(iii) Horses intended for importation from South America or Central America, or that have transited any country in South America or Central America, within 7 days immediately preceding importation, shall be quarantined for 7 days at a quarantine facility operated and maintained by Veterinary Services.

(Sec. 2, 32 Stat. 792, as amended; secs. 2, 4, and 11, 76 Stat. 129, 130, 132 (21 U.S.C. 111, 134a, 134c, and 134f); 7 CFR 2.17, 2.51, and 371.2(d))

Done at Washington, D.C., this 3rd day of January 1983.

K. R. Hook,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 83-399 Filed 1-4-83; 11:30 am]

BILLING CODE 3410-34-M

CIVIL AERONAUTICS BOARD

14 CFR Parts 221 and 296

[Order 82-12-24]

Tariffs and Indirect Air Transportation of Property; Waiver of Certain Rules for Indirect Cargo Air Carriers

AGENCY: Civil Aeronautics Board.

ACTION: Waiver of rule by Order 82-12-24.

SUMMARY: The CAB is waiving provisions of its rules to the extent necessary to permit indirect cargo air carriers to participate in joint tariffs filed by direct air carriers and direct foreign air carriers for the foreign air transportation of cargo, with certain conditions. In response to a request by Emery Air Freight the Board takes this action to provide greater operating flexibility for indirect and direct carriers and to continue its policy of removing itself from the regulation of cargo pricing practices.

DATES:

Adopted: December 9, 1982.

Effective: December 9, 1982, however this order may be amended at any time at the Board's discretion without hearing.

FOR FURTHER INFORMATION CONTACT: Lawrence Myers, Office of the General Counsel, Pricing & Entry Division, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 28420; (202) 673-5205.

SUPPLEMENTARY INFORMATION: The Board is granting a waiver from the provisions of Part 296 of its Economic Regulations, 14 CFR Part 296, which prevent U.S. airfreight forwarders and cooperative shippers associations ("indirect cargo air carriers") from participating in through cargo service on an "interline" basis with direct carriers. The principal relief granted would permit indirect carriers such as Emery to participate in through joint tariffs, published where required by law, as if they were direct carriers, and to divide the revenues with their interline partners pursuant to unfiled prorate agreements. The Board's regulations prohibit the division of primary transportation responsibility inherent in direct/indirect carrier interlining and also prohibit indirect cargo air carriers from filing or participating in any tariffs. The waiver is subject to the conditions that the shipper be provided actual advance notice that the shipment will be interlined and that the shipment not be consolidated by the indirect carrier for rating purposes. As in the case of direct carrier interlining, the arrangements permitted by the Board's action are not accorded antitrust immunity. The Board takes this action to provide greater operating flexibility for indirect and direct carriers and to continue its policy of removing itself from the regulation of cargo pricing practices.

By the Civil Aeronautics Board: December 9, 1982.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 83-496 Filed 1-6-83; 8:45 am]

BILLING CODE 6320-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Part 399

[Docket No. 21117-232]

Reformat of the Commodity Control List

Correction

In FR Doc. 82-34908 beginning on page 58122 in the issue of Wednesday, December 29, 1982 some material was inadvertently omitted. On page 58135, at the bottom of the first column, preceding paragraph (a) add the following material:

3261A Neutron generator systems, including tubes, designed for operation without an external vacuum system, and utilizing electrostatic acceleration to induce a tritium-deuterium nuclear reaction; and specially designed parts therefor.

Controls for ECCN 3261A

Unit: Report systems and tubes in "number"; parts and accessories in "$ value."

Validated License Required: Country Groups PQSTVWYZ.

GLV $ Value Limit: $0 for all destinations.

Processing Code: EE.

Reason for Control: National security, nuclear non-proliferation.

Special Licenses Available: None.

Advisory Notes: 1. Licenses are likely to be approved for export to satisfactory end-users in Country Groups PQSWY of neutron generator systems, including tubes, as defined in ECCN 3261A.

2. Licenses are likely to be approved for export to satisfactory end-users in Country Groups PQSWY of tubes and systems whose technical specifications are essentially the same as those for previously approved exports, provided that they are for civil uses.

4261B Particle accelerators having all of the specifications described in the List below.

Controls for ECCN 4261B

Unit: Report in "number"; parts and accessories in "$ value."

Validated License Required: Country Groups PQSTVWYZ.

GLV $ Value Limit: $500 for Country Groups T and V; $0 for all other destinations.

Processing Code: EE.

Special Licenses Available: None.

List of Specifications for Particle Accelerators Controlled by ECCN 4261B

* * * * *

BILLING CODE 1505-01-M

15 CFR Part 399

[Docket No. 21223-258]

Clarification of Commodity Interpretation 29 of Supp. No. 1 to § 399.2, General Industrial Equipment

AGENCY: Office of Export Administration, International Trade Administration, Commerce.

ACTION: Final rule

SUMMARY: This rule makes one clarification of the change in controls on the U.S.S.R. and Poland published in the **Federal Register** on November 18, 1982. The definition of "seismograph thumper mounted trucks" in Interpretation 29 of Supp. No. 1 to section 399.2 is clarified to read " seismograph thumper/vibrator mounted trucks."

DATE: Effective January 7, 1983.

FOR FURTHER INFORMATION CONTACT: Archie Andrews, Director, Exporters' Service Staff, Office of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230 (Telephone: (202) 377-4811).

Rulemaking Requirements

In connection with various rulemaking requirements, the Office of Export Administration has determined that:

1. This rule is exempt from the public participation in rulemaking procedures of the Administrative Procedure Act by section 13(a) of the Export Administration Act of 1979 (Pub. L. 97-72, 50 U.S.C. app. 2401 *et seq.*). This rule does not impose new controls on exports, and it is therefore exempt from section 13(b) of the Act, which expresses the intent of Congress that where practicable "regulations imposing controls on exports" be published in proposed form.

2. This rule does not impose a burden under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

3. This rule is not subject to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*

4. This rule is not a major rule within the meaning of section 1(b) of Executive Order 12291 (46 FR 13193, February 19, 1981), "Federal Regulation."

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

List of Subjects in CFR Part 399

Exports.

PART 399—[AMENDED]

Accordingly, the Export Administration Regulations (15 CFR Part 368, *et seq.*) are amended as follows:

§ 399.2 [Amended]

Commodity Interpretation 29: General Industrial Equipment, of Supplement No. 1 to § 399.2, is amended by revising the listing "Special purpose vehicles, n.e.s. * * *" to read: Special purpose vehicles, n.e.s., non-military, *e.g.* cement mixers, street and airfield cleaning equipment, asphalt mixers, mine shuttle vehicles, trucks with derrick assemblies, and similar equipment mounted integral to the truck frame, seismograph thumper/vibrator mounted trucks and oil/gas well drilling rigs.[1]

(Secs. 4, 6, 13, 15, 16, and 21, Pub. L. 96-72, 93 Stat. 503, 50 U.S.C. App. 2401 *et seq.*, as amended; E.O. No. 12002 (42 FR 35623, July 11, 1977); and E.O. No. 12214 (45 FR 29783, May 6, 1980)

Dated: December 22, 1982.

John K. Boidock,

Director, Office of Export Administration.

[FR Doc. 83-465 Filed 1-6-83; 8:45 am]

BILLING CODE 3510-25-M

[1] * * *

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1, 3, 4, 15, 16, 18, 21, 32, 33, 145, 147, 155, 170 and 180

Domestic Exchange-Traded Commodity Options; Expansion of Pilot Program To Include Options on Physicals

Correction

In FR Doc. 82-34538 beginning on page 56996 in the issue of Wednesday, December 22, 1982, make the following changes:

1. On page 57007, the third column, the paragraph designated "(D)", the ninth line, the word "the" should be removed.

2. On page 57017, the third column, the paragraph designated "(c)", the seventeenth line, the word "officer" should read "offer".

3. On page 57018, the third column, the thirty-seventh line, the word "or" should read "of".

4. On page 57019, the first and second columns, the paragraphs designated "(2)", "(3)", "(5)" and "(6)", the italicized material immediately following the numbers should be capitalized.

5. On the same page, the second column, the paragraph designated "(7)", the italicized material immediately following the number and before "(i)" should be capitalized.

BILLING CODE 1505-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 1, 1b, 2, 3, 3a, 4, 12, 16, 25, 32, 33, 34, 35, 41, 45, 131, 152, 153, 154, 156, 157, 158, 250, 270, 271, 275, 281, 282, 284, 286, 292, 375, 385, and 388

[Docket No. RM78-22-000]

Revision of Rules of Practice and Procedure To Expedite Trial-Type Hearings; Correction

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule; correcton.

SUMMARY: This document makes corrections to: (1) The final rule revising the Commission's Rules of Practice and Procedure that was published on May 3, 1982 (47 FR 19014), and (2) corrections of the final rule that were published on August 18, 1982 (47 FR 35952). This action is necessary to correct certain typographical, cross-reference, and editorial errors.

FOR FURTHER INFORMATION CONTACT: Fredric D. Chanania, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington D. C. 20426, (202) 357-8033.

Kenneth F. Plumb,

Secretary.

A. The following corrections are made in FR Doc. 82-11675 appearing on 19014 in the issue of May 3, 1982:

1. On page 19022, in § 1.101(c), "means" is corrected to read "mean".

2. On page 19057, in § 157.10, "§ 385.209" is corrected to read "§ 385.211".

3. On page 19058, in § 375.307(g), "§ 385.214" is corrected to read "§ 385.216".

4. On page 19026, column three, in § 385.214(b), the last subparagraph, which is erroneously designated as subparagraph "(2)" is redesignated as subparagraph "(3)".

5. On page 19026, in § 385.213(d)(2) (i) and (ii) add "notice of" after the word "If", so that both introductory clauses begin "If notice of the pleading . . .".

6. On page 19028, in § 385.504(b)(14)(iii), "approprite" is corrected to read "appropriate".

7. On page 19042, in § 385.1110(c), the last six words "grant on denial of that adjustment" are corrected to read "grant or denial of that adjustment".

8. On page 19046, in § 385.1902, open and closed parentheses are inserted respectively in lieu of the first and fourth commas; thus, the first sentence, as corrected, reads as follows: "Any staff action (other than a decision or ruling of a presiding officer, as defined in Rule 102(e)(1), made in a proceeding set for hearing under Subpart E of this part) taken persuant to authority delegated to the staff by the Commission that would be final, but for the provisions of this section, may be appealed to the Commission by a party."

9. On page 19049, in § 385.2006, paragraphs (1) and (2) are redesignated as paragraphs (a) and (b) respectively.

10. On page 19052, in § 388.101, the last paragraph, which now is erroneously designated as paragraph "(b)", is redesignated as paragraph "(f)".

11. On page 19053, in § 388.105(a)(15)(iii), a second closed parentheses is added after "(other than 5 U.S.C. 552(b)" and before the following comma.

12. On page 19054, in § 388.108, third line, the word "for" that precedes "material" is removed.

B. The following correction is made in FR Doc. 82-22510 appearing on 35952, in the issue of August 18, 1982:

1. On page 35956, column one, the amendatory language in paragraph (1) is corrected to read: "1. On page 19025, column three, the period at the end of paragraph (a)(2) of § 385.212 is changed to a semicolon and a new paragraph (a)(3) is added to read as follows:".

Dated: December 30, 1982.

[FR Doc. 83-377 Filed 1-6-83; 8:45 am]
BILLING CODE 6717-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 429

[Docket No. 82N-0221]

Fees for Certifying Insulin Drugs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the insulin regulations by increasing the fees for certification services. The increases are needed to maintain an adequate insulin certification program, as required by the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Effective March 8, 1983; comments by February 7, 1983.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David Petak, Division of Financial Management, Accounting Branch (HFA-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1768.

SUPPLEMENTARY INFORMATION: Section 506(b)(5) of the act (21 U.S.C. 356(b)(5)) requires that fees adequate to maintain an insulin certification program be specified in agency regulations. The current fee schedule specified in § 429.55(b) (21 CFR 429.55(b)) was published as a final regulation in the Federal Register of May 27, 1977 (42 FR 27227). An internal agency review of the costs and revenues associated with insulin certification was completed in 1980, and at that time it was determined not to alter the schedule that had been established in 1977. Another review of the insulin certification activities and associated revenues and costs was completed in 1982. It concluded that current fees are now insufficient to provide, equip, and maintain an adequate certification service, and that a revised fee structure is necessary.

Program costs associated with insulin certification have been altered in four ways:

1. A dramatic increase in the number of samples requiring bioassay analysis is occurring and is projected to be sustained for the foreseeable future. These bioassay analyses are required for each master lot of insulin manufactured. In the past, firms produced very large master lots and maintained large inventories of insulin crystals. Recently, firms have been found to be producing much smaller master lots more frequently, reportedly to reduce the costs associated with carrying large inventories. This practice substantially increases the number of master lots that FDA must bioassay. In addition, two other factors are also increasing the number of master lots that FDA must bioassay—new insulin manufacturers have entered the market and there is occurring an increase in the types of insulin being manufactured.

2. New techniques in the manufacture of insulin, such as recombinant DNA technology, make it essential to increase the resources devoted to insulin research and the development of testing methodology.

3. The insulin program will need to carry the full costs of certification support activities that in the past were shared with the recently terminated antibiotic certification program.

4. Inflation since 1977 would make it necessary to increase the fees required to support the existing certification program even if the increased costs in the program described above had not occurred.

These factors taken together require the raising of fees to ensure adequate funding for the insulin certification program. Unlike the statutory provision on antibiotic certification (21 U.S.C. 357), the provision on insulin certification (21 U.S.C. 356) does not provide for regulations granting exemptions from certification. Moreover, FDA believes there is a need to continue the independent replication of manufacturer tests that has in the past comprised the agency's insulin certification program. Diabetic patients depend not only on a continuing supply of insulin, but on a supply whose quality generally, and particularly whose potency, have been determined with precision. Independent replication ensures best that quality has not been subject to variation and that potency remains within safe limitations. In all, maintaining an adequate certification service will require increases in the laboratory and equipment needs associated with the insulin certification program and an increase in the staff associated with the program from 10 to 16 positions.

The new fee schedule for the insulin certification program is as follows. The fee for each master lot is raised from $195 to $450, for each trial dilution from $3,177 to $7,000, and for each trial mixture of Protamine Zinc Insulin from $2,754 to $5,000. These changes reflect FDA's true cost of performing these tests as well as the cost of expanding the agency's capability to perform bioassay analysis. The amendment also increases the fee on each vial contained in the sample of the final batch from $16 to $100 per vial. The manufacturer is required to submit for analysis one vial for each 10,000 vials in the batch, with a minimum of 10. The amendment eliminates the administrative fee of $85 per batch, the facsimile fee of $1.25 per certificate, and the fees for a trial mixture of globin zinc insulin ($2,754) and globin hydrochloride ($386). The latter two products are no longer produced. The total cost of FDA's fees, after the changes made in this regulation, will amount to about 2 cents for each vial of insulin produced. Documents supporting the need for increased fees and which set forth the basis on which the agency has established the new fee schedule are available for review in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.24(b)(22) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required. Because this provision is issued as a final rule without being preceded by general notice of proposed rulemaking, a final regulatory analysis under section 604 of the Regulatory Flexibility Act (94 Stat. 1167) is not required. In any event, the rule will not have a significant economic impact on a substantial number of small entities. Only a small number of large companies will be affected, and the costs involved are minuscule in relation to the revenues affected. Accordingly, the agency certifies that a regulatory flexibility analysis is not required. In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this rule and has determined that it is not a major rule as defined by that Order.