PART 33—REGULATION OF DOMESTIC EXCHANGE-TRADED COMMODITY OPTION TRANSACTIONS

1. Section 33.4 is amended by revising paragraph (a)(6) to read as follows (the introductory text has not been changed but is included for the convenience of the reader):

§ 33.4 Designation as a contract market for the trading of commodity options.

The Commission may designate any board of trade located in the United States as a contract market for the trading of options on contracts of sale for future delivery or options on physicals when the applicant complies with and carries out the requirements of the Act (as provided in § 33.2), these regulations, and the following conditions and requirements with respect to the commodity option for which the designation is sought:

(a) Such board of trade—

* * * * *

(6) Is not designated as a contract market for more than one other commodity option.

* * * * *

Issued in Washinton, D.C. by the Commission on September 13, 1983.

Jane K. Stuckey,

Secretary of the Commission.

[FR Doc. 83-25342 Filed 9-15-83; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 211, 700, and 800

[Docket Nos. 82N-0330 and 82N-0332]

Tamper-Resistant Packaging Requirements; Interim Stay of Retail Level Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; interim stay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is announcing an interim stay of the retail level effective date of its tamper-resistant packaging requirements for certain over-the-counter (OTC) human drugs, cosmetics, and contact lens solutions and tablets pending its decision whether to issue a final stay based on a proposal published elsewhere in this issue of the **Federal Register**. The proposed stay affects a provision that requires all affected products held for sale to be packaged in tamper-resistant packages by February 6, 1984. This retail level effective date is being stayed on an interim basis until the agency has completed and evaluated a survey and reviewed other relevant information to determine the need for implementing a retail level effective date.

EFFECTIVE DATE: September 16, 1983.

FOR FURTHER INFORMATION CONTACT: Paul O. Fehnel, Jr., National Center for Drugs and Biologics (HFN-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 5, 1982 (47 FR 50442), FDA published final regulations setting forth tamper-resistant packaging and labeling requirements for certain OTC human drug products (21 CFR 211.132) and for certain cosmetic products (21 CFR 700.25). In the same issue of the **Federal Register** (47 FR 50452), the agency also published tamper-resistant packaging and labeling requirements for contact lens solutions and tablets (21 CFR 800.12). Amendments to those regulations were published in the **Federal Register** of April 19, 1983 (48 FR 16658, 16665) and August 19, 1983 (48 FR 37624). The purpose of the regulations was to assure package integrity and product security in light of cases of malicious adulteration of OTC drug products that resulted in seven deaths in the Chicago area.

The tamper-resistant packaging and labeling regulations included three effective dates for the new requirements. The requirements subject to the first two dates, February 7, 1983 and May 5, 1983, are already in effect. The regulations specified that the third effective date, called the retail level effective date, is to be effective February 6, 1984. At that time, all products covered by the regulations held for sale in retail establishments are required to be packaged in tamper-resistant packaging.

In the preamble to the November 5, 1982 tamper-resistant packaging and labeling regulations the agency stated that, "Because of the uncertainty involved in attempting to estimate the circumstances that will prevail at the time of the retail level effective date, the agency will review the need for such a date and what the date should be after it has had an opportunity to determine the effects of this regulation on the marketplace" (47 FR 50446). The agency has initiated such a review. However, according to information recently submitted to the agency, to comply with the February 6, 1984 deadline, the industry must begin taking action before FDA can complete its review.

Pending final resolution of its review, the agency is announcing this interim stay of the retail level effective date. If, as a result of that review, the agency concludes that a retail level effective date should be retained, the agency plans to specify that the new retail level effective date selected be 4 months after the date that the decision is published as a final rule in the **Federal Register**. The agency believes that this time should be sufficient for industry to comply. Any new retail level effective date would be sometime later than February 3, 1984.

This interim stay applies only to the requirement that products shipped prior to the first two effective dates that are held for sale on February 6, 1984, be packaged in tamper-resistant packaging. It does not affect the stay to February 6, 1984, of one of the labeling requirements, as announced in the August 19, 1983 **Federal Register** (48 FR 37624).

The agency believes that good cause exists to stay the retail level effective date immediately while it conducts a review of the marketplace to establish whether such an effective date is necessary. Both the Administrative Procedure Act and FDA regulations provide that a general notice of proposed rulemaking need not be published in the **Federal Register** when the agency for good cause finds that "notice and public procedure * * * are impracticable, unnecessary, or contrary to the public interest" (5 U.S.C. 553(b)(B) and 21 CFR 10.40(e)(1)). Good cause exists because it would be contrary to the public interest to require compliance with a requirement that is under evaluation looking toward possible modification or revocation. Elsewhere in this issue of the **Federal Register** the agency is publishing a notice of proposed rulemaking, inviting comments on the need for a retail level effective date. Following receipt of comments on that proposal and completion of the agency's survey of the marketplace, FDA will publish a final rule on the subject of a retail level effective date.

List of Subjects

21 CFR Part 211

Drugs, Manufacturing, Labeling, Laboratories, Packaging and containers, Warehouses.

21 CFR Part 700

Cosmetics; Definitions; Prohibited cosmetic ingredients.

21 CFR Part 800

Administrative detention; Administrative practice and procedure; Medical devices.

§§ 211.132, 700.25, 800.12 [Temporarily deferred in part]

Accordingly, the agency announces an interim stay of 21 CFR 211.132(g)(3), 700.25(e)(3), and 800.12(f)(3).

Dated: September 12, 1983.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 83-25296 Filed 9-15-83; 8:45 am]

BILLING CODE 4100-01

21 CFR Part 540

Penicillin Antibiotic Drugs for Animal Use; Amoxicillin Trihydrate for Oral Suspension

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 A. H. Robins Co., Inc., and Biocraft Laboratories, Inc., providing for oral use of amoxicillin trihydrate for suspension for treating bacterial dermatitis and soft tissue infections in dogs.

EFFECTIVE DATE: September 15, 1983.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: A. H. Robins Co., Inc., 1405 Cummings Drive, P.O. Box 26609, Richmond, VA 23261, and Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407, jointly filed NADA 65-495 providing for oral use of amoxicillin trihydrate suspension (Robamox®-V) for treating soft tissue infections (abscesses, wounds, and lacerations) and bacterial dermatitis in dogs. The agency approved an application for amoxicillin trihydrate tablets for the same indications in the **Federal Register** of May 10, 1983 (48 FR 20901). The application is approved and the regulations are amended accordingly. 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, 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 540

Animal drugs, Antibiotics, Penicillin.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i) and (n), 82 Stat. 347, 350-351 (21 U.S.C. 360b (i) and (n))) 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 540 is amended in § 540.103b by revising paragraph (c) to read as follows:

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

§ 540.103b Amoxicillin trihydrate for oral suspension.

* * * * *

(c) *Conditions of marketing*—(1) *Specifications.* The drug conforms to the requirements for certification as in paragraph (a) of this section.

(2) *Conditions of use.* (i) *Sponsor.* See No. 000029 in § 510.600(c) of this chapter.

(a) Dogs. (1) Dosage. 5 milligrams per pound of body weight twice daily.

(2) Indications for use. For the treatment of infections caused by susceptible strains of organisms as follows: respiratory tract (tonsillitis, tracheobronchitis) caused by *Staphylococcus aureus, Streptococcus* spp., *Escherichia coli,* and *Proteus mirabilis;* genitourinary tract (cystitis) caused by *Staphylococcus aureus, Streptococcus* spp., *Escherichia coli,* and *Proteus mirabilis;* gastrointestinal tract (bacterial gastroenteritis) caused by *Staphylococcus aureus, Streptococcus* spp., *Escherichia coli,* and *Proteus mirabilis;* bacterial dermatitis caused by *Staphylococcus aureus, Streptococcus* spp. and *Proteus mirabilis;* and soft tissues (abscesses, lacerations, and wounds) caused by *Staphylococcus aureus, Streptococcus* spp., *Escherichia coli,* and *Proteus mirabilis.*

(b) Cats. (1) Dosage. 50 milligrams (5 to 10 milligrams per pound) once daily.

(2) Indications for use. For the treatment of infections caused by susceptible strains of organisms as follows: upper respiratory tract due to *Staphylococcus* spp., *Streptococcus* spp., *Hemophilus* spp., *Escherichia coli, Pasteurella* spp., and *Proteus mirabilis;* genitourinary tract (cystitis) due to *Staphylococcus aureus, Streptococcus* spp., *Escherichia coli, Proteus mirabilis,* and *Corynebacterium* spp.; gastrointestinal tract due to *Escherichia coli, Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp., skin and soft tissue (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., streptococcus supp., *Escherichia coli,* and *Pasteurella multocida.*

(c) Limitations. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Sponsor.* See Nos. 000031 and 000332 in § 510.600(c) of this chapter.

(a) Dogs. (1) Dosage. 5 milligrams per pound of body weight twice daily.

(2) Indications for use. For the treatment of bacterial dermatitis due to *Staphylococcus aureus, Streptococcus* spp., *Staphylococcus* spp., and *Escherichia coli,* and soft tissue infections (abscesses, wounds, lacerations) due to *Staphylococcus aureus, Streptococcus* spp., *Escherichia coli, Proteus mirabilis* and *Staphylococcus* spp.

(b) Limitations. Use for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date: September 16, 1983.

(Sec. 512(i) and (n), 82 Stat. 347, 350-351 (21 U.S.C. 360b (i) and (n)).)

Dated: September 8, 1983.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 83-25291 Filed 9-15-83; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 256

Housing Improvement Program

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Indian Affairs (BIA) is publishing a final rule which amends the regulations of the Housing Improvement Program (HIP) by: (1)

Requiring the return of a HIP grant if the sale of a house whose purchase was assisted by a grant from the HIP is sold within a period of five (5) years from its date of purchase and (2) requiring the return of a HIP grant if a house which was built by a HIP grant is sold within a period of ten (10) years from the date of its construction.

These changes are required because under current regulations some individuals who have obtained grant assistance from the BIA, either for a down payment or the full cost of a house, subsequently sold the house and retained the proceeds which resulted in personal monetary gains from Federal grants. Such actions have served to defeat the purpose of the program to provide housing for needy Indians. This rule amendment will correct that problem.

EFFECTIVE DATE: This document will become effective September 16, 1983.

FOR FURTHER INFORMATION CONTACT: G. Ronald Peake, Chief, Division of Housing Assistance, Bureau of Indian Affairs, Washington, D.C. 20245, telephone number (202) 343–4876.

SUPPLEMENTARY INFORMATION: The authority to issue rules and regulations is vested in the Secretary of the Interior by 5 U.S.C. 301 and 463 and 465 of the Revised Statutes (25 U.S.C. 2 and 9). This final rule is published in exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

The Inspector General's Audit Report (C–IA–BIA–20–82(a)) in September 1982, discovered that implementation of the existing HIP regulations had led to certain abuses. Individuals that had obtained grant assistance from the BIA to purchase or build a house would subsequently sell the house for personal gain. These practices tended to defeat the purpose of the program which is to help needy Indians obtain decent housing. The BIA is taking action to amend the HIP regulations to incorporate the Inspector General's recommendations. The changes in the regulations require the return of HIP grants to BIA if the resale of a house occurs within a certain period of time, to assure that housing needs are met rather than the house being sold and the funds being used for the personal profit of individuals. Sales of houses without the requirement that the HIP grant be repaid would be permitted only in later years after the families had made significant use of the houses. The BIA will be able to reclaim part of the original grant on a declining scale if a house built under § 256.4(d) is sold after ten years but before 20 years from the time of the completion of the construction.

In addition, in paragraph (b)(3) of § 256.4 the word "cumulative" is deleted. Its original insertion in the provisions was inadvertent and erroneous. The reason for the deletion is that although § 256.5(b) states that "After July 1, 1975, an applicant can only receive assistance one time under categories given in paragraphs (b), (c), and (d) of § 256.4", the word "cumulative" in paragraph (b)(3) of § 256.4 is being used in some instances to justify more than one grant being made to an applicant. This has occurred notwithstanding that the repair and improvements permitted under § 256.4(b) are clearly intended to be one time improvements designed to bring the house to standard condition. Once the house has been brought up to standard condition, no additional repair and improvements are authorized. Further responsibility for repair or improvements, should they be desired, are the responsibility of the family. Elimination of the word "cumulative" from § 256.4(b) will make it clearer that separate sums are not to be awarded an applicant on the ground that they are only part payments of a single grant.

These amendments will have no adverse impact on eligibility requirements to participate in the HIP because they do not change existing criteria for eligibility. These amendments are solely to protect the Federal investment in HIP and also to protect the program integrity by reducing the likelihood that the recipient of an HIP grant will use the proceeds of the grant for personal gain.

For the reasons just stated, the Department of the Interior finds that good cause exists under 5 U.S.C. 553 (b)(B) to dispense with notice and public procedure thereon since to do otherwise would be contrary to the public interest in that unless the amendments are made effective immediately the abuse of the HIP grants described above would continue during the notice and public procedure period. Further, since this amendment corrects the described misuse of HIP grant funds, the 30-day deferred effective date is dispensed with under the exception provided in subsection (d)(3) of 5 U.S.C. 553 (1970). Accordingly, this amendment will become effective upon the date of publication in the **Federal Register.**

The Department of the Interior has determined that this document is not a major rule and does not require a regulatory analysis under Executive Order 12291. It has no impact on prices and costs of housing or other services on Indian reservations.

The Department of the Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under criteria established by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule change will affect the individuals that are recipients of Federal HIP grants. The impact of these changes on these individuals will be to reduce the likelihood that the recipients of HIP grants will use the proceeds of the grants for personal gain as opposed to improving their housing conditions.

This rule does not contain any information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

This rule does not constitute a major Federal action significantly affecting the quality of the human environment under the National Environmental Policy Act of 1969.

List of Subjects in 25 CFR Part 256

Grant programs—housing and community development, Grant programs—Indians, Housing and Indians.

Section 256.4 of Part 256 of Chapter I of Title 25 of the Code of Federal Regulations is hereby amended as follows:

PART 256—HOUSING IMPROVEMENT PROGRAM

Paragraphs (b)(3), (c)(2), (c)(3) and (d)(4) of § 256.4 are revised to read as follows:

§ 256.4 Program categories

* * * * *

(b) * * *

(3) The total expenditure of the Housing Improvement Program funds should not exceed $20,000 for any one dwelling.

* * * * *

(c) * * *

(2) The grant should not exceed the amount necessary to secure the loan plus the closing costs or ten percent (10%) of the purchase price of the house plus the closing costs or $5,000 whichever is less. (In the case of Alaska, the grant amount should not exceed $6,000).

(3) The method of advancing the grant must insure that the funds are used for the purpose intended. The applicant must sign a written agreement that if he/she sells the house within five (5) years following the date of purchase, the grant is voided and the amount of the grant will be fully repaid by the grantee to the Bureau of Indian Affairs.

(d) * * *

(4) The applicant must have ownership (as defined in § 256.2(h)) of the land on which the house is built. In the case of a leasehold interest, it must be for not less than 25 years. The applicant must sign a written agreement that if he/she sells the house within the first ten (10) years from the date of ownership, the grant is voided and the full amount of the HIP grant will be repaid by the grantee to the Bureau of Indian Affairs. Subsequent to the first ten years, if the grantee sells the house, he/she may retain ten percent (10%) of the original grant amount per year beginning in the eleventh (11th) year with the remaining amount to be repaid to the Bureau of Indian Affairs. If the sale occurs twenty (20) years or more after the date of ownership, no repayment of any part of the grant will be due the Bureau of Indian Affairs.

* * * * *

John W. Fritz,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 83-25332 Filed 9-15-83; 8:45 am]

BILLING CODE 4310-02-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[T.D. 7907]

Rate of Interest for Overpayments and Underpayments of Tax

Correction

In a correction published on page 41018 in the issue of Tuesday, September 13, 1983, the CFR citation in the fifth line which read "§ 301.6621-1(b)(2)" should have read "§ 301.6621-1(c)(2)".

BILLING CODE 1505-01-M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 62b

[DOD Directive 1010.7]

Drunk and Drugged Driving by DOD Personnel

AGENCY: Office of the Secretary, DOD.

ACTION: Final rule.

SUMMARY: This rule is issued to reduce the number of deaths and injuries within the Department of Defense due to intoxicated driving. It provides specific guidance to all heads of DOD Components and DOD commanders on the importance of the DOD Intoxicated Driving Prevention Program and information requirements. This rule addresses only administrative actions to be taken in the case of intoxicated drivers. Legal actions to be taken are covered in other DOD issuances.

EFFECTIVE DATE: This rule was approved and signed by the Secretary of Defense on August 10, 1983, and is effective as of that date.

FOR FURTHER INFORMATION CONTACT: Captain Roger L. McFillen, USN, Office of the Deputy Assistant Secretary of Defense (Health Promotion), Office of the Assistant Secretary of Defense (Health Affairs), The Pentagon, Room 3D200, Washington, D.C. 20301; telephone (202) 695-7116/7.

SUPPLEMENTARY INFORMATION: In FR Doc. 83-9387 appearing in the **Federal Register** on April 11, 1983 (48 FR 15485), the Office of the Secretary of Defense published a proposed rule under this Part. Public comments were to be submitted by May 11, 1983. No comments were received.

Executive Order 12291. The Department of Defense has determined that this proposed rule is not a major rule because it is not likely to result in an annual effect on the economy of $100 or more.

Paperwork Reduction Act. This rule imposes no obligatory information requirements beyond internal DOD use.

Regulatory Flexibility Act of 1980. The Assistant Secretary of Defense (Manpower, Reserve Affairs, and Logistics) certifies that this rule, if promulgated, shall be exempt from the requirements under 5 U.S.C. 601-612. In addition, this rule does not have a significant economic impact on small entities as defined in the Act.

List of Subjects in 32 CFR Part 62b

Alcohol, Drugs, Highway safety intoxicated driving prevention program, Military and civilian personnel.

Accordingly, 32 CFR is amended by adding a new Part 62b, reading as follows:

PART 62b—DRUNK AND DRUGGED DRIVING BY DOD PERSONNEL

Sec.

62b.1 Purpose.
62b.2 Applicability.
62b.3 Policy.
62b.4 Procedures.
62b.5 Responsibilities.
62b.6 DOD Intoxicated Driving Prevention Task Force.
62b.7 Definitions.
Appendix 1—Driver's License Information.
Appendix 2—State Driver's License Agencies.

Authority: 10 U.S.C. 131.

§ 62b.1 Purpose.

This part:

(a) Establishes DOD policy regarding drunk and drugged driving by DOD personnel (hereafter referred to as "intoxicated driving").

(b) Assigns responsibility for and explains DOD policy and procedures on the establishment and operation of the DOD Intoxicated Driving Prevention Program, which is designed to address the problem of and increase the awareness and attention given to intoxicated driving by DOD personnel.

(c) Establishes the DOD Intoxicated Driving Prevention Task Force (DIDPTF).

§ 62b.2 Applicability.

This part applies to the Office of the Secretary of Defense, the Military Departments, the Organization of the Joint Chiefs of Staff, the Unified and Specified Commands, and the Defense Agencies (hereafter referred to collectively as "DOD Components"). The term "Military Services," as used herein, refers to the Army, Navy, Air Force, and Marine Corps.

§ 62b.3 Policy.

(a) Intoxicated driving is incompatible with the maintenance of high standards of performance, military discipline, DOD personnel reliability, and readiness of military units and supporting activities. It is DOD policy to reduce significantly the incidence of intoxicated driving within the Department of Defense through a coordinated program of education, indentification, law enforcement, and treatment. Specifically, the goal of the DOD Intoxicated Driving Prevention Program is to reduce the number of fatalities and injuries suffered by DOD personnel and the amount of property damage that result from intoxicated driving. Persons who engage in intoxicated driving, regardless of the geographic location of the incident, have demonstrated a serious disregard for the safety of themselves and others. It is appropriate for military commanders, in the exercise of their inherent authority, to protect the mission of an installation and the safety of persons and property therein to restrict driving privileges of persons who engage in such actions.

(b) The Department of Defense shall participate in the national effort to prevent intoxicated driving by maintaining appropriate relationships with other governmental agencies and private organizations and shall cooperate with responsible civil