

Executive Order 12291

This document does not meet the criteria for a "major rule" as specified in section 1(b) of E.O. 12291. Accordingly, no regulatory impact analysis has been prepared.

Regulatory Flexibility Act

Pursuant to the provisions of section 3 of the Regulatory Flexibility Act (Pub. L. 96-353, 5 U.S.C. 601, *et seq.*), it is hereby certified that the regulations set forth in this document will not have a significant economic impact on a substantial number of small entities. Accordingly, it is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Drafting Information

The principal author of this document was Charles Rassin, Regulations Control Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 18

Customs duties and inspection, Imports, Common carriers, Freight forwarders, Motor carriers, and Freight.

Amendments to the Customs Regulations

Section 18.10a, Customs Regulations (19 CFR 18.10a), is amended as set forth below.

Alfred R. De Angelis,
Acting Commissioner of Customs.

Approved: October 3, 1983.
John M. Walker, Jr.,
Assistant Secretary of the Treasury.

PART 18—TRANSPORTATION IN BOND AND MERCHANDISE IN TRANSIT

Section 13.10a, Customs Regulations (19 CFR 18.10a), is revised to read as follows:

§ 18.10a Special manifest.

(a) *General.* Merchandise for which no other type of bonded movement is appropriate (e.g., prematurely discharged or overcarried merchandise and other such types of movements whereby the normal transportation-in-bond procedures are not applicable) may be shipped in bond from the port of unloading to the destination shown on the importing carrier's manifest (manifested port) when authorized by the district director having custody of the merchandise. For this purpose, Custom's Form 7512 prepared in quadruplicate shall be used as a special manifest.

(b) *Manifest procedures.* (1) Written application shall be made to the district director where the merchandise is being held for permission to return it as a bonded shipment under a special manifest to the manifested port, including to the port of diversion (see section 4.33 of this chapter), when different from the original manifested port.

(2) The application and accompanying completed Customs Form 7512 shall identify the prematurely discharged or overcarried merchandise on the inward manifest of the importing carrier; and also identify the date and entry number of any entry made at the manifested port covering the merchandise to be returned, if known. If the district director is satisfied that the merchandise will be delivered to Customs custody at the manifest port before expiration of 90 days from the date of the entry identified, or 90 days from the date of the importing carrier's arrival at the manifested port when arrival at the manifested port when no entry is identified, the district director may approve the shipment under a special manifest.

(R.S. 251, as amended, sections 315, 484, 498, 624, 46 Stat. 722, as amended, 728, as amended, 759 (19 U.S.C. 66, 1315, 1484, 1498, 1624))

[FR Doc. 83-28596 Filed 10-19-83; 8:45 am]

BILLING CODE 4820-02-M

19 CFR Part 134

[T.D. 83-217]

Customs Regulations Amendment Relating to Liquidated Damages and Country of Origin Marking

AGENCY: Customs Service, Treasury.
ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations by modifying the negligence or bad faith requirement to one of bad faith before the district director may grant relief from the payment of liquidated damages incurred for failure to (a) properly mark imported articles (or their containers) with the country of origin, or (b) redeliver all released articles to Customs custody for marking, exportation, or destruction. This change gives district directors the same discretion in handling petitions relating to relief from liquidated damages incurred for other types of violations.

EFFECTIVE DATE: November 21, 1983.

FOR FURTHER INFORMATION CONTACT: Kathryn C. Peterson, Entry Procedures and Penalties Division, U.S. Customs

Service, 1301 Constitution Avenue NW., Washington, D.C. 20229 (202-566-5746).

SUPPLEMENTARY INFORMATION:**Background**

Under section 304, Tariff Act of 1930, as amended (19 U.S.C. 1304), every article of foreign origin (or its container) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the article or container will permit, in such manner as to indicate to an ultimate purchaser, the English name of the country of origin of the article. Section 304(c) provides that any articles not marked as required, shall be subject to a duty of 10 percent ad valorem, in addition to any other duty imposed by law and whether or not the article is exempt from the payment of ordinary Customs duties, unless the article is exported, destroyed, or marked under Customs supervision. These marking duties cannot be remitted, wholly or in part.

In addition to the requirement for marking duties under section 304(c) for a country of origin marking violation, civil penalties may be incurred under section 592, Tariff Act of 1930, as amended (19 U.S.C. 1592), for importing merchandise by means of false documents. Further, criminal sanctions may be assessed under 18 U.S.C. 1001 for presenting false and misrepresented documents to the Government in connection with an entry. If merchandise released from Customs custody under a bond is found not to be legally marked, liquidated damages also may be assessed for breach of the bond conditions.

In some instances, the total amount of liabilities which may be assessed for articles found not legally marked can far exceed the dutiable value of the imported merchandise.

Part 134, Customs Regulations (19 CFR Part 134), sets forth the country of origin marking requirements and exceptions from 19 U.S.C. 1304, as well as the consequences of violation and procedures to be followed if imported articles are not legally marked.

Under § 134.51(a), Customs Regulations (19 CFR 134.51(a)), if merchandise is found upon examination not to be legally marked, the district director shall notify the importer to arrange with the district director's office to properly mark the articles or containers, or to return all released articles to Customs custody for marking, exportation, or destruction. If the importer does not properly mark or redeliver all merchandise previously released to him, as provided in § 134.54(a), the district director shall

demand payment of liquidated damages incurred under the importer's bond in an amount equal to the entered value of the articles not properly marked or redelivered, plus any estimated duty determined at the time of entry. Section 134.54(b), Customs Regulations (19 CFR 134.54(b)), states that a petition for relief from the payment of liquidated damages may be filed with the district director in accordance with Part 172, Customs Regulations (19 CFR Part 172). However, § 134.54(c) provides that any relief from the payment of full liquidated damages incurred will be contingent upon the deposit of the marking duties required by 19 U.S.C. 1304(c).

Section 134.54(c) further provides that the district director may grant relief from the payment of full liquidated damages only if he is satisfied that the importer: (1) Was not guilty of negligence or bad faith in permitting the illegally marked articles to be distributed; (2) has been diligent in attempting to secure compliance with the marking requirements; and (3) has attempted by all reasonable means to effect redelivery of the articles to Customs custody.

Under the provisions of § 172.21, Customs Regulations (19 CFR 172.21), the district director may cancel any claim for liquidated damages incurred under such terms and conditions as, under the law and in view of the circumstances, he shall deem appropriate when the claim is \$50,000 or less. Guidelines for the cancellation of bond charges are set out in Appendix AA, Section 6.11, Customs Fines, Penalties and Forfeitures Handbook (HB 4400, March 1979 Revision).

These guidelines pertain to situations involving negligent, but unintentional failures to redeliver merchandise. The guidelines, which are in line with present Customs policy regarding the remission and mitigation of assessed liabilities, are not rigid rules. If circumstances indicate, the district director may deviate from them.

The provisions of § 134.54(c) generally conflict with Part 172 in that they are contrary to the discretionary provisions in Part 172. They also contradict the guidelines set out in the Customs Fines, Penalties and Forfeitures Handbook. Further, the requirements in § 134.54(c) work a hardship on petitioners where the violation is caused by ordinary negligence or where the violation resulted from an unintentional mistake.

Accordingly, to afford district directors the same discretion in handling petitions for relief from liquidated damages resulting from improperly marked merchandise as they have in handling petitions filed under the

provisions of Part 172, by notice published in the *Federal Register* on August 27, 1982 (47 FR 37926), Customs proposed to amend § 134.54(c) to modify the negligence or bad faith requirement to one of bad faith. The requirement that the district director be satisfied that the importer was not guilty of negligence in permitting the illegally marked items to be distributed was deleted.

Discussion of Comments

Seven comments were received in response to the notice of proposed rulemaking (NPRM). Three of the comments received were favorable and four were opposed. Basically, domestic interests opposed the modification and importers favored the change.

Those opposing stressed the importance of the marking requirements, the threat to domestic industry by lax enforcement, and the perception that the proposed change would create. One commenter said it would oppose a "proposal [which would] further weaken the potential penalties an importer faces for distributing illegally marked imported articles."

The proposed change would amend the negligence standard as it is applied in consideration of petitions for relief from liquidated damages demanded for failure to redeliver merchandise recalled because of improper marking. One commenter seemed to believe that the proposed change would mean full relief for importers entering improperly marked goods.

This is not true. The provisions of § 134.54(c) currently prohibit any relief if the importer is simply negligent, not that he acts intentionally but that he acts negligently. The standard therein is simply too harsh. Sanctions will not be completely removed by the modification. Importers will continue to be subject to liability, just not the full amount of the bond (which is written in the amount of the value of the merchandise).

One commenter suggests that Customs should maintain the present standards because of Congress's express intent that goods be clearly marked in order to insure that domestic purchasers may make an informed choice when selecting between domestic and foreign manufactured goods. The modification made by this document will not abandon or undermine this objective. This modification relates simply to liquidated damages for failure to redeliver merchandise in a narrow sense, not failure to mark the merchandise. Section 1304 provides the sanction for not marking which is a 10 percent marking duty. The bond contract provides another sanction for failing to

meet the conditions of the bond. It is the bond obligation that we are dealing with in this case. The commenter would have one infer the worst of motives to all offending importers and to treat all importers alike. Customs has through experience found, however, that not all importers are alike, in motive or deed, and that there is a need for flexibility to deal with and sanction different importers differently. This is the purpose to be served by the amendment.

After consideration of the comments, and further review of the matter, it has been decided to adopt the change as proposed. However, rather than set forth the entire section, the amendment is being made by removing the words "negligence or" from § 134.54(c).

Executive Order 12291

This document will not result in a regulation which is a "major rule" as defined by section 1(b) of Executive Order 12291. Accordingly, a regulatory impact analysis has not been prepared.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603, 604), are not applicable to this amendment because the rule will not have a significant impact on a substantial number of small entities.

Accordingly, it is certified under the provisions of section 3, Regulatory Flexibility Act (5 U.S.C. 605(b)) that the rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This document is not subject to the Paperwork Reduction Act.

Drafting Information

The principal authors of this document were Jesse V. Vitello and John E. Elkins, Regulations Control Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 134

Containers, Customs duties and inspection, Importers, Imports, Labeling, Packaging.

Amendment to the Regulations

Part 134, Customs Regulations (19 CFR Part 134), is amended as set forth below.

Dated: August 24, 1983.

William von Raab,
Commissioner of Customs.

Approved: October 3, 1983.

John M. Walker, Jr.,
Assistant Secretary of the Treasury.

PART 134—COUNTRY OF ORIGIN MARKING

§ 134.54 [Amended]

Section 134.54, Customs Regulations (19 CFR 134.54), is amended by removing the words "negligence or" from paragraph (c).

(R.S. 251, as amended, sections 304, 624, 46 Stat. 687, as amended, 759, 77A Stat. 14; (19 U.S.C. 66, 1202 (General Headnote 11), 1304, 1624))

[FR Doc. 83-28595 Filed 10-19-83; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522

Implantation or Injectable Dosage Form New Animal Drugs Not Subject to Certification; Estradiol Benzoate and Testosterone Propionate, Progesterone and Estradiol Benzoate

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADA's) filed by Syntex Agribusiness Inc., providing for deletion of the slaughter withdrawal period for use of estradiol benzoate and testosterone propionate in combination and for progesterone and estradiol benzoate in combination in subcutaneous ear implants for cattle for growth promotion and feed efficiency.

EFFECTIVE DATE: October 20, 1983.

FOR FURTHER INFORMATION CONTACT: Jack C. Taylor, Bureau of Veterinary Medicine (HFV-126), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION: Syntex Agribusiness, Inc., 3401 Hillview Ave., Palo Alto, CA 94304, filed supplemental NADA's 9-576 and 11-427, providing for deletion of the withdrawal period for use of two products as ear implants in cattle. NADA 9-576 is for use of Synovex[®]S (estradiol benzoate and progesterone) as an ear implant in steers for growth promotion and feed efficiency. NADA 11-427 is for use of

Synovex[®] H (estradiol benzoate and testosterone propionate) as an ear implant in heifers for growth promotion and feed efficiency. The supplements are approved and the regulations are amended to reflect the approvals. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(ii) (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.

List of Subjects in 21 CFR Part 522

Animal drugs, Injectable.

Therefore, under 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 of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

§ 522.842 [Amended]

1. In § 522.842 *Estradiol benzoate and testosterone propionate in combination* in paragraph (d)(3) by removing the phrase "not to be used within 60 days of slaughter."

§ 522.1940 [Amended]

2. In § 522.1940 *Progesterone and estradiol benzoate in combination* in paragraph (d)(2)(iii) by removing the phrase "not to be used within 60 days of slaughter."

Effective date. October 20, 1983.

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

Dated: October 14, 1983.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 83-28531 Filed 10-19-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Pyrantel Tartrate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed for Southern Micro-Blenders, Inc., providing for use of a 48-gram-per-pound pyrantel tartrate premix to make 9.6- and 19.2-gram-per-pound pyrantel tartrate intermediate premixes for making complete swine feeds.

EFFECTIVE DATE: October 20, 1983.

FOR FURTHER INFORMATION CONTACT:

Benjamin A. Puyot, Bureau of Veterinary Medicine (HFV-130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION:

Southern Micro-Blenders, Inc., 3801 North Hawthorne St., Chattanooga, TN 37406, is sponsor of NADA 135-243 submitted on its behalf by Pfizer, Inc. The NADA provides for use of a 48-gram-per-pound pyrantel tartrate premix to make 9.6- and 19.2-gram-per-pound pyrantel tartrate intermediate premixes for making complete swine feeds used for aid in prevention of migration and establishment of large roundworm (*Ascaris suum*) infections, for aid in prevention of establishment, removal, and control of nodular worm (*Oesophagostomum*) infections, and for removal and control of large roundworm (*Ascaris suum*) infections.

The basis for approval of this NADA is discussed in the freedom of information summary. The NADA is approved and the regulations are amended to reflect this approval.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (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.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under 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 of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 558 is amended in § 558.485 by adding new paragraph (a)(15) to read as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

§ 558.485 Pyrantel tartrate.

(a) * * *

(15) To No. 049685: 9.6 and 19.2 grams per pound, paragraph (e)(1) through (3) of this section.

Effective date. October 20, 1983.

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

Dated: October 13, 1983.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 83-28533 Filed 10-19-83; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF STATE

Bureau of Consular Affairs

22 CFR Part 41

[Dept. Reg. 108.835]

Nonresident Alien Mexican Border Crossing Card

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule amends § 41.128 to combine the use of border crossing cards and B-1/B-2 visitor visas in the form of a stamp affixed to a valid Mexican Federal passport. The rule also terminates the provisions in § 41.128 relating to the issuance of border crossing cards on Forms I-186 by consular officers stationed at interior consular posts in Mexico and adds the United States consulate at Hermosillo, Mexico, to the list of consular posts where consular officers are authorized to issue border crossing cards, during a trial period, to qualified applicants who are citizens and residents of Mexico. Public Notice 797 of March 12, 1982 and Public Notice 831 of October 29, 1982 are superseded by the incorporation into this rule of designated consular posts listed in those Notices.

EFFECTIVE DATE: October 11, 1983.

FOR FURTHER INFORMATION CONTACT:

Gerald M. Brown, Chief Legislation and Regulations Division, Visa Services, (202) 632-1900.

SUPPLEMENTARY INFORMATION: The new border crossing card and B-1/B-2 visitor visa stamp will be easier to obtain at any United States consular office in Mexico, longer lasting and immediately available to qualified applicants. The stamp will be placed on a page in a valid Mexican Federal passport and is expected to facilitate travel for certain classes of Mexican nationals who are traveling through the United States from points other than contiguous territory. In such cases bearers of combined stamps will not be compelled to carry two documents, i.e. a border crossing card and a valid Mexican Federal passport when entering the United States at non-border ports. The stamp will be used in place of the present indefinite B-1/B-2 visitor visa and in place of the laminated border crossing card. Use of the combination stamp will have considerable time saving impact over the border crossing card lamination procedure currently in use at interior U.S. consular offices in Mexico.

Compliance with the provisions of the Administrative Procedure Act, 5 U.S.C. 553, relative to notice of proposed rulemaking and delayed effective date is unnecessary in this instance because this rule establishes new procedures which confer a benefit upon the affected persons by relieving certain restrictions and considerably reducing time presently required for issuance of duplicate documents.

List of Subjects in 22 CFR Part 41

Aliens, Nonimmigrant visas, Border Crossing Identification Cards

PART 41—[AMENDED]

Accordingly, § 41.128 is revised as follows:

§ 41.128 Nonresident alien Mexican border crossing identification cards.

(a)(1) *Aliens eligible to apply.* Under the conditions prescribed by this section consular officers assigned to consular offices located in Ciudad Juarez, Hermosillo, Nuevo Laredo, Matamoros, and Tijuana, may issue border crossing identification cards, as that term is defined in section 101(a)(6) of the Act, to nonimmigrant aliens who satisfactorily establish that they are:

- (i) Citizens and residents of Mexico; and
- (ii) Bona fide temporary visitors who, if applying for temporary visitor visas for business or pleasure, would be eligible to receive such visas.

(2) *Application for nonresident alien Mexican border crossing identification card.* A citizen of Mexico shall apply for a nonresident alien border crossing identification card on Form OF-156, supporting the application with evidence of Mexican citizenship and residence, a valid or expired Mexican passport and one photograph, 1 and ½ inches square. Each applicant applying at a consular office shall appear in person before a consular officer and be interviewed regarding his eligibility for a temporary visitor visa. The personal appearance may be waived in the discretion of the consular officer.

(3) *Issuance and format of border crossing identification cards.* A nonresident alien Mexican border crossing identification card shall consist of a stamp placed in the alien's Federal passport document by consular officers stationed at posts designated in paragraph (a)(1). The stamps shall be numbered serially by each consular office beginning with the number 1 on each October 1 and shall be in the format prescribed by the Department and contain the following data:

- (i) The post symbol;
- (ii) The number of the card;
- (iii) The title and location of the issuing office;
- (iv) The date of issuance;
- (v) The name(s) of the person(s) to whom issued; and
- (vi) The signature and title of the issuing officer.

(b) *Nonresident alien Mexican border crossing identification card and B-1/B-2 nonimmigrant visitor visa.*

(1) *Aliens eligible to apply.* Under the conditions prescribed in this section, consular officers assigned to any consular office in Mexico may issue a nonresident alien border crossing identification card, as that term is defined in section 101(a)(6) of the Act, in combination with a B-1/B-2 nonimmigrant visitor visa, to a nonimmigrant alien who satisfactorily establishes that he:

- (i) Is a citizen of Mexico;
- (ii) Seeks to enter the United States as a bona fide temporary visitor for business or pleasure as defined in section 101(a)(15)(B) of the Act for periods of stay not exceeding 6 months; and
- (iii) Is otherwise eligible to receive a temporary visitor visa or is the beneficiary of a waiver under section 212(d)(3)(A) of the Act of a ground of ineligibility which is valid for multiple applications for admission into the United States and for an indefinite period of time and which contains no