

[Reg. ER-766, Amdt. 1]

PART 241—UNIFORM SYSTEM OF ACCOUNTS AND REPORTS FOR CERTIFICATED AIR CARRIERS

Amendment of Reporting Requirements for CAB Form 41, Schedule T-6

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 27th day of September 1972.

By SPR-61 (Part 372a), ER-761 (Part 207), and ER-762 (Part 208), published contemporaneously herewith, the Board is establishing a new class of charters, called travel group charters, and is authorizing direct air carriers to perform flights in connection with such charters.

The instructions for Schedule T-6—Summary of Civil Aircraft Charters—in sections 25 and 35 of Part 241 presently require that data shall be reported for all civil charter flights performed by the route and supplemental air carriers, respectively. It is thus necessary to amend Schedule T-6 itself in order to provide for the reporting of this newly established class of pro rata civil charters.¹ This amendment of Part 241 is thus basically editorial in nature, in that it merely reflects the establishment in Part 372a of a new class of civil charters to be reported. Since it imposes no significant burden on anyone, the Board finds that notice and public procedure thereon are unnecessary, and it may be made effective immediately.

Accordingly, the Civil Aeronautics Board hereby amends Part 241 of the Economic Regulations (14 CFR Part 241) effective September 27, 1972, as follows:

1. Amend section 25, Schedule T-6, by revising paragraph (c) (2) and (7) and paragraph (i) to read as follows:

Section 25—Traffic and Capacity Elements

Schedule T-6—Summary of Civil Aircraft Charters

(c) * * *

(2) Pro rata charter (other than travel group charter), as defined in Part 207 of the Board's economic regulations. Mixed charters, as defined in Part 207, are to be reported as pro rata charters.

(7) Travel group charter, as defined in Part 372a of the Board's special regulations.

(i) Columns 4 and 5 shall reflect, respectively, the aggregate number of seats

¹ Paragraph (c) (2) of the instructions for Schedule T-6 in section 25 of Part 241, and paragraph (b) (4) of parallel instructions in section 35 of said part, presently call for the separate reporting of pro rata charters as defined in Part 208 (prior affinity pro rata charters). Since travel group charters are distinguishable from other kinds of pro rata charters and are governed by Part 372a, the Board wishes reports on charter operations to differentiate specifically between ordinary pro rata charters and travel group charters.

and the aggregate cargo capacity in tons contracted for on flights reported in column 3. Column 4 on the split charter report shall reflect a breakdown of the aggregate number of seats contracted for (on flights reported in column 3) by type of charter group. The following symbols shall be used: A—single entity; B—ordinary pro rata; C—study group; D—overseas military personnel; and E—travel group.

2. Amend section 35, Schedule T-6, by revising paragraphs (b) (4) and (8) and paragraph (h), to read as follows:

Section 35—Traffic and Capacity Elements

Schedule T-6—Summary of Civil Aircraft Charters

(b) * * *

(4) Pro rata charter (other than travel group charter), as defined in Part 208 of the Board's economic regulations. Mixed charters, as defined in Part 208, are to be reported as pro rata charters.

(8) Travel group charter, as defined in Part 372a of the Board's special regulations.

(h) Columns 4 and 5 shall reflect, respectively, the aggregate number of seats and the aggregate cargo capacity in tons contracted for on flights reported in column 3. Column 4 on the split-charter report shall reflect a breakdown of the aggregate number of seats contracted for (on flights reported in column 3) by type of charter group. The following symbols shall be used: A—single entity; B—ordinary pro rata; C—study group; D—inclusive tour; E—overseas military personnel; and F—travel group.

(Secs. 204, 407, Federal Aviation Act of 1958, as amended, 72 Stat. 743, 766; 49 U.S.C. 1324, 1377)

NOTE: The reporting requirements herein have been approved by the Office of Management and Budget in accordance with the Federal Reports Act of 1942.

By the Civil Aeronautics Board.

[SEAL] HARRY J. ZINK,
Secretary.

[FR Doc.72-16839 Filed 10-2-72; 8:54 am]

[Reg. ER-767, Amdt. 20]

PART 249—PRESERVATION OF AIR CARRIER ACCOUNTS, RECORDS, AND MEMORANDA

Preservation of Records by Travel Group Charter Organizers

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 27th day of September 1972.

By SPR-61 (Part 372a), published contemporaneously herewith, the Board is establishing a new class of charters, to be called travel group charters, and is authorizing a new class of charter opera-

tors to act as indirect air carriers with respect to such charters. The rule being adopted in SPR-61 contains certain record retention requirements for the travel group charter organizer. Specifically, he will be required to retain documents reflecting deposits made by, or refunds made to, each charter participant and statements, bills, and receipts from vendors of goods and services furnished in connection with the travel group charters. In the interest of uniformity, we are herein amending Part 249 so as to reflect the new record retention requirement.

Since the amendments contained herein impose no significant burden upon any person, and are needed to reflect the record retention requirements imposed by Part 372a, the Board finds that notice and public procedure thereon are unnecessary and they may be made effective immediately.

Accordingly, the Civil Aeronautics Board hereby amends Part 249 of the Economic Regulations (14 CFR Part 249), effective September 27, 1972, as follows:

1. Amend the Table of Contents by revising the title of § 249.9, the table as amended to read, in pertinent part, as follows:

Sec.
249.9 Period of preservation of records by tour operators, study group charterers, overseas military personnel charter operators, and travel group charter organizers.

2. Amend § 249.1 to read as follows:

§ 249.1 Applicability.

Except as otherwise provided in this subpart or other parts of this subchapter, the provisions of this subpart shall apply to (a) air carriers, as defined in section 101(3) of the Act, which hold certificates of public convenience and necessity, supplemental air carriers, subject to the reporting requirements of Part 241 of this subchapter and former Part 242 of this subchapter, (b) holders of a permit authorizing the navigation in the United States of foreign civil aircraft pursuant to Part 375 of this chapter (Board's Special Regulations), (c) foreign air carriers, as defined in section 101(19) of the Act, (d) tour operators as defined in § 378.2(d) of this chapter, (e) study group charterers, as defined in § 373.2 of this chapter, (f) overseas military personnel charter operators, as defined in § 372.2 of this chapter, and (g) travel group charter organizers, as defined in § 372a.2 of this chapter.

3. Amend § 249.2 by inserting therein, in alphabetical sequence, the definition of "travel group charter organizer," as follows:

§ 249.2 Definitions.

"Travel group charter organizer" means (1) any citizen of the United States, as defined in section 101(13) of the Act (other than a direct air carrier), who is authorized under Part 372a to engage in the formation of travel groups in accordance with the provisions of

Part 372a; or (2) any person not a citizen of the United States, as defined in section 101(13) of the Act (other than a direct foreign air carrier), who is engaged in the formation of travel groups for transportation on travel group charters which originate in the United States in accordance with the provisions of Part 372a, and who holds a permit issued pursuant to section 402 of the Act authorizing such transportation.

4. Amend § 249.9 by revising the title and adding a new paragraph (d), as follows:

§ 249.9 Period of preservation of records by tour operators, study group charterers, overseas military personnel charter operators, and travel group charter organizers.

(d) Every travel group charter organizer (as defined in § 249.2) conducting a travel group charter pursuant to Part 372a of this chapter shall retain for 2 years after completion of the travel group charter or series of travel group charters true copies of the following documents at its principal or general office in the United States and shall make them available upon request by an authorized representative of the Board.

(1) All documents which evidence or reflect deposits made by, and refunds made to, each charter participant; and

(2) All statements, invoices, bills, and receipts from suppliers or furnishers of goods and services in connection with the travel group charter or series of travel group charters.

(Secs. 204(a), 402, 407, Federal Aviation Act of 1958, as amended, 72 Stat. 743, 757, 766; 49 U.S.C. 1324, 1372, 1377)

NOTE: The record-retention requirements herein have been approved by the Office of Management and Budget in accordance with the Federal Reports Act of 1942.

By the Civil Aeronautics Board.

[SEAL] HARRY J. ZINK,
Secretary.

[FR Doc. 72-16840 Filed 10-2-72; 8:54 am]

Title 19—CUSTOMS DUTIES

Chapter I—Bureau of Customs,
Department of the Treasury

[T.D. 72-266]

TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

SEPTEMBER 21, 1972.

On December 19, 1970, notice of proposed rule making pertaining to a revision of the Customs Regulations relating to trademarks, trade names, and copyrights (19 CFR 11.14-11.21) was published in the FEDERAL REGISTER (35 F.R. 19269). An extension of time for filing comments to April 19, 1971, was granted (36 F.R. 3527).

After consideration of all comments received, the following changes are made in the proposed Part 133:

1. Section 133.0 is revised to more adequately explain the provisions contained in Part 133.

2. Paragraph (b) of § 133.1 is changed by inserting the words "or denial" after the word "approval," and by consolidating the references to the provisions under which applications are filed.

3. In the center heading for Subpart C, the word "infringing" is changed to "bearing."

4. Paragraph (b) of § 133.21 is changed by inserting the words "seizure and" after the words "subject to."

5. Paragraph (c) of § 133.21 is changed as follows:

In subparagraph (2), the cross-reference "(see §§ 133.2(d) and 133.12 (d))" is inserted before the semicolon.

Subparagraph (6) is rephrased to provide for those situations in which a general consent is filed with the Bureau, as well as cases in which the importer obtains written consent to a specific importation.

6. Paragraph (c) of § 133.23 is changed to permit an addressee appearing in person to obtain skillful removal of marks, and to delete the procedure permitting the package to be sent to the addressee for removal.

7. Section 133.31 is changed as follows:

a. A new paragraph (b) is inserted stating the persons eligible to record a copyright, and paragraphs (b) and (c) are redesignated as (c) and (d), respectively.

b. In redesignated paragraph (d), the words "or denial" are inserted after the word "approval," and the references to provisions under which applications are filed are consolidated.

8. Section 133.32 is changed as follows:
a. Paragraphs (b) and (c) are designated as (c) and (e), respectively.

b. Requirements that the application contain a statement setting forth the circumstances of actual or potential injury if the applicant claims such injury by reason of importations of works eligible for recordation of copyright, and that the foreign title of the work be identified if it differs from the U.S. title are added as paragraphs (b) and (d), respectively.

c. Redesignated paragraph (e) is changed by inserting the word "first" before the word "publication" the first two times that word appears.

9. Section 133.33 is changed as follows:

a. In subparagraph (1) of paragraph (a), the cross-reference is changed to read "§ 133.32(e)," and the second sentence is rephrased to more clearly state the nature of the document to be filed showing ownership interest and the circumstances in which it is required.

b. In subparagraph (2) of paragraph (a), the words "reproduced on paper" are inserted after the word "likenesses," and a sentence is added providing for the submissions relating to a component part to accompany an application for an entire copyrighted work.

10. Section 133.34 is changed as follows:

a. Paragraph (b) is rephrased to show that the term of recordation of a copyright is coextensive with the ownership interest of the recordant.

b. Paragraph (c) is changed by inserting after the word "canceled" the words "upon the request of the recordant or" to provide for cancellation at the instance of the recordant.

11. Section 133.35 is changed as follows:

a. In paragraph (a), the word "new" before the word "owner" is deleted.

b. In paragraph (b), subparagraph (1) is rephrased to clearly indicate the type of document required to show ownership interest.

12. In paragraph (a) of § 133.36, the words "title to be presently in the name as changed" are changed to read "the change in the name of the owner."

13. In paragraph (a) of § 133.37, the words "copyright registration" are changed to read "term of the copyright" in the first sentence, and subparagraphs (1) and (2) are rephrased to clearly state the information required as part of an application to renew Customs recordation of a copyright.

14. In § 133.42, paragraph (b) is redesignated as (c), and paragraph (a) is divided into paragraphs (a) and (b) to separately state the definition of piratical copies.

15. In § 133.43, paragraph (b) is changed by substituting 30 days for 10 days and deleting "exclusive of any intervening Saturday, Sunday, or holiday," to provide a reasonable time for the copyright owner to make representations as to piratical copying.

16. Section 133.45 is changed as follows:

a. The heading of the section, and the heading of paragraph (b) are clarified.

b. Paragraph (c) is rephrased to clarify the provision pertaining to release of works under the Universal Copyright Convention.

17. In § 133.51, subparagraph (3) of paragraph (b) is rephrased to clarify its application only to books or periodicals manufactured abroad contrary to the terms of the "American manufacturing clause" of the Copyright Act.

18. Paragraph (b) of § 133.52 is changed to clarify the disposition of articles forfeited for violation of the copyright laws.

In addition, editorial corrections are made in §§ 133.6, 133.13, and 133.15, and in the heading of § 133.46.

There is included as part of the revision a parallel reference table showing the relationship of sections in Part 133 to superseded sections in 19 CFR Parts 11 and 24.

Accordingly, new Part 133, and the conforming changes in Parts 11 and 24 of the Customs Regulations, Chapter I, Title 19 of the Code of Federal Regulations, are hereby adopted as set forth below.

Effective date. These amendments shall become effective 30 days after publication in the FEDERAL REGISTER.

[SEAL] EDWIN F. RAINS,
Acting Commissioner of Customs.

Approved: September 21, 1972.

EUGENE T. ROSSIDES,
Assistant Secretary of the
Treasury.

PART 11—PACKING AND STAMPING; MARKING

The heading of Part 11 is amended to read as set forth above.

§§ 11.14–11.21 [Deleted]

Part 11 is amended by deleting §§ 11.14 through 11.21.

(R.S. 251, as amended, sec. 624, 46 Stat. 759; 19 U.S.C. 66, 1624)

PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE

§ 24.12 [Amended]

In § 24.12, paragraph (a) (1) is amended by deleting subdivision (i).

(R.S. 251, as amended, sec. 624, 46 Stat. 759; 19 U.S.C. 66, 1624)

PART 133—TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

Chapter I of title 19 of the Code of Federal Regulations is amended by adding Part 133 entitled, "Trademarks, Trade Names, and Copyrights" as follows:

133.0 Scope.

Subpart A—Recordation of Trademarks

- 133.1 Recordation of trademarks.
- 133.2 Application to record trademark.
- 133.3 Documents and fee to accompany application.
- 133.4 Effective date, term, and cancellation of trademark recordation and renewals.
- 133.5 Change of ownership of recorded trademark.
- 133.6 Change in name of owner of recorded trademark.
- 133.7 Renewal of trademark recordation.

Subpart B—Recordation of Trade Names

- 133.11 Trade names eligible for recordation.
- 133.12 Application to record a trade name.
- 133.13 Documents and fee to accompany application.
- 133.14 Publication of trade name recordation.
- 133.15 Term of Customs trade name recordation.

Subpart C—Importations Bearing Recorded Trademarks or Trade Names

- 133.21 Restrictions on importation of articles bearing recorded trademarks and trade names.
- 133.22 Detention of articles subject to restrictions.
- 133.23 Release of detained articles.
- 133.24 Demand for redelivery of released merchandise.

Subpart D—Recordation of Copyrights

- 133.31 Recordation of copyrighted works.
- 133.32 Application to record copyright.

Sec.

- 133.33 Documents and fee to accompany application.
- 133.34 Effective date, term, and cancellation of recordation.
- 133.35 Change of ownership of recorded copyright.
- 133.36 Change in name of owner of recorded copyright.
- 133.37 Renewal of copyright recordation.

Subpart E—Importations Violating Copyright Laws

- 133.41 False notice of copyright.
- 133.42 Piratical copies.
- 133.43 Procedure on suspicion of piratical copying.
- 133.44 Decision of disputed claim of piratical copying.
- 133.45 United States manufacturing requirements for books and periodicals.
- 133.46 Demand for redelivery of released articles.

Subpart F—Procedure Following Forfeiture or Assessment of Liquidated Damages

- 133.51 Relief from forfeiture or liquidated damages.
- 133.52 Disposition of forfeited merchandise.
- 133.53 Refund of duty.

AUTHORITY: The provisions of this Part 133 issued under R.S. 251, as amended, sec. 624, 46 Stat. 759; 19 U.S.C. 66, 1624. Subpart D also issued under sec. 109, 61 Stat. 664, 17 U.S.C. 109.

§ 133.0 Scope.

This part provides for the recordation of trademarks, trade names, and copyrights with the Bureau of Customs for the purpose of prohibiting the importation of certain articles. It also sets forth the procedures for the disposition of articles bearing prohibited marks or names, and copyrighted or piratical articles, including release to the importer in appropriate circumstances.

Subpart A—Recordation of Trademarks

§ 133.1 Recordation of trademarks.

(a) **Eligible trademarks.** Trademarks registered by the U.S. Patent Office under the Trademark Act of March 3, 1881, the Trademark Act of February 20, 1905, or the Trademark Act of 1946 (15 U.S.C. 1051 et seq.) except those registered on the supplemental register under the 1946 Act (15 U.S.C. 1096), may be recorded with the Bureau of Customs if the registration is current.

(b) **Notice of recordation and other action.** Applicants and recordants will be notified of the approval or denial of an application filed in accordance with §§ 133.2, 133.5, 133.6, and 133.7 of this subpart.

(Secs. 28, 42, 60 Stat. 436, 440; 15 U.S.C. 1096, 1124)

§ 133.2 Application to record trademark.

An application to record one or more trademarks shall be in writing, addressed to the Commissioner of Customs, Washington, D.C. 20226, and shall include the following information:

(a) The name, complete business address, and citizenship of the trademark owner or owners (if a partnership, the

citizenship of each partner; if an association or corporation the State, country, or other political jurisdiction within which it was organized, incorporated, or created);

(b) The places of manufacture of goods bearing the recorded trademark;

(c) The name and principal business address of each foreign person or business entity authorized or licensed to use the trademark and a statement as to the use authorized; and

(d) The identity of any parent or subsidiary company or other foreign company under common ownership or control which uses the trademark abroad. For this purpose:

(1) "Common ownership" means individual or aggregate ownership of more than 50 percent of the business entity; and

(2) "Common control" means effective control in policy and operations and is not necessarily synonymous with common ownership.

(Sec. 42, 60 Stat. 440; 15 U.S.C. 1124)

§ 133.3 Documents and fee to accompany application.

(a) **Documents.** The application shall be accompanied by:

(1) A status copy of the certificate of registration certified by the U.S. Patent Office showing title to be presently in the name of the applicant; and

(2) Seven hundred copies of this certificate, or of a U.S. Patent Office facsimile. The copies may be reproduced privately and shall be on paper approximately 8½" by 11" in size. If the certificate consists of two or more pages, the copies may be reproduced on both sides of the paper.

(b) **Fee.** The application shall be accompanied by a fee of \$100 for each trademark to be recorded. However, if the trademark is registered for more than one class of goods (see 37 CFR Part 6) the fee for recordation shall be \$100 for each class for which the applicant desires to record the trademark with the Bureau of Customs. For example, to secure recordation of a trademark registered for three classes of goods, a fee of \$300 is payable. The check or money order shall be made payable to the Bureau of Customs.

(Sec. 42, 60 Stat. 440, sec. 501, 65 Stat. 290; 15 U.S.C. 1124, 31 U.S.C. 483a)

§ 133.4 Effective date, term, and cancellation of trademark recordation and renewals.

(a) **Effective date.** Recordation of trademark and protection thereunder shall be effective on the date an application for recordation is approved, as shown on the recordation notice issued by the Bureau of Customs instructing Customs officers as to the terms and conditions of import protection appropriate.

(b) **Term.** The recordation or renewal of an existing recordation of a trademark shall remain in force concurrently with the 20-year current registration period or last renewal thereof in the Patent Office.

(c) **Cancellation of recordation.** Recordation of a trademark with the Bureau

of Customs shall be canceled if the trademark registration is finally canceled or revoked.

(Sec. 42, 60 Stat. 440; 15 U.S.C. 1124)

§ 133.5 Change of ownership of recorded trademark.

If there is a change in ownership of a recorded trademark and the new owner wishes to continue the recordation with the Bureau of Customs, he shall apply therefor by:

- (a) Complying with § 133.2;
- (b) Describing any time limit on the rights of ownership transferred;
- (c) Submitting a status copy of the certificate of registration certified by the United States Patent Office showing title to be presently in the name of the new owner; and

(d) Paying a fee of \$40 which covers all trademarks included in the application which have been previously recorded with the Bureau of Customs. The check or money order shall be payable to the Bureau of Customs.

(Sec. 42, 60 Stat. 440, sec. 501, 65 Stat. 290; 15 U.S.C. 1124, 31 U.S.C. 483a)

§ 133.6 Change in name of owner of recorded trademark.

If there is a change in the name of the owner of a recorded trademark, but no change in ownership, written notice thereof shall be given to the Commissioner of Customs, accompanied by:

- (a) A status copy of the certificate of registration certified by the U.S. Patent Office showing title to be presently in the name as changed; and

(b) A fee of \$40 which covers all trademarks included in the application which have been previously recorded with the Bureau of Customs. The check or money order shall be payable to the Bureau of Customs.

(Sec. 42, 60 Stat. 440, sec. 501, 65 Stat. 290; 15 U.S.C. 1124, 31 U.S.C. 483a)

§ 133.7 Renewal of trademark recordation.

(a) *Application to renew.* To continue uninterrupted Customs protection for trademarks, the trademark owner shall submit a written application to renew Customs recordation to the Commissioner of Customs not later than 3 months after the date of expiration of the current 20-year trademark registration issued by the Patent Office. A timely application to renew a Customs recordation must include the following:

- (1) A status copy of the certificate of registration certified by the U.S. Patent Office showing renewal of the trademark and title to be in the name of the applicant;

(2) A statement describing any change of ownership or in the name of owner, in compliance with §§ 133.5 and 133.6 of this part, and any change of addresses of owners or places of manufacture; and

(3) A fee of \$40 which covers all recordation renewals submitted with the fee. The check or money order shall be made payable to the Bureau of Customs.

(b) *Delayed application.* Upon request made during the grace period of 3 months afforded by paragraph (a) of this section, a trademark owner whose application for renewal of recordation is unavoidably delayed may be afforded a reasonable extended period within which to comply with the requirements of paragraph (a) of this section. The request shall be in writing, addressed to the Commissioner of Customs, and shall set forth the circumstances due to which application is delayed.

(c) *Untimely application.* Failure of the trademark owner to submit a renewal application within the 3-month grace period afforded in accordance with paragraph (a) of this section or within an extension of time granted in accordance with paragraph (b) of this section, shall deprive the trademark owner of the renewal process. A delinquent applicant will be required to apply anew to record the renewed trademark in accordance with the procedures and requirements of §§ 133.2 and 133.3.

(Sec. 42, 60 Stat. 440, sec. 501, 65 Stat. 290; 15 U.S.C. 1124, 31 U.S.C. 483a)

Subpart B—Recordation of Trade Names

§ 133.11 Trade names eligible for recordation.

The name or trade style used for at least 6 months to identify a manufacturer or trader may be recorded with the Bureau of Customs. Words or designs used as trademarks, whether or not registered in the Patent Office shall not be accepted for recordation as a trade name. Generally, the complete business name will be recorded unless convincing proof establishes that only a part of the complete name is customarily used.

(Sec. 42, 60 Stat. 440; 15 U.S.C. 1124)

§ 133.12 Application to record a trade name.

An application to record a trade name shall be in writing addressed to the Commissioner of Customs, Washington, D.C. 20226, and shall include the following information:

- (a) The name, complete business address, and citizenship of the trade name owner or owners (if a partnership, the citizenship of each partner; if an association or corporation, the State, country, or other political jurisdiction within which it was organized, incorporated or created);

(b) The name or trade style to be recorded;

(c) The name and principal business address of each foreign person or business entity authorized or licensed to use the trade name and a statement as to the use authorized;

(d) The identity of any parent or subsidiary company, or other foreign company under common ownership or control which uses the trade name abroad (see § 133.2(d)); and

(e) A description of the merchandise with which the trade name is associated.

(Sec. 42, 60 Stat. 440; 15 U.S.C. 1124)

§ 133.13 Documents and fee to accompany application.

(a) *Documents.* The application shall be accompanied by a statement of the owner, partners, or principal corporate officer, and by statements by at least two other persons not associated with or related to the applicant but having actual knowledge of the facts, stating that to his best knowledge and belief:

- (1) The applicant has used the trade name in connection with the class or kind of merchandise described in the application for at least 6 months;

(2) The trade name is not identical or confusingly similar to any other trade name or registered trademark used in connection with such class or kind of merchandise; and

(3) The applicant has the sole and exclusive right to the use of such trade name in connection with the merchandise of that class or kind.

(b) *Fee.* The application shall be accompanied by a fee of \$100 for each trade name to be recorded. The check or money order shall be made payable to the Bureau of Customs.

(Sec. 42, 60 Stat. 440, sec. 501, 65 Stat. 290; 15 U.S.C. 1124, 31 U.S.C. 483a)

§ 133.14 Publication of trade name recordation.

(a) *Notice of tentative recordation.* Notice of tentative recordation of a trade name shall be published in the FEDERAL REGISTER and the Customs Bulletin. The notice shall specify a procedure and a time period within which interested parties may oppose the recordation.

(b) *Notice of final action.* After consideration of any claims, rebuttals, and other relevant evidence, notice of final approval or disapproval of the application shall be published in the FEDERAL REGISTER and the Customs Bulletin.

§ 133.15 Term of Customs trade name recordation.

Protection for a recorded trade name shall remain in force as long as the trade name is used. The recordation shall be canceled upon request of the recordant or upon evidence of disuse. From time to time, the Commissioner of Customs may request the trade name owner to advise whether the name is still in use. The failure of a trade name owner to respond to such a request shall be regarded as evidence of disuse.

(Sec. 42, 60 Stat. 440; 15 U.S.C. 1124)

Subpart C—Importations Bearing Recorded Trademarks or Trade Names

§ 133.21 Restrictions on importation of articles bearing recorded trademarks and trade names.

(a) *Copying or simulating marks or names.* Articles of foreign or domestic manufacture bearing a mark or name copying or simulating a recorded trademark or trade name shall be denied entry and are subject to forfeiture as prohibited importations. A "copying or simulating" mark or name is an actual counterfeit of the recorded mark or name or is one which so resembles it as to be

likely to cause the public to associate the copying or simulating mark with the recorded mark or name.

(b) *Identical trademark.* Foreign-made articles bearing a trademark identical with one owned and recorded by a citizen of the United States or a corporation or association created or organized within the United States are subject to seizure and forfeiture as prohibited importations.

(c) *Restrictions not applicable.* The restrictions set forth in paragraphs (a) and (b) of this section do not apply to imported articles when:

(1) Both the foreign and the U.S. trademark or trade name are owned by the same person or business entity;

(2) The foreign and domestic trademark or trade name owners are parent and subsidiary companies or are otherwise subject to common ownership or control (see §§ 133.2(d) and 133.12(d));

(3) The articles of foreign manufacture bear a recorded trademark or trade name applied under authorization of the U.S. owner;

(4) The objectionable mark is removed or obliterated prior to importation in such a manner as to be illegible and incapable of being reconstituted, for example by:

(i) Grinding off imprinted trademarks wherever they appear;

(ii) Removing and disposing of plates bearing a trademark or trade name;

(5) The merchandise is imported by the recordant of the trademark or trade name or his designate; or

(6) The recordant gives written consent to an importation of articles otherwise subject to the restrictions set forth in paragraphs (a) and (b) of this section, and such consent is furnished to appropriate Customs officials.

(Sec. 42, 60 Stat. 440, sec. 526, 46 Stat. 741; 15 U.S.C. 1124, 19 U.S.C. 1526)

§ 133.22 Detention of articles subject to restrictions.

(a) *In general.* Articles subject to the restrictions of § 133.21 shall be detained for 30 days from the date of notice to the importer that such restrictions apply to permit the importer to establish that any of the circumstances described in § 133.21(c) are applicable.

(b) *Notice of detention.* Notice of detention of articles found subject to the restrictions of § 133.21 shall be given the importer in writing, except that for articles accompanying the importer or arriving by mail, notice of detention shall be given in the following manner:

(1) *Articles accompanying importer.* When the articles are carried as accompanying baggage or on the person of persons arriving in the United States, the Customs inspector shall orally advise the importer that the articles are subject to detention.

(2) *Mail importations.* When the articles arrive by mail in noncommercial shipments, or in commercial shipments valued at \$250 or less, notice of the detention shall be given on Customs Form 8.

(c) *Failure to obtain release in 30 days.* If the importer has not obtained release of detained articles within the 30-day period of detention, the merchandise shall be seized and forfeiture proceedings instituted. The importer shall be promptly notified of the seizure and liability to forfeiture and his right to petition for relief in accordance with the provisions of Part 171 of this chapter.

§ 133.23 Release of detained articles.

(a) *General.* Articles detained in accordance with § 133.22 may be released to the importer during the 30-day period of detention if any of the circumstances allowing exemption from trademark or trade name restriction set forth in § 133.21(c) are established.

(b) *Articles accompanying importer.* Articles arriving as accompanying baggage or on the person of the importer may be exported or destroyed under Customs supervision at the request of the importer, or may be released if:

(1) The importer removes or obliterates the marks in a manner acceptable to the Customs officer at the time of examination of the articles; or

(2) The request of the importer to obtain skillful removal of the marks is granted by the district director on such conditions as he may deem necessary, and upon return of the article to Customs for verification, the marks are found to be satisfactorily removed.

(c) *Mail importations.* Articles arriving by mail in noncommercial shipments, or in commercial shipments valued at \$250 or less may be exported or destroyed at the request of the addressee or may be released if:

(1) The addressee appears in person at the appropriate Customs office and at that time removes or obliterates the marks in a manner acceptable to the Customs officer; or

(2) The request of the addressee appearing in person to obtain skillful removal of the marks is granted by the district director on such conditions as he may deem necessary, and upon return of the article to Customs for verification, the marks are found to be satisfactorily removed.

§ 133.24 Demand for redelivery of released merchandise.

If it is determined that merchandise which has been released from Customs custody is subject to the restrictions of § 133.21, the district director shall promptly make demand for the redelivery of the merchandise under the terms of the entry bond in accordance with § 8.26 of this chapter. If the merchandise is not redelivered to Customs custody, a claim for liquidated damages shall be made in accordance with § 25.17 of this chapter.

Subpart D—Recordation of Copyrights

§ 133.31 Recordation of copyrighted works.

(a) *Eligible works.* Claims to copyright which have been registered in accordance with the provisions of the Copyright Act of July 30, 1947, as amended (17 U.S.C. 1-32), or unregistered claims to copy-

right in works entitled to protection under section 9(c) of that Act, as amended (17 U.S.C. 9(c)), by virtue of the Universal Copyright Convention, may be recorded with the Bureau of Customs if the copyright is subsisting.

(b) *Persons eligible to record.* The copyright proprietor, or any person claiming actual or potential injury by reason of actual or contemplated importations of copies of eligible works, may file an application to record a copyright.

(c) *Countries party to the Universal Copyright Convention.* The following countries are party to the Universal Copyright Convention:

Andorra.	Laos.
Argentina.	Lebanon.
Australia.	Liberia.
Austria.	Liechtenstein.
Belgium.	Luxembourg.
Brazil.	Malawi.
Cambodia.	Malta.
Canada.	Mexico.
Chile.	Monaco.
Costa Rica.	Netherlands.
Cuba.	New Zealand.
Czechoslovakia.	Nicaragua.
Denmark.	Nigeria.
Ecuador.	Norway.
Finland.	Pakistan.
France.	Panama.
Germany, Federal	Paraguay.
Republic of.	Peru.
Ghana.	Philippines.
Greece.	Portugal.
Guatemala.	Spain.
Haiti.	Sweden.
Holy See.	Switzerland.
Iceland.	Tunisia.
India.	United Kingdom.
Ireland.	United States
Israel.	of America.
Italy.	Venezuela.
Japan.	Yugoslavia.
Kenya.	Zambia.

(d) *Notice of recordation and other action.* Applicants and recordants will be notified of the approval or denial of an application filed in accordance with § 133.32, § 133.35, § 133.36, or § 133.37.

§ 133.32 Application to record copyright.

An application to record a copyright to secure Customs protection against the importation of piratical copies shall be in writing addressed to the Commissioner of Customs, Washington, D.C. 20226, and shall include the following information:

(a) The name and complete address of the copyright owner or owners;

(b) If the applicant is a person claiming actual or potential injury by reason of actual or contemplated importations of copies of eligible works, a statement setting forth the circumstances of such actual or potential injury;

(c) The name and principal address of any foreign person or business entity authorized or licensed to use the copyright, and a statement as to the use authorized;

(d) The foreign title of the work, if different from the U.S. title; and

(e) In the case of protection claimed under section 9(c) of the Copyright Act, by virtue of the Universal Copyright

Convention, a statement setting forth the name of the author and his citizenship and domicile at the time of first publication, the date and country of first publication, and a description of the work, including its title, and a statement that all copies bore the Universal Copyright Convention notice from the date of first publication.

§ 133.33 Documents and fee to accompany application.

(a) *Documents.* The application for recordation shall be accompanied by the following documents:

(1) An "additional certificate" of copyright registration issued by the U.S. Copyright Office, except for unregistered Universal Copyright Convention works as described in § 133.32(e) of this subpart. If the name of the applicant differs from the name of the copyright owner identified in the certificate, or from the name appearing in the Universal Copyright Convention notice referred to in § 133.32(e), the application shall also be accompanied by a certified copy of any assignment, exclusive license, or other document recorded in the Copyright Office showing that the applicant has acquired an ownership interest in the copyright.

(2) Seven hundred 8" x 10 1/2" photographic or other likenesses reproduced on paper of any three-dimensional work, design, print, label, or other work not readily identifiable by title and author. An application shall be excepted from this requirement if it covers a work such as a book, magazine, periodical, or similar copyrighted matter readily identifiable by title and author. Seven hundred likenesses of a component part of a copyrighted work, together with the name or title, if any, by which the part so depicted is identifiable, may accompany an application covering an entire copyrighted work.

(b) *Fee.* Each application shall be accompanied by a fee of \$100 for each copyright to be recorded. The check or money order shall be made payable to the Bureau of Customs.

(Sec. 501, 65 Stat. 290; 31 U.S.C. 483a)

§ 133.34 Effective date, term, and cancellation of recordation.

(a) *Effective date.* Recordation of copyright and protection thereunder shall be effective on the date an application for recordation is approved, as shown on the recordation notice issued by the Bureau of Customs instructing Customs officers as to the terms and conditions of import protection appropriate.

(b) *Term.* The recordation of a copyright shall remain in force until the ownership interest of the recordant in the copyright expires. Unless such ownership interest expires sooner, the recordation shall remain in force until the end of the initial 28-year term of copyright, or, if the recordation is renewed in accordance with § 133.37, until the end of the renewal term of the copyright.

(c) *Cancellation.* Recordation of a copyright with the Bureau of Customs shall be canceled upon request of the recordant, or if the registration in the U.S. Copyright Office is finally canceled or revoked.

§ 133.35 Change of ownership of recorded copyright.

(a) *Application.* If the ownership of a recorded copyright is transferred and the owner wishes to continue the recordation with the Bureau of Customs, he shall make written application to the Commissioner of Customs as follows:

(1) Comply, as appropriate, with § 133.32; and

(2) Describe any time limit on the rights of ownership transferred.

(b) *Document and fee.* The application shall be accompanied by:

(1) A certified copy of any assignment, exclusive license, or other document recorded in the U.S. Copyright Office showing the applicant has acquired an ownership interest in the copyright; and

(2) A fee of \$40. The check or money order shall be payable to the Bureau of Customs.

(Sec. 501, 65 Stat. 290; 31 U.S.C. 483a)

§ 133.36 Change in name of owner of recorded copyright.

If there is a change in the name of the owner of a recorded copyright, but no transfer of ownership, written notice specifying the change shall be given to the Commissioner of Customs accompanied by the following:

(a) A certified copy of any document recorded in the U.S. Copyright Office showing the change in the name of the owner; and

(b) Payment of a fee of \$40. The check or money order shall be payable to the Bureau of Customs.

(Sec. 501, 65 Stat. 290; 31 U.S.C. 483a)

§ 133.37 Renewal of copyright recordation.

(a) *Application for renewal.* To continue uninterrupted Customs protection for a recorded copyright, the copyright owner shall make written application to the Commissioner of Customs to renew Customs recordation not later than 3 months from the date of expiration of the term of the copyright. An application to renew a Customs recordation shall include the following:

(1) An "additional certificate" of the renewal registration issued by the U.S. Copyright Office showing that a claim to renewal copyright in the name of the applicant or his predecessor in interest has been registered;

(2) A statement describing any change of ownership or name of owner, in compliance with §§ 133.35 and 133.36 and any change of address of the owner; and

(3) Payment of a fee of \$40. The check or money order shall be payable to the Bureau of Customs.

(b) *Delayed application.* Upon request made during the grace period of 3 months afforded by paragraph (a) of this section,

a copyright owner whose application for renewal of recordation is unavoidably delayed may be afforded a reasonable extended period within which to comply with the requirements of paragraph (a) of this section. The request shall be in writing, addressed to the Commissioner of Customs, and shall set forth the circumstances due to which application is delayed.

(c) *Untimely application.* Failure of the copyright owner to submit a renewal application within the 3-month grace period afforded in accordance with paragraph (a) of this section, or within an extension of time granted in accordance with paragraph (b) of this section, shall deprive the copyright owner of the renewal process. A delinquent applicant will be required to apply anew to record the renewed copyright in accordance with the procedures and requirements of §§ 133.22 and 133.33.

Subpart E—Importations Violating Copyright Laws

§ 133.41 False notice of copyright.

(a) *Importation prohibited.* The importation of articles bearing a false notice of copyright is prohibited. Books, periodicals, newspapers, music, moving picture films, and other articles which bear words indicating they are entitled to copyright protection in the United States, when in fact they are not so entitled, bear a false notice of copyright.

(b) *Seizure and forfeiture.* All articles bearing a false notice of copyright shall be seized and forfeited, except when imported in the mails. Such articles imported in the mails shall be returned to the postmaster for return to the sender as nondeliverable.

(Secs. 106, 108, 61 Stat. 663, 664; 17 U.S.C. 106, 108)

§ 133.42 Piratical copies.

(a) *Definition.* Piratical copies are actual copies or substantial copies of a recorded copyrighted work, produced and imported in contravention of the rights of the copyright owner.

(b) *Importation prohibited.* The importation of piratical copies of works copyrighted in the United States is prohibited.

(c) *Seizure and forfeiture.* The district director shall seize and forfeit an imported article which he determines constitutes a piratical copy of a recorded copyrighted work. The district director shall also seize and forfeit an imported article if the importer does not deny a representation that the article is a piratical copy as provided in § 133.43(a).

(Secs. 106, 108, 61 Stat. 663, 664; 17 U.S.C. 106, 108)

§ 133.43 Procedure on suspicion of piratical copying.

(a) *Notice to the importer.* If the district director has any reason to believe that an imported article may be a piratical copy of a recorded copyrighted work, he shall withhold delivery, notify the importer of his action, and advise him that

if the facts so warrant he may file a statement denying that the article is in fact a piratical copy and alleging that the detention of the article will result in a material depreciation of its value, or a loss or damage to him. The district director shall also advise the importer that in the absence of receipt within 30 days of a denial by the importer that the article constitutes a piratical copy, it shall be considered to be such a copy and shall be subject to seizure and forfeiture.

(b) *Notice to copyright owner.* If the importer of suspected piratical copies files a denial as provided in paragraph (a) of this section, the district director shall furnish the copyright owner a representative sample of the imported articles, together with notice that the imported articles will be released to the importer unless within 30 days from the date of the notice the copyright owner files with the district director:

(1) A written demand for the exclusion from entry of the detained imported articles; and

(2) A bond in the form and amount specified by the district director, conditioned to hold the importer or owner of such imported articles harmless from any loss or damage resulting from Customs detention in the event the Commissioner of Customs or his designee determines that the article is not a piratical copy prohibited importation under section 106 of the Copyright Act (17 U.S.C. 106).

(c) *Result of action or inaction by copyright owner.* After notice to the copyright owner that delivery is being withheld for imported articles suspected to be piratical copies of his recorded copyrighted work, the district director shall proceed in accordance with the applicable procedure set forth below:

(1) *Demand and bond filed.* If the copyright owner files a written demand for exclusion of the suspected piratical copies together with a proper bond, the district director shall promptly notify the importer and the copyright owner that, during a specified time limited to not more than 30 days, they may submit further evidence, legal briefs, or other pertinent material to substantiate the claim or denial of piratical copying. The burden of proof shall be upon the party claiming that any article is in fact a piratical copy. At the close of the period specified for submission of evidence, the district director shall forward the entire file in the case, together with a representative sample of the imported articles and his views or comments, to the Commissioner of Customs or his designee for decision of the disputed claim of piratical copying.

(2) *Piracy disclaimed or unsupported.* If the copyright owner disclaims that the specific imported article is a piratical copy of his recorded copyrighted work, or concedes that he possesses in sufficient evidence or proofs to substantiate a claim of piracy, the district director shall release the detained shipment to the importer, and shall release all further importations of the same article, by whomsoever imported, without further notice to the copyright owner.

(3) *Failure to file demand or bond.* If the copyright owner fails to file a written demand for exclusion and bond as required by paragraph (b) of this section, the district director shall release the detained articles to the importer, and notify the copyright owner of the release. The district director shall withhold delivery of all further importations of the same article by the same importer, and shall notify the copyright owner of each such subsequent shipment as provided in paragraph (b) of this section.

(4) *Withdrawal of bond.* At any time prior to transmittal of the case to the Commissioner of Customs or his designee for decision, the copyright owner may withdraw a bond filed in accordance with paragraph (b) of this section. Prior to returning the bond to the copyright owner and release of the detained articles, the district director shall require the copyright owner and the importer to file written statements agreeing to hold the Bureau of Customs and the district director harmless for any consequence of return of the bond and release of the detained articles. After withdrawal of a bond, the district director shall release importations of the same article by the same importer without further notice to the copyright owner.

§ 133.44 Decision of disputed claim of piratical copying.

(a) *Claim of piracy sustained.* Upon determination by the Commissioner of Customs or his designee that the detained article forwarded in accordance with § 133.43(c)(1) is a piratical copy, the district director shall seize and forfeit the imported articles in accordance with Part 23 of this chapter, and shall return the bond to the copyright owner.

(b) *Denial of piracy sustained.* Upon determination by the Commissioner of Customs or his designee that the detained article forwarded in accordance with § 133.43(c)(1) is not a piratical copy, the district director shall release all such detained merchandise and transmit the copyright owner's bond to the importer.

(Secs. 106, 108, 61 Stat. 663, 664; 17 U.S.C. 106, 108)

§ 133.45 U.S. manufacturing requirements for books and periodicals.

(a) *Importation prohibited.* Books and periodicals manufactured abroad contrary to the terms of the "American manufacturing clause" of the Copyright Act (17 U.S.C. 16) which requires manufacture in the United States may not be imported during the existence of the U.S. copyright unless:

(1) The importation is permitted under one of the limited exceptions in 17 U.S.C. 107;

(2) The importation is entitled to U.S. copyright protection under the provisions of 17 U.S.C. 9(c) by virtue of the Universal Copyright Convention (see paragraph (c) of this section); or

(3) The importation is permitted by an ad interim copyright (see paragraph (b) of this section).

(b) *Release under ad interim copyright.* Upon compliance with the usual Customs requirements, the district director may release up to 1,500 copies of a book or periodical covered by an ad interim copyright when imported pursuant to the quantitative exception in 17 U.S.C. 16 if:

(1) There is presented with the entry an "Import Statement" issued by the Register of Copyrights authorizing the importation of a number of copies not in excess of 1,500 copies; and

(2) The copies are otherwise admissible.

(c) *Release under Universal Copyright Convention—(1) Determination of eligibility.* The district director shall release books under the Universal Copyright Convention without an "Import Statement" and in unlimited quantities upon a determination that either:

(i) The book was first published in a Convention country other than the United States, and the author was not a citizen or domiciliary of the United States at the time of first publication; or

(ii) The book was first published abroad, and at the time of first publication, the author was a citizen of a Convention country other than the United States and was not domiciled in the United States.

(2) *Information required.* Prior to releasing the books, the district director shall require the importer to supply the following information in writing:

(i) The country in which the book was first published;

(ii) The country of which the author was a citizen at the time of first publication; and

(iii) Whether the author was domiciled in the United States at the time of first publication.

(Secs. 9, 16, 107, 61 Stat. 655, as amended, 657, as amended, 663; 17 U.S.C. 9, 16, 107)

§ 133.46 Demand for redelivery of released articles.

If it is determined that articles which have been released from Customs custody are subject to the prohibitions or restrictions of this subpart, the district director at the port of entry shall promptly make demand for redelivery of the articles under the terms of the entry bond in accordance with § 8.26 of this chapter. If the articles are not redelivered to Customs custody, a claim for liquidated damages shall be made in accordance with § 25.17 of this chapter.

Subpart F—Procedure Following Forfeiture or Assessment of Liquidated Damages

§ 133.51 Relief from forfeiture or liquidated damages.

(a) *Petition for relief.* The importer may petition in accordance with Parts 171 and 172 of this chapter for relief from, or cancellation of, a forfeiture incurred for violation of the trademark or copyright laws, or a claim for liquidated damages for failure to redeliver released merchandise incurred under the provisions of § 133.24 or § 133.46.

(b) *Conditioned relief.* In appropriate cases, relief from a forfeiture may be granted pursuant to a petition for relief upon the following conditions and such other conditions as may be specified by the appropriate Customs authority:

(1) The unlawfully imported or prohibited articles are exported or destroyed under Customs supervision and at no expense to the Government;

(2) All offending trademarks or trade names are removed or obliterated prior to release of the articles;

(3) In the case of books or periodicals manufactured abroad contrary to the terms of the "American manufacturing clause" of the Copyright Act (17 U.S.C. 16):

(i) Satisfactory evidence is submitted that a statement of abandonment has been filed and recorded in the Copyright Office by the copyright owner in accordance with the procedures of the Copyright Office; and

(ii) The notice of copyright is completely obliterated prior to release of the books or periodicals.

§ 133.52 Disposition of forfeited merchandise.

(a) *Trademark or trade name violation.* Articles forfeited for violation of the trademark laws shall be disposed of in accordance with the procedures applicable to forfeitures for violation of the Customs laws, after the removal or obliteration of the name, mark, or trademark by reason of which the articles were seized.

(b) *Copyright violations.* Articles for which forfeiture for violation of the copyright laws has been perfected shall be destroyed.

(Sec. 42, 60 Stat. 440, sec. 108, 61 Stat. 664; 15 U.S.C. 1124, 17 U.S.C. 108)

§ 133.53 Refund of duty.

If a violation of the trademark or copyright laws is not discovered until after entry and deposit of estimated duty, the entry shall be endorsed with an appropriate notation and the duty refunded as an erroneous collection upon exportation or destruction of the prohibited articles in accordance with § 8.49 or § 15.5 of this chapter.

(Sec. 558(a), 46 Stat. 744, as amended; 19 U.S.C. 1558(a))

ANNEX TO REVISED PART 133

Parallel Reference Table

(This table shows the relation of sections in revised part 133 to superseded 19 CFR Part 11.)

Revised section	Superseded section
133.0	None.
133.1(a)	11.15(a).
133.1(b)	None.
133.2	11.15(a).
133.3	11.15(a).
133.4	None.
133.5	None.
133.6	None.
133.7	11.15(c).
133.11	None.
133.12	11.16.
133.13	11.16.

Revised Section	Superseded section
133.14	None.
133.15	None.
133.21	11.14.
133.22(a)	11.17(a).
133.22(b)	11.17(b).
133.22(c)	11.17(b).
133.23(a)	None.
133.23(b)	None.
133.23(c)	11.17.
133.24	None.
133.31(a)	11.19(a).
133.31(b)	None.
133.31(c)	11.19(b).
133.31(d)	None.
133.32	11.19(a).
133.33	11.19(a).
133.34	None.
133.35	None.
133.36	None.
133.37	None.
133.41	11.18.
133.42(a) & (b)	11.20(a).
133.42(c)	11.20(b).
133.43(a) & (b)	11.20(c).
133.43(c) (1)	11.20(d).
133.43(c) (2-4)	None.
133.44	11.20(e).
133.45(a)	11.21(a).
133.45(b)	11.21(c).
133.45(c)	None.
133.46	None.
133.51	None.
133.52(a)	11.17(c).
133.52(b)	None.
133.53	11.17(d).

[FR Doc. 72-16793 Filed 10-2-72; 8:52 am]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER C—DRUGS

PART 135c—NEW ANIMAL DRUGS IN ORAL DOSAGE FORMS

Trifluomeprazine Tablets, Veterinary

The Commissioner of Food and Drugs has evaluated a supplemental new animal drug application (12-746V) filed by Norden Laboratories Inc., Lincoln, Nebr. 68501, proposing revised labeling for the safe and effective use of trifluomeprazine tablets, veterinary, as a tranquilizer for dogs. The supplemental application is approved.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i)) and under authority delegated to the Commissioner (21 CFR 2.120), Part 135c is amended by adding a new section as follows:

§ 135c.84 Trifluomeprazine tablets, veterinary.

(a) *Chemical name.* Phenothiazine, 10-[3-(dimethylamino)-2-methyl-propyl]-2-(trifluoromethyl), maleate.

(b) *Specifications.* Trifluomeprazine tablets, veterinary, contain 10 milligrams of trifluomeprazine in each tablet.

(c) *Sponsor.* See code No. 026 in § 135.501(c) of this chapter.

(d) *Conditions of use.* (1) The tablets are administered orally to dogs for tran-

quilization and chemical restraint at a dosage level of 1/4 to 1 milligram per pound of body weight once or twice daily as required.

(2) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (10-3-72).

(Sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i))

Dated: September 25, 1972.

C. D. VAN HOUWELING,
Director, Bureau of
Veterinary Medicine.

[FR Doc. 72-16747 Filed 10-2-72; 8:45 am]

PART 135e—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

PART 135g—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

Carbadox

The Commissioner of Food and Drugs has evaluated a new animal drug application (41-061V) filed by Pfizer, Inc., 235 East 42d Street, New York, NY 10017, proposing the safe and effective use of carbadox in feed for swine. The application is approved.

Having considered the submitted data and other relevant material, the Commissioner concludes that a tolerance limitation is required to assure that edible tissues of swine treated with the drug are safe for human consumption.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i)) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 135e and 135g are amended as follows:

1. Part 135e is amended by adding the following new section:

§ 135e.63 Carbadox.

(a) *Chemical name.* Methyl 3-(2-quinoxalinylnmethylene) carbazate-N¹,N⁴-dioxide.

(b) *Approvals.* Premix level containing 2.2 percent (10 grams per pound) of carbadox has been granted; for sponsor, see code No. 030 in § 135.501(c) of this chapter.

(c) *Assay limits.* Finished feed not less than 75 percent nor more than 125 percent of labeled amount.

(d) *Related tolerances.* See § 135g.81 of this chapter.

(e) *Special considerations.* (1) Finished feeds processed from feed supplements that contain up to 0.055 percent of carbadox and that comply with the provisions of both this paragraph and paragraph (f) of this section are exempted from the requirements of section 512(m) of the act.

(2) Do not use in feeds containing bentonite.

(f) *Conditions of use.* It is used as follows:

CARBADOX IN ANIMAL FEED

	Grams per ton	Limitations	Indications for use
1. Carbadox...	10-25 (0.0011-0.00275%)	For swine; do not feed to swine weighing more than 75 pounds body weight; do not feed to swine within 10 weeks of slaughter; do not use in complete feeds containing less than 15 percent crude protein.	For increase in rate of weight gain and improvement of feed efficiency.
2. Carbadox...	50 (0.0055%)	do	For control of swine dysentery (vibriotic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by <i>Salmonella choleraesuis</i>); increase rate of weight gain and improve feed efficiency.

2. Part 135g is amended by adding a new section as follows:

§ 135g.81 Carbadox.

No residues of carbadox (Methyl 3-(2-quinoxalinylmethylene) carbazate-*N*, *N'*-dioxide) and its metabolite (quinoxaline-2-carboxylic acid) are found in the uncooked edible tissues of swine as determined by the following method of analysis:

I. REAGENTS

- Benzene—Distilled-in-Glass grade, Burdick and Jackson Laboratories or equivalent.
- Ethyl acetate—Distilled-in-Glass grade, Burdick and Jackson Laboratories or equivalent.
- n-Hexane—Distilled-in-Glass grade, Burdick and Jackson Laboratories or equivalent.
- 1-Propanol—reagent grade, dried over molecular sieve pellets (5A).
- Citric acid monohydrate—U.S.P., Pfizer, Inc., or equivalent.
- Potassium hydroxide—pellets, reagent grade.
- Sodium hydroxide—pellets, reagent grade.
- Hydrochloric acid—reagent, A.C.S.
- Sulfuric acid—reagent, A.C.S.
- Sodium sulfate—anhydrous, reagent grade.
- Quinoxaline-2-carboxylic acid—Pfizer Inc., or equivalent.
- Propyl quinoxaline-2-carboxylate—Pfizer, Inc., or equivalent.
- Acridine—practical grade; Matheson, Coleman and Bell or equivalent.

II. SOLUTIONS

- 1M Citric acid.
- 5M Sodium hydroxide.
- 3th Potassium hydroxide.
- 0.5M Citric acid buffer. Adjust the pH of 100 milliliters of 1M citric acid to pH 6.0 with 5M sodium hydroxide (approximately 55 milliliters), using a previously calibrated pH meter. Adjust the final volume to 200 milliliters with distilled water. Before making the final pH adjustment, cool the buffer to room temperature.
- 1-Propanol-sulfuric acid reagent (97:3). Dilute 3 milliliters of concentrated sulfuric acid to 100 milliliters with dried, filtered, and cooled 1-propanol.
- Acridine solution. Dissolve 1 milligram of acridine in 100 milliliters of benzene.
- Quinoxaline-2-carboxylic acid solutions:
 - Stock solution A. Dissolve 1.25 milligram of quinoxaline-2-carboxylic acid in enough 1-propanol to make 100.0 milliliters (concentration 12.5 micrograms per milliliter).
 - Stock solution B. Dilute 1.0 milliliter of stock solution A to 100.0 milliliters with 1-propanol-sulfuric acid reagent (concentration 0.125 microgram per milliliter).

- Working standard solution C. Dilute a 3.0 milliliter aliquot of stock solution B to 10.0 milliliters with 1-propanol-sulfuric acid reagent (concentration 25.0 nanograms per milliliter).
- Working standard solution D. Dilute a 3.0 milliliter aliquot of stock solution B to 10.0 milliliters with 1-propanol-sulfuric acid reagent (concentration 37.5 nanograms per milliliter).
- Working standard solution E. Dilute a 4.0 milliliter aliquot of stock solution B to 10.0 milliliters with 1-propanol-sulfuric acid reagent (concentration 50.0 nanograms per milliliter).
- Fortification solution. Dilute 3.0 milliliters stock solution A to 250 milliliters with distilled water (concentration 150 nanograms per milliliter).
- Propyl quinoxaline-2-carboxylate solution. Dissolve 1.00 milligram of propyl quinoxaline-2-carboxylate in enough ethyl acetate to make 10 milliliters (concentration 100 micrograms per milliliter).

III. APPARATUS

- Column, glass-tapered at one end, 0.9 centimeters x 21.5 centimeters, prepared from a 10-milliliter serological pipette.
- Centrifuge tubes, heavy duty—50-milliliter graduated (60-milliliter capacity), equipped with glass stoppers, R. C. Ewald, Inc., or equivalent.
- Centrifuge tubes—50 milliliters graduated, equipped with glass stoppers.
- Volumetric flasks—5-, 10-, 100-, and 250-milliliter capacity, glass stoppered.
- Pipettes, automatic transfer—10-, 15-, and 25-milliliter delivery volume.
- Pipettes, measuring—0.1 and 0.5 milliliter delivery volume.
- Pipettes, volumetric—1-, 2-, 3-, 4-, and 5-milliliter delivery volume.
- Pipette, serological—10 milliliter delivery volume.
- Pipettes—Pasteur, disposable.
- Propipette bulb.
- Syringe—10 microliter capacity, Hamilton or equivalent.
- Crystallizing dish—190 millimeter (diameter) x 100 millimeter (height), for oil bath.
- Test tube rack.
- Test tube mixer—Vortex mixer or equivalent.
- Lab jack—Cenco or equivalent.
- Thermo-stir hotplate.
- Magnetic stirrer bar (teflon).
- Thermometer—centigrade, 0° to 150° C. range.
- Knife (for cutting frozen tissue).
- Ultraviolet light—254 nanometers and 366 nanometers.
- Scalpel.
- Torsion balance—style RX-1, class A, Torsion Balance Co., or equivalent.
- Cahn electrobalance—Cahn Model C-2 or equivalent.
- Centrifuge—International, size 2, model K, or equivalent.

Y. Rotary evaporator equipped either with a water aspirator or with a vacuum pump and condenser.

- Alkacid test paper.
- Glassine paper.
- Glass wool.
- Flask—round bottom, 29/42 ST, 250 milliliters.
- Flask—round bottom, 19/22 ST, 65 milliliters.
- Funnel—burette.
- Hair dryer.
- pH meter.
- Tray—instrument, stainless steel.
- Water bath.
- Precoated thin layer plates—20 x 20 centimeters; 250 micron thickness, Silica gel GF, E. Merck, Darmstadt; distributed by Brinkmann Instruments Inc., Westbury, N.Y., 11590 or equivalent.
- Desaga multiplate developing tanks for five 20 x 20 centimeters plates—distributed by Brinkmann Instruments Inc. or equivalent.
- Gas-liquid chromatograph—Micro Tek 220 model instrument (or equivalent) equipped with a Ni⁶³ electron affinity pulsed detector and a 0-1 MV recorder. Conditions and operating parameters for the gas-liquid chromatograph are: Isothermal column temperature, 175° C.; inlet heater, 270° C.; EC detector temperature, 275° C.; argon-methane (95:5) flowrate, 100 milliliters per minute (40 pounds per square inch); chart speed, 1/2 inch per minute, attenuation, 10 x 64. Electrometer pulse parameters: RF mode; voltage output, 55; pulse rate, 270 micro-seconds; pulse width, 3.0 micro-seconds.

A glass sleeve injection port liner is installed for off-column injections.

MM. Packing—3 percent OV-17 on Gas Chrom Q, 60-80 mesh, Applied Sciences Laboratories, Inc. or equivalent.

NN. Column—pyrex glass, U-tube, 6 feet (length) x 4 millimeters (inside diameter). Condition the packed column at 280° C. for at least 72 hours with argon-methane (95:5) flow, detached from the detector input.

OO. Septum—high temperature type (HT-13), Applied Sciences Laboratories, Inc. or equivalent.

PP. Detector—Nickel⁶³ electron capture. The voltage current profile for this detector should plateau at 30 volts or less in the DC mode when a stream of nitrogen gas is passed through the column and the electron capture detector.

IV. PROCEDURE

A. DISSOLUTION AND HYDROLYSIS STEP

Transfer 5 grams of swine tissue (freshly sliced from frozen tissue) to a 50-milliliter centrifuge tube. Add 10 milliliters of 3M potassium hydroxide, stopper, and place in a 100° C. silicone oil bath for 1 hour.

NOTE: The level of the silicone oil bath should exceed that of the tissue sample. Stopper the tubes lightly in order to allow the digestion mixture to "breathe". To determine the recovery of quinoxaline-2-carboxylic acid in swine tissue at the 30 p.p.b. level, fortify 5 grams of sample with 1 milliliter of fortification solution (concentration 150 nanograms per milliliter).

B. EXTRACTION STEP

- Cool the alkaline hydrolyzate in an ice bath and acidify to ≤ 1 pH 1 (deep red to alkacid test paper) with 4 milliliters of concentrated hydrochloric acid. Add 15 milliliters of ethyl acetate to the acidified hydrolyzate, stopper, and extract by shaking for 20 seconds. Centrifuge the mixture at 1,500 revolutions per minute for 5 minutes to clarify the ethyl acetate phase. Recover the ethyl acetate phase with a blowout pipette equipped with a propipette bulb, and transfer this extract to a 60-milliliter separatory

funnel equipped with teflon stopcocks. Re-extract the hydrolyzate with two additional 15-milliliter portions of ethyl acetate, and combine the organic extracts.

NOTE: Do not contaminate the ethyl acetate phase with interfacial material during these extractions. Quinoxaline-2-carboxylic acid is unstable in strongly acidic solutions. Continue to process these extracts through the benzene extraction and evaporation steps.

2. Add 5 milliliters of 0.5M citric acid buffer (pH 6.0) to the ethyl acetate extract, shake, and allow the lower phase to clarify for about 20 minutes. Collect the aqueous phase in a 50-milliliter glass-stoppered centrifuge tube. Reextract the ethyl acetate phase with an additional 5 milliliters of pH 6 buffer, wait for the aqueous phase to clarify, and combine the aqueous extracts. Acidify ($\leq$ pH 1) the aqueous extract with 2 milliliters of concentrated hydrochloric acid, stopper, and extract with 25 milliliters of benzene. Centrifuge to clarify the benzene layer and transfer the organic phase, using a blowout pipette equipped with a propipette bulb, to a 250-milliliter round bottom flask. Repeat the extraction and centrifugation steps three times. Combine the benzene extracts (about 100 milliliters) and evaporate to near-dryness, using a rotary evaporator equipped with a water aspirator and with a water bath set at 40° C.

NOTE: A rotary evaporator equipped with a vacuum pump and condenser may be used at this point. These residues may be stored overnight.

C. ESTERIFICATION STEP

Reconstitute the residue from the previous step by rinsing the walls of the round bottom flask with 2 x 2 milliliters of 1-propanol-sulfuric acid reagent; transfer each rinse with a disposable pipette to a 50-milliliter centrifuge tube. Stopper and heat the tube in a silicone oil bath at 90° C. for 1 hour. Cool the reaction mixture in an ice bath before proceeding to the following extraction step.

NOTE: Samples and standards may be stored overnight at room temperature in the propanol-sulfuric acid medium.

D. EXTRACTION OF THE ESTER DERIVATIVE

Add 10 milliliters of water and 15 milliliters of n-hexane to the esterification mixture. Extract and centrifuge to clarify the n-hexane phase. Transfer the n-hexane extract to a 65-milliliter round bottom flask; reextract the aqueous-propanol phase with two additional 15-milliliter portions of n-hexane. Centrifuge after each extraction and combine the n-hexane extracts. (**NOTE:** Avoid taking any of the aqueous phase in this extraction step; otherwise, the n-hexane extracts will have to be washed with 3 x 10 milliliters of water and dried over sodium sulfate.) Concentrate this solution to 0.5 milliliter, using a rotary evaporator equipped with a water aspirator and with a water bath set at 25° C. (**NOTE:** A rotary evaporator equipped with a vacuum pump and condenser may be used at this point.) Fortify this solution with 0.1 milliliter of acridine marker (1 milligram per 100 milliliters benzene).

NOTE: Do not store the n-hexane extracts of the propyl ester derivative overnight. Continue to process these solutions by the following thin-layer chromatography step E.

E. THIN-LAYER CHROMATOGRAPHY

1. Quantitatively transfer the concentrated n-hexane extract to the "origin" of a 20-centimeters x 20-centimeters silica gel thin-layer plate, using a disposable pipette. When pipetting this extract, streak it in a uniform band approximately 15 centimeters across and approximately 20 millimeters

above the lower edge of the plate, making sure not to scratch or remove appreciable portions of adsorbent and avoiding application of the sample to the sides of the plate. The applied band should not diffuse or penetrate to the end of the silica gel layer, but should remain 10 millimeters above the lower edge of the silica gel layer. Rinse the round bottom flask (containing residual n-hexane) with three portions of approximately 0.25 milliliter each of ethyl acetate; transfer each portion with the same pipette and cover the same area of the plate as described above. Following each application of the extract and ethyl acetate washes, evaporate the solvent from the plate by directing a stream of cool air to the sample zone ("origin"). Prior to chromatographic development, place an edge (approximately 5 millimeters deep) of the thin-layer plate into a tray of ethyl acetate so that the solvent will rise through the applied sample zone to form it into a narrow band approximately 10 millimeters above the "origin." Air dry this plate before chromatographic development.

2. Place the prepared plate in a chromatographic chamber lined with blotting paper and saturated with the benzene-ethyl acetate system (85:15). Develop the plate twice in this system, maintaining straight solvent fronts and allowing the solvent front to reach the top of the plate during each irrigation. Air dry the thin-layer plate for approximately 5 minutes between the first and second irrigations. Each irrigation takes approximately 75 minutes. Developed plates should not be stored overnight. Examine the developed plate under long wavelength (366 nanometers) ultraviolet light and locate the blue fluorescent band of acridine (R_f approximately 0.5). Mark out a 12-millimeters x 20-centimeters band of silica gel encompassing an area 5 millimeters above and 7 millimeters below the center of the acridine marker and extending from one side of the plate to the other.

NOTE: The relative mobilities of propyl quinoxaline-2-carboxylate and acridine must be checked in each laboratory to determine where a 12-millimeters x 20-centimeters zone of silica gel is to be excised in order to quantitatively recover the propyl ester derivative. This may be accomplished by mixing 0.1 milliliter of acridine solution (1 milligram per 100 milliliters) with 0.4 milliliter of propyl quinoxaline-2-carboxylate (100 micrograms per milliliter) and chromatographing this solution as directed above. Examine the developed plate under long wavelength (366 nanometers) ultraviolet light and locate the blue fluorescent band of acridine (R_f approximately 0.5). Examination of the plate under short wavelength (254 nanometers) ultraviolet light locates the blue absorbing band of propyl quinoxaline-2-carboxylate (R_f approximately 0.5).

3. Reduce the sample zone to a fine powder by making a series of horizontal cuts with a scalpel. Gently transfer this powder with the aid of a stainless steel spatula to glassine paper; pour this material into a burette funnel atop a small glass column packed with a glass wool plug. Elute the adsorbent with ethyl acetate (about 6 milliliters), and collect the eluate to mark in a 5-milliliter volumetric flask. Examine this eluate by gas-liquid chromatography.

NOTE: Contamination of thin-layer chromatographic plates can be checked by gas-liquid chromatographic examination of an eluate prepared by processing a blank plate as in paragraph 1 above, starting at the point: "place a edge (approximately 5 millimeters deep) of the thin-layer plate into a tray of ethyl acetate * * *". If the plate is contaminated, examine alternate lots of precoated thin-layer plates.

F. STANDARD CURVE

Pipette 4-milliliter aliquots of quinoxaline-2-carboxylic acid working standard solutions C, D, and E, respectively, and 4-milliliter portions of 1-propanol-sulfuric acid reagent into 50-milliliter centrifuge tubes; stopper, react, extract, and concentrate as directed in the esterification and extraction steps described in subsections C and D above; however, omit the addition of acridine to the n-hexane concentrate and do not chromatograph it by thin-layer chromatography. Instead, reconstitute the n-hexane concentrate with ethyl acetate and quantitatively transfer this solution to a 5-milliliter volumetric flask to give working standard solutions C, D, and E. The final concentrations of working standard solutions C, D, and E, are 20, 30, and 40 nanograms per milliliter, respectively, and are equivalent to 20, 30, and 40 p.p.b., respectively.

G. GAS-LIQUID CHROMATOGRAPHY

Separately inject 4 microliters of each of the working standard solutions C, D, and E (prepared as described above (F)) into the gas-liquid chromatograph to determine the retention time of propyl quinoxaline-2-carboxylate and the relative response of the EC detector. Construct a standard curve by plotting concentration (p.p.b.) versus peak height (millimeters).

(**NOTE:** The reagent blank must show no interfering gas-liquid chromatographic peaks.) The peak height of propyl quinoxaline-2-carboxylate at the 30-p.p.b. level (working standard solution D) should approximate 10 percent of full-scale deflection with a retention time of 5 minutes. Follow these injections with 4-microliter injections of the tissue eluates, allowing 20 minutes between injections to clear the instrument of background peaks.

Measure the peak heights of samples and determine their concentration (p.p.b.) by reference to the standard curve.

H. CALCULATIONS

From the standard curve and the observed peak height of quinoxaline-2-carboxylic acid in the sample, determine its concentration (p.p.b.).

Effective date: This order shall become effective upon publication in the FEDERAL REGISTER (10-3-72).

(Sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i))

Dated: September 27, 1972.

C. D. VAN HOUWELING,
Director, Bureau of
Veterinary Medicine.

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PART 164—CERTIFICATION OF BATCHES OF DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

Increase in Fee for Sterility Testing of Insulin

In a notice published in the FEDERAL REGISTER of June 13, 1972 (37 F.R. 11729), the Commissioner of Food and Drugs proposed that Part 164 be amended to increase the fee for sterility testing of insulin to a level equal to the fee for sterility testing of all antibiotic drugs. Interested persons were invited to submit their comments in response to the notice of proposed rule making within 60 days. No comments were re-