§ 235.2 Other regulations related to this part.

This part is related to a number of other parts in this chapter:

(a) Part 216 describes when a person is eligible for an annuity under the Railroad Retirement Act.

(b) Part 222 defines family relationships (for example, who is the wife or widow of an employee) for use when it is necessary to establish such a relationship in order to receive a benefit under the Railroad Retirement Act.

§ 235.3 Who is paid social security benefits by the Board.

The following individuals, if entitled to social security benefits, are paid such benefits by the Board:

(a) A railroad employee who has been credited with at least 120 months of railroad service;

(b) A wife or husband of a railroad employee who has been credited with at least 120 months of railroad service;

(c) A divorced wife or husband of a railroad employee who has been credited with at least 120 months of railroad service, but only if the divorced wife or husband is claiming social security benefits based upon the railroad employee's social security wages;

(d) A survivor of a railroad employee, including a surviving divorced spouse, remarried widow(er), surviving divorced mother or father, who is entitled, or upon application would be entitled, to an annuity under the Railroad Retirement Act;

(e) Any other person entitled to benefits under Title II of the Social Security Act based on the social security wages of a railroad employee who has been credited with at least 120 months of railroad service, except survivors of a railroad employee when the Social Security Administration has jurisdiction for survivor benefits. See Part 221 of this title.

§ 235.4 How the Board pays social security benefits.

(a) When an individual described in § 235.3 of this part is determined by the Social Security Administration to be entitled to social security benefits, the Social Security Administration certifies such benefits to the Board for payment by the Board. Once social security entitlement is certified to the Board, the Board then certifies the amount of the social security benefit to the Department of the Treasury for payment and makes any necessary adjustments in the individual's railroad retirement benefit.

(b) The Board has no authority with respect to the adjudication of the benefit to be paid under the Social Security Act. Entitlement to and the computation of such benefits is a matter solely within the jurisdiction of the Social Security Administration.

Dated: January 26, 1989.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 89-2396 Filed 2-1-89; 8:45 am]

BILLING CODE 7905-01-M

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20 CFR Parts 302 and 337

Railroad Unemployment Insurance Benefits

AGENCY: Railroad Retirement Board.

ACTION: Final rule; removal.

SUMMARY: The Railroad Retirement Board (Board) hereby removes Part 302, Reduction in Unemployment and Sickness Benefits, and Part 337, Rate of Railroad Unemployment, because these parts are now obsolete.

EFFECTIVE DATE: This regulation is effective February 2, 1989.

ADDRESS: Secretary to the Board, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Thomas W. Sadler, General Attorney, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611, (312) 751-4513, (FTS) 386-4513.

SUPPLEMENTARY INFORMATION: Under section 10(d) of the Railroad Unemployment Insurance Act (RUIA) (45 U.S.C. 360(d)), the Board has the authority to require the Secretary of the Treasury to transfer as a loan from the Railroad Retirement Account to the credit of the railroad unemployment insurance account such funds which in the estimate of the Board are necessary to pay benefits under the RUIA if the funds in the railroad unemployment insurance account are insufficient before such transfer to pay such benefits.

Section 302 of Pub. L. 98-76, August 12, 1983, 97 Stat. 411, 432, prohibited such transfers after September 30, 1985, for purposes of paying benefits and refunds due after such date. By subsequent amendments this date was extended to December 19, 1985.

Part 302 was added at 50 FR 36870, September 10, 1985, effective October 1, 1985, to describe how the Board would continue to pay benefits under the RUIA at a reduced rate following the repeal of the borrowing authority referred to above. At 50 FR 3993, October 1, 1985, the effective date was deferred until further notice and the regulation has never become effective. Section 13302 of Pub. L. 99-272, April 7, 1986, 100 Stat. 82, 327, restored the Board's authority under section 10(d) of the RUIA and thus Part 302 is no longer needed.

Section 2(h)(1) of the RUIA provides for an extended benefit period during which an employee, with less than 10 years of service, may continue to receive unemployment benefits after he or she has exhausted his or her normal rights to benefits in a benefit year pursuant to section 2(c) of the RUIA. This extended benefit period begins with a period of high unemployment as defined in section 2(h)(2). This section in turn defines high unemployment with reference to a national rate of unemployment as indicated by a national "on" and "off" indicator provided for in section 203(d) of the Federal-State Extended Unemployment Insurance Compensation Act of 1970, Pub. L. 91-373, August 10, 1970, 84 Stat. 695. However, the national indicator in section 203(d) was repealed by section 2401 of Pub. L. 97-35, August 13, 1981, 95 Stat. 356, 874. Consequently, section 2(h) of the RUIA is now inoperative. Part 337 was added at 42 FR 29486, June 9, 1977, to describe how the Board, on a monthly basis, would make determinations of high unemployment under section 2(h). Thus, Part 337 is now obsolete.

Because this rule simply removes regulations which are now clearly out of date, public comment was not considered necessary and thus, this rule was not published in proposed form.

The Board has determined that this is not a major rule under Executive Order 12291. Therefore no regulatory impact analysis is required. There are no information collections associated with this rule.

List of Subjects

20 CFR Part 302

Railroad employees, Unemployment compensation.

20 CFR Part 337

Railroad employees, Unemployment compensation.

For the reasons set forth in the preamble, and in accord with the authority provided in 45 U.S.C. 362l, Chapter II, Title 20 of the Code of Federal Regulations is amended as follows:

PART 302—[REMOVED AND RESERVED]

1. Part 302, consisting of §§ 302.1 through 302-5, is hereby removed and reserved.

PART 337—[REMOVED AND RESERVED]

2. Part 337, consisting of §§ 337.1 through 337.4, is hereby removed and reserved.

By Authority of the Board.

Dated: January 26, 1989.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 89–2408 Filed 2–1–89; 8:45 am]

BILLING CODE 7905–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 88N–0027]

Tamper-Resistant Packaging Requirements for Certain Over-the-Counter (OTC) Human Drug Products

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its current tamper-resistant packaging regulation for over-the-counter (OTC) drug products. Under the final rule, manufacturers of two-piece, hard gelatin capsules must package their products using at least two tamper-resistant packaging features. Where the capsules themselves are sealed by a suitable tamper-resistant technology, the standard OTC tamper-resistant packaging requirement of a minimum of one tamper-resistant feature is sufficient. The new requirement applies only to hard gelatin capsules, and has no applicability to soft capsules (also known as soft gels). The revisions apply to all OTC human drug products, except dermatologics, dentifrices, insulin, and throat lozenges. This rule is part of agency efforts to improve consumer protection from the the threat of product tampering.

EFFECTIVE DATE: February 2, 1990.

FOR FURTHER INFORMATION CONTACT: Diane P. Goyette, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8049.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 5, 1988 (53 FR 16150), FDA proposed to amend the tamper-resistant packaging regulation for certain OTC drug products (21 CFR 211.132). FDA is now adopting these proposed requirements in a final rule.

The final rule requires that OTC drug products, marketed in two-piece, hard gelatin capsules, be packaged using a minimum of two tamper-resistant packaging features. However, where capsules have been sealed by a tamper-resistant technology such as gelatin-banding, a single additional tamper-resistant packaging feature is sufficient. This action is taken as part of the agency's continuing review of the potential public health threat posed by product tampering.

Although tamper-resistant features on OTC packages have been widely and effectively used since first required in 1982, more recent cases of product contamination show that two-piece, hard gelatin capsules remain vulnerable to malicious tampering. The agency believes that the requirement of two tamper-resistant features for these products will provide a necessary additional measure of consumer protection. Many manufacturers have already voluntarily taken measures that are consistent with the new rule. By amending the regulation, the agency intends to ensure that all manufacturers of this dosage form provide the increased level of protection.

II. Comments on Proposed Rule

Interested persons were given 60 days to comment on the proposed rule. FDA received three comments. One comment from a major pharmaceutical manufacturer, and another comment from a national trade association that represents manufacturers of OTC drug products, expressed agreement and support for the amendment. The third comment asked for inclusion of a particular tamper-resistant packaging technology in the amended regulation and in the related Compliance Policy Guide (CPG 7132a.17).

The agency believes that the tamper-resistant packaging regulation is not the appropriate place to include a description or listing of specific packaging designs. Section 211.132 defines acceptable technology by describing, in general, consumer protection standards that must be met by a tamper-resistant package. Specific examples are given only to illustrate the general requirements of the regulation. Manufacturers and packagers are free to use any packaging systems that meet these tamper-resistant standards. This allows for innovation and flexibility in choosing the best packaging system for a product.

The comment also requested that the specific form of tamper-resistant packaging be included in the agency's Compliance Policy Guide 7132a.17 ("Tamper-Resistant Packaging Requirements for Certain Over-the-Counter (OTC) Human Drug Products"). The availability of this CPG, recently updated to reflect changes in tamper-resistant technology, was announced in the **Federal Register** of May 5, 1988 (53 FR 16192). At this time, FDA is considering the issue of including new packaging systems in this CPG.

In the proposed rule, FDA specifically invited comments on certain aspects of the amendment, including its impact on State and local regulations and the costs to industry of implementing the new requirements. No comments were received on these or other issues. FDA is therefore adopting the amendment as proposed.

III. Economic Impact

FDA previously analyzed the potential economic effects of this rule, finding the projected cost to be less than $100 million annually and less than one-tenth of 1 percent of manufacturers' sales of OTC drug products. The agency thus determined that the rule is not a major rule as defined by Executive Order 12291, and a regulatory impact analysis is not required. As mentioned earlier, the agency has not received any new information that would alter its previous determination.

The costs of this regulation are not expected to pose a significant economic impact on small manufacturers. Therefore, in accordance with the Regulatory Flexibility Act (Pub. L. 96–543), the agency certifies that this rule will not have a significant impact on a substantial number of small entities.

IV. Executive Order 12612: Federalism

Executive Order 12612 requires that Federal agencies carefully examine regulatory actions to determine if they would have significant federalism implications. As stated in the preamble to the proposed rule (May 5, 1988; 53 FR 16150 at 16152), FDA believes that the amendment provides adequate safeguards to protect consumers from tampering of OTC drug products utilizing two-piece, hard gelatin capsules, and the amendment, therefore, should eliminate the need for additional action at the State or local level. FDA invited comments on the adequacy of the agency's amendment in this regard and received no comments. Thus, the agency concludes that no assessment under Executive Order 12612 is necessary.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a) (10) and (11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Effective Date

To allow sufficient time for necessary manufacturing and packaging changes, manufacturers are given until February 2, 1990 to comply with the new requirements. The effective date applies to products subject to this final rule and initially introduced or initially delivered for introduction into interstate commerce.

List of Subjects in 21 CFR Part 211

Drugs, Labeling, Laboratories, Manufacturing, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act, Part 211 is amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. The authority citation for 21 CFR Part 211 is revised to read as follows:

Authority: Secs. 201(n), 501, 502, 505, 506, 507, 701 (21 U.S.C. 321(n), 351, 352, 355, 356, 357, 371); 21 CFR 5.10, 5.11.

2. Section 211.132 is revised to read as follows:

§ 211.132 Tamper-resistant packaging requirements for over-the-counter (OTC) human drug products.

(a) *General.* The Food and Drug Administration has the authority under the Federal Food, Drug, and Cosmetic Act (the act) to establish a uniform national requirement for tamper-resistant packaging of OTC drug products that will improve the security of OTC drug packaging and help assure the safety and effectiveness of OTC drug products. An OTC drug product (except a dermatological, dentifrice, insulin, or throat lozenge product) for retail sale that is not packaged in a tamper-resistant package or that is not properly labeled under this section is adulterated under section 501 of the act or misbranded under section 502 of the act, or both.

(b) *Requirement for tamper-resistant package.* Each manufacturer and packer who packages an OTC drug product (except a dermatological, dentifrice, insulin, or throat lozenge product) for retail sale shall package the product in a tamper-resistant package, if this product is accessible to the public while held for sale. A tamper-resistant package is one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the likelihood of successful tampering and to increase the likelihood that consumers will discover if a product has been tampered with, the package is required to be distinctive by design (e.g., an aerosol product container) or by the use of one or more indicators or barriers to entry that employ an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture). For purposes of this section, the term "distinctive by design" means the packaging cannot be duplicated with commonly available materials or through commonly available processes. For purposes of this section, the term "aerosol product" means a product which depends upon the power of a liquified or compressed gas to expel the contents from the container. A tamper-resistant package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-resistant feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

(1) For two-piece, hard gelatin capsule products subject to this requirement, a minimum of two tamper-resistant packaging features is required, unless the capsules are sealed by a tamper-resistant technology.

(2) For all other products subject to this requirement, including two-piece, hard gelatin capsules that are sealed by a tamper-resistant technology, a minimum of one tamper-resistant feature is required.

(c) *Labeling.* Each retail package of an OTC drug product covered by this section, except ammonia inhalant in crushable glass ampules, aerosol products as defined in paragraph (b) of this section, or containers of compressed medical oxygen, is required to bear a statement that is prominently placed so that consumers are alerted to the specific tamper-resistant feature of the package. The labeling statement is also required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing. If the tamper-resistant feature chosen to meet the requirement in paragraph (b) of this section is one that uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say "For your protection, this bottle has an imprinted seal around the neck."

(d) *Request for exemptions from packaging and labeling requirements.* A manufacturer or packer may request an exemption from the packaging and labeling requirements of this section. A request for an exemption is required to be submitted in the form of a citizen petition under § 10.30 of this chapter and should be clearly identified on the envelope as a "Request for Exemption from Tamper-Resistant Rule." The petition is required to contain the following:

(1) The name of the drug product or, if the petition seeks an exemption for a drug class, the name of the drug class, and a list of products within that class.

(2) The reasons that the drug product's compliance with the tamper-resistant packaging or labeling requirements of this section is unnecessary or cannot be achieved.

(3) A description of alternative steps that are available, or that the petitioner has already taken, to reduce the likelihood that the product or drug class will be the subject of malicious adulteration.

(4) Other information justifying an exemption.

(e) *OTC drug products subject to approved new drug applications.* Holders of approved new drug applications for OTC drug products are required under § 314.70 of this chapter to provide the agency with notification of changes in packaging and labeling to comply with the requirements of this section. Changes in packaging and labeling required by this regulation may be made before FDA approval, as provided under § 314.70(c) of this chapter. Manufacturing changes by which capsules are to be sealed require prior FDA approval under § 314.70(b) of this chapter.

(f) *Poison Prevention Packaging Act of 1970.* This section does not affect any requirements for "special packaging" as defined under § 310.3(l) of this chapter and required under the Poison Prevention Packaging Act of 1970.

(Information collection requirements approved by the Office of Management and

Budget under OMB control number 0910-0149)

Frank E. Young,

Commissioner of Food and Drugs.

Otis R. Bowen,

Secretary of Health and Human Services.

Dated: January 18, 1989.

[FR Doc. 89-2409 Filed 2-1-89; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 556 and 558

Animal Drugs, Feeds, and Related Products; Maduramicin Ammonium

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 by American Cyanamid Co. The application provides for the use of maduramicin ammonium 1 percent Type A medicated articles to make Type C medicated feeds for the prevention of coccidiosis in broiler chickens.

EFFECTIVE DATE: February 2, 1989.

FOR FURTHER INFORMATION CONTACT: Diane T. McRae, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION: American Cyanamid Co., Berdan Ave., Wayne, NJ 07470, is the sponsor of NADA 139-075 for maduramicin ammonium 1 percent Type A medicated articles for making Type C medicated broiler feeds. The Type C medicated feeds are for broiler chickens for the prevention of coccidiosis caused by *Eimeria acervulina, E. tenella, E. brunetti, E. maxima, E. necatrix,* and *E. mivati.* The NADA is approved, 21 CFR 558.4 is amended, and new 21 CFR 558.340 is added to reflect the approval. Additionally, the tolerance for residues of maduramicin ammonium in the edible tissues of chickens is established in 21 CFR 556.375.

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 agency has carefully considered the potential environmental effects of this section. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 556

Animal drugs, Foods, Residues.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR Part 556 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

2. New § 556.375 is added to read as follows:

§ 556.375 Maduramicin ammonium.

A tolerance is established for residues of maduramicin ammonium in chickens as follows:

(a) A tolerance for maduramicin ammonium (marker residue) in chickens is 0.38 parts per million in fat (target tissue). A tolerance refers to the concentration of marker residues in the target tissue used to monitor for total drug residues in the target animals.

(b) The safe concentrations for total maduramicin ammonium residues in uncooked edible chicken tissues are: 0.24 parts per million in muscle; 0.72 parts per million in liver; 0.48 parts per million in skin; and 0.48 parts per million in fat. A safe concentration refers to the total residue concentration considered safe in edible tissues.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR Part 558 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

4. Section 558.4 is amended in paragraph (d) in the table entitled "Category II" by alphabetically adding a new entry "Maduramicin ammonium" to read as follows:

§ 558.4 Medicated feed applications.

* * * * *

(d) * * *

CATEGORY II

Drug	Assay limits, percent [1] Type A	Type B maximum (100x)	Assay limits, percent [1] type B/C [2]
*	*	*	*
Maduramicin ammonium.	90-110	54.5 g/ton (.006%).	80-120
*	*	*	*

[1] Percent of labeled amount.

[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

* * * * *

5. New § 558.340 is added to read as follows:

§ 558.340 Maduramicin ammonium.

(a) *Approvals.* Type A medicated articles: 4.54 grams per pound to 010042 in § 510.600(c) of this chapter.

(b) *Tolerances.* See § 556.375 of this chapter.

(c) *Conditions of use. (1) Amount.* 4.54 to 5.45 grams per ton (5 to 6 parts per million) (1 to 1.2 pounds per ton).

(2) *Indications for use.* For prevention of coccidiosis caused by *Eimeria acervulina, E. tenella, E. brunetti, E. maxima, E. necatrix, and E. mivati.*

(3) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter.

Dated: January 27, 1989.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 89-2463 Filed 2-1-89; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Parts 500 and 515

Foreign Assets Control Regulations and Cuban Assets Control Regulations

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTIONS: Final rule; amendments.

SUMMARY: This rule makes three sets of parallel amendments to the Foreign