters addressed the remittance deadline for fourth quarter immigration user fees. One commenter objected to the September 20 due date for the remittance of fourth quarter fees. A second suggested that the final rule clarify that the fourth quarter remittance should include collections from the months of July and August for that year.

The rule establishes the fourth quarter remittance due dates in order to make the regulation consistent with a statutory change. The 1991 Department of Justice Appropriations Act (Public Law 101-515, November 5, 1990), as amended by section 309(a)(2)(b) of Miscellaneous and Technical Immigration and Naturalization Amendments of 1991 (Pub. L. 102-232, December 12, 1991), changed the remittance schedule for the fourth quarter.

D. Change in the Immigration User Fee

One commenter urged that the Immigration User Fee not be raised from \$5.00 to \$6.00 per passenger.

The change in the User Fee is mandated by statute. The 1994 Department of Justice Appropriations Act (Pub. L. 103-121, October 27, 1993) increased the fee to \$6.00 per passenger. The regulation is being changed to be consistent with the law.

Regulatory Flexibility Act

The Commissioner of the Immigration and Naturalization Service, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it, certifies that the rule will not have a significant economic impact on a substantial number of small entities because of the following factors. Most of the regulation updates the CFR to conform with current law. The reporting requirement is constructed so that only major entities are required to report. Further, the information required under this rule should be readily available from business records which must be maintained as a routine business practice.

Executive Order 12866

This rule is not considered by the Department of Justice, Immigration and Naturalization Service, to be a "significant regulatory action" under Executive Order 12866, § 3(f), Regulatory Planning and Review, and the Office of Management and Budget has waived its review process under section 6(a)(3)(A).

Executive Order 12612

The regulations adopted herein will not have substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Paperwork Reduction Act

The information collection requirements contained in this rule have been cleared by the Office of Management and Budget under the provisions of the Paperwork Reduction Act. The OMB Clearance number is 1115-0142.

List of Subjects in 8 CFR Part 286

Air carriers, Immigration, Maritime carriers, Reporting and recordkeeping requirements.

Accordingly, part 286 of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 286—IMMIGRATION USER FEES

1. The authority citation for part 286 continues to read as follows:

Authority: 8 U.S.C. 1103, 1356; 8 CFR part 2.

2. Section 286.2 is revised to read as follows:

§ 286.2 Fee for arrival of passengers aboard commercial aircraft or commercial vessels.

(a) Under the provisions of section 286(b) of the Act, a \$6.00 fee per individual is charged and collected by the Commissioner for the immigration inspection of each passenger aboard a commercial aircraft or commercial vessel, arriving at a Port-of-Entry in the United States, or for the preinspection of a passenger in a place outside the United States prior to such arrival, except as provided in § 286.3.

(b) Each commercial aircraft and vessel carrier or ticket-selling agent whose monthly collections in any month exceed \$50,000 shall submit a summary statement showing the amount of user fees collected that month. The summary statement is due on the last business day of the following month. This information shall be forwarded to the Immigration and Naturalization Service, Chief, Fee Analysis and Operations Branch, 425 I Street, NW., Room 6307, Washington, DC 20536. For the months of December, March, June, and August, the quarterly remittance and statement required by § 286.5 will serve as the monthly report for those months. Therefore, a monthly report is required for all other months in which monthly collections exceed \$50,000.

3. In § 286.3 paragraph (a) is revised to read as follows:

§ 286.3 Exceptions.

(a) Persons, other than aircraft passengers, whose travel originated in Canada, Mexico, the adjacent islands, and territories or possessions of the United States;

4. In § 286.5 paragraphs (b), (c) and (d) are revised to read as follows:

§ 286.5 Remittance and statement procedures.

(b)(1) Fee remittances shall be sent to the Immigration and Naturalization Service, at a designated Treasury depository, for receipt no later than 31 days after the close of the calendar quarter in which the fees are collected, except the fourth quarter payment for fees collected shall be made on the date that is 10 days before the end of the U.S. Government's fiscal year, and the first quarter payment shall include any collections made in the preceding quarter that were not remitted with the previous payment. The fourth quarter payment shall include collections for the months of July and August. The fiscal year referenced is the U.S. Government's fiscal year which begins on October 1 and ends on September 30.

(2) Late payments will be subject to interest, penalty, and handling charges as provided in the Debt Collection Act of 1982 (31 U.S.C. 3717). Refunds by a remitter of fees collected in conjunction with unused tickets or documents for transportation shall be netted against the next subsequent remittance.

(c) Along with the remittance, as set forth in paragraph (b) of this section, each remitter making such remittance shall attach a statement which sets forth the following:

- (1) Name and address;
- (2) Taxpayer identification number;
- (3) Calendar quarter covered by the payment;
- (4) Interest and penalty charges; and
- (5) Total amount collected and remitted.

(d) Remittances shall be made in U.S. dollars by check or money order through a U.S. bank, to Associate Commissioner, Finance, INS.

* * * * *

§§ 286.1(e), 286.4(c), 286.5(e), and 286.6 [Amended]

5. §§ 286.1(e), 286.4(c), 286.5(e), and 286.6, are amended by removing the word "Comptroller" and adding in its place "Associate Commissioner, Finance" wherever it appears.

§ 286.5(e) [Amended]

6. In § 286.5(e), the first sentence, is amended by removing the word "Auditing" in the title "Statement on Auditing Standards for Attestation Engagement."

§ 286.5(g) [Amended]

7. In § 286.5(g), the first sentence, is amended by removing the citation "§ 28.4" and adding "§ 287.4."

Dated: September 22, 1994.

Doris Meissner,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 94-23954 Filed 9-27-94; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 93-NM-234-AD; Amendment 39-9018; AD 94-18-05]

Airworthiness Directives; Saab Model SF340A and SAAB 340B Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects a typographical error that appeared in the above-captioned airworthiness directive (AD), applicable to certain Saab Model SF340A and SAAB 340B series airplanes. That AD currently requires inspections to detect discrepancies of certain main landing gear (MLG) retract actuator bracket retaining bolts; replacement of discrepant parts; installation of washers, if necessary; and eventual replacement of certain MLG retract actuator bracket retaining bolts and certain nose landing gear (NLG) trunnion pin cross bolts. This action corrects terms in the compliance time specified for the requirement to remove the NLG trunnion pin cross bolts. This action is necessary to ensure that operators are not required to perform actions at a time that does not correspond with scheduled maintenance.

DATES: Effective October 11, 1994.

The incorporation by reference of certain publications listed in the regulations was previously approved by the Director of the Federal Register as of October 11, 1994 (59 FR 46543, September 9, 1994).

ADDRESSES: The service information referenced in this AD may be obtained from Saab Aircraft AB, Product Support, S581.88, Linköping, Sweden. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mark Quam, Aerospace Engineer, Standardization Branch, ANM-113,

FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2145; fax (206) 227-1320.

SUPPLEMENTARY INFORMATION: On August 24, 1994, the FAA issued AD 94-18-05, amendment 39-9018 (59 FR 46543, September 9, 1994), to require inspections to detect discrepancies of certain main landing gear (MLG) retract actuator bracket retaining bolts; replacement of discrepant parts; installation of washers, if necessary; and eventual replacement of certain MLG retract actuator bracket retaining bolts and certain nose landing gear (NLG) trunnion pin cross bolts. That action was prompted by reports of extension and retraction problems on the MLG, due to loose retract actuator brackets on the MLG shock struts. The actions required by that AD are intended to prevent a loose retract actuator bracket from interfering with the MLG shock strut trunnion support, which could result in the inability of the MLG to extend or retract.

Recently, the FAA has become aware of a typographical error that appeared in paragraph (c) of the published final airworthiness directive, which would incorrectly require operators to replace the NLG trunnion pin cross bolts at a time that may not correspond with scheduled maintenance for the NLG. The compliance time for paragraph (c) was incorrectly published as, "At the next MLG overhaul, or within 12,000 landings after the effective date of this AD, whichever occurs earlier * * *". However, the correct compliance time for that requirement should have referred to " * * * at the next NLG overhaul."

Since it is essential that operators perform the replacement in a timely manner and at a time when the NLG is normally serviced, this document corrects the compliance terms of paragraph (c) of AD 94-18-05, amendment 39-9018, to read as follows:

"(c) At the next NLG overhaul, or within 12,000 landings after the effective date of this AD, whichever occurs earlier, remove the existing nose landing gear trunnion pin cross bolt, P/N NAS 1305-54D, and replace it with a new bolt, P/N NAS 1305-50D, in accordance with Paragraphs C. through F. of the Accomplishment Instructions of Saab Service Bulletin 340-32-094, dated October 29, 1993, or Revision 1, dated March 4, 1994."

The effective date of the rule remains October 11, 1994.

Since no other portion of the regulatory information has been changed, the final rule is not being republished.

Issued in Renton, Washington, on September 21, 1994.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94-23815 Filed 9-27-94; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 77N-0094]

RIN 0905-AA06

Drug Products for the Treatment and/or Prevention of Nocturnal Leg Muscle Cramps for Over-The-Counter Human Use; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the *Federal Register* of August 22, 1994 (59 FR 43234). The document established that any over-the-counter (OTC) drug product for the treatment and/or prevention of nocturnal leg muscle cramps is not generally recognized as safe and effective and is misbranded. The document was published with some typographical errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Lajuana D. Caldwell, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

In FR Doc. 94-20449, appearing on page 43234, the following corrections are made:

1. On page 43239, in the third column, in reference 3, line 5, and in reference 4, line 2, the word "Q-VELR" is corrected to read "Q-VEL®".

2. On page 43242, in the second column, line 21, and in the first full paragraph, line 19, the number "106" is corrected to read "106".

3. On page 43245, in the second column, in reference 4, line 2, and in reference 5, line 4, the word "Q-VELR" is corrected to read "Q-VEL®".

4. On page 43249, in the second column, in reference 1, line 2, and in reference 2, line 4, the word "Q-VELR" is corrected to read "Q-VEL®".

5. On page 43250, in the third column, in reference 1, line 2, and in reference 2, line 4, the word "Q-VELR" is corrected to read "Q-VEL®".

6. On page 43252, in the first column, in the second paragraph, in line 2, "regulatuion" is corrected to read "regulation"; and in line 7, the word "agencies" is corrected to read "agency's"; and in line 8, the word "substances" is corrected to read "substance".

Dated: September 21, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94-24014 Filed 9-27-94; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Parts 600, 610, 630, and 640

[Docket No. 93N-0392]

Biologics; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by substituting the term "supplement" for "amendment" when referring to the submission of a change to an approved establishment license or product license application. This action is being taken to harmonize the regulations with terminology used in the Prescription Drug User Fee Act of 1992.

DATES: Effective September 28, 1994; written comments by December 12, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

SUPPLEMENTARY INFORMATION: The Prescription Drug User Fee Act of 1992 (Pub. L. 102-571) (section 735 (21 U.S.C. 379g)) defines the term "supplement" as "a request to the Secretary to approve a change in a human drug application which has been approved." Also in section 735 of the Prescription Drug User Fee Act, a "human drug application" includes "an application for licensure of a biological product under section 351 of the Public Health Service Act." FDA is amending the biologics regulations by substituting the term "supplement" for "amendment." This change is being made to harmonize the regulations with

the terminology used in the Prescription Drug User Fee Act of 1992.

Prior to this announced change in terminology, the term "amendment" was used for all changes to both approved and unapproved license applications and amendments. In general, FDA intends to use the term "supplement" when referring to the submission of a change to an approved license application, and the term "amendment" when referring to the submission of a change to an unapproved license application or amendment. This change will not affect pending supplements (amendments) to establishment or product license applications.

This final rule contains only a minor change that is necessary to clarify terminology in the regulations. The rule change will not affect the way a license amendment or supplement to an application should be submitted to the agency, except in the way it is identified; nor will the change affect the way a license amendment or supplement will be reviewed by FDA. Therefore, FDA finds that there is good cause to dispense with a notice of proposed rulemaking as unnecessary, pursuant to the Administrative Procedure Act (5 U.S.C. 553) and FDA's administrative practices and procedures regulations (21 CFR 10.40(e)). FDA also finds, in accordance with the Administrative Procedure Act, that there is good cause to make this final rule effective on the date of publication in the *Federal Register*. FDA, however, is allowing 75 days for public comment on this final rule, in accordance with 21 CFR 10.40(e)(1).

Interested persons may, on or before December 12, 1994, submit to the Dockets Management Branch (address above) written comments regarding this rule. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will consider any comments submitted to determine if any additional changes to the regulations are necessary.

List of Subjects

21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.