

List of Subjects in 18 CFR Part 1310

Government property.

For the reasons set out in the preamble, Title 18 of the Code of Federal Regulations is amended by adding a new Part 1310 reading as follows:

PART 1310—ADMINISTRATIVE COST RECOVERY

Sec.

1310.1 Purpose.

1310.2 Application.

1310.3 Assessment of administrative charge.

Authority: Tennessee Valley Authority Act of 1933, as amended (16 U.S.C. 831-831dd); Title V, Independent Offices Appropriations Act of 1952 (31 U.S.C. 9701).

§ 1310.1 Purpose.

The purpose of the regulations in this part is to establish a schedule of fees to be charged in connection with the disposition and uses of, and activities affecting, real property in TVA's custody or control, and certain other activities in order to help ensure that such activities are self-sustaining to the full extent possible.

§ 1310.2 Application.

(a) TVA will undertake the following actions only upon the condition that the applicant pay to TVA such administrative charge as the Director of Land and Forest Resources or Chief of the Power Management Services Staff (hereinafter "responsible land manager"), as appropriate, shall assess in accordance with § 1310.3 of this part; provided, however, that no payment shall be required where the responsible land manager determines that there is a corresponding benefit to TVA:

(1) Conveyance and abandonment of TVA land or landrights, except as provided in paragraph (b)(5) of this section.

(2) Other private uses of TVA land not involving the disposition of TVA real property or interests in real property.

(3) Actions taken to suffer the presence of unauthorized fills and structures over, on, or across TVA land or landrights, and including actions not involving the abandonment or disposal of TVA land or landrights.

(4) Actions taken to approve fills or structures constructed either without prior approval of plans under Section 26a of the Tennessee Valley Authority Act of 1933, as amended (16 U.S.C. 831y-1), and TVA's regulations issued thereunder at 18 CFR Part 1304, or not in accordance with such plans previously approved by TVA.

(b) **Exemption.** An administrative charge shall not be made for the following actions:

(1) Agricultural licenses.

(2) Firewood cutting permits and timber sale contracts.

(3) Permits for the nonexclusive short-term use of TVA land.

(4) Uses of TVA land, at no charge, for utility line crossings, not involving the disposition of TVA real property or interests in real property.

(5) Conveyance and abandonment of TVA land or landrights at no charge to States and municipalities, and political subdivisions and agencies thereof.

(6) Conveyances pursuant to section 4(k)(d) of the Tennessee Valley Authority Act of 1933, as amended (16 U.S.C. 831c(k)(d)).

(7) Releases of unneeded mineral right options.

(8) TVA phosphate land and mineral transactions.

(9) Permits and licenses for use of TVA land by distributors of TVA power.

§ 1310.3 Assessment of administrative charge.

(a) **Range of charges.** Except as otherwise provided herein, the responsible land manager shall assess a charge which he determines in his sole judgment to be approximately equal to the administrative costs incurred by TVA for each action including both the direct cost to TVA and applicable overheads. With respect to the following categories of actions, a charge of not less than the minimum or greater than the maximum amount specified herein shall be assessed except as otherwise provided in paragraph (c) of this section.

(1) Land transfers—\$500-\$4,400.

(2) Use permits or licenses—\$50-\$625.

(3) Actions taken to approve plans for fills or structures constructed either without prior approval by TVA under Section 26a of the TVA Act or not in accordance with such plans previously approved by TVA, and other actions, where appropriate, to suffer the presence of such fills or structures or to reach other agreements with respect to such fills or structures—\$100-\$2,500.

(4) Abandonment of transmission line easements and rights of way—\$100-\$1,500.

(b) **Basis of charge.** The administrative charge assessed by the responsible land manager shall, to the extent applicable, include the following costs:

(1) Appraisal of the land or landrights affected;

(2) Assessing applicable rental fees;

(3) Field inspections and investigations;

(4) Title and record searches;

(5) Preparation for conducting public auction and negotiated sales;

(6) Mapping and surveying;

(7) Preparation of conveyance instrument, permit, or other authorization or approval instrument;

(8) Coordination of the proposed action within TVA and with other Federal, State, and local agencies;

(9) Legal review; and

(10) Administrative overheads associated with the transaction.

(c) **Assessment of charge when actual administrative costs significantly exceed established range.** When the responsible land manager determines that the actual administrative costs are expected to significantly exceed the range of costs established in paragraph (a) of this section, such manager shall not proceed with the TVA action until agreement is reached on payment of a charge calculated to cover TVA's actual administrative costs.

(d) **Additional charges.** In addition to the charges assessed under these regulations, TVA may charge for its services if TVA is required to make environmental investigations or otherwise incur additional expenses as provided in section 5.7.2 of TVA's procedures implementing the National Environmental Policy Act (45 FR 54,511-15).

W. F. Willis,

General Manager.

April 12, 1983.

[FR Doc. 83-10203 Filed 4-18-83; 8:45 am]

BILLING CODE 8120-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 520****Oral Dosage Form New Animal Drugs Not Subject to Certification; Furosemide Tablets**

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 Bolar Pharmaceutical Co., Inc., providing for safe and effective use of furosemide tablets for oral treatment of dogs for edema associated with cardiac insufficiency and acute noninflammatory tissue edema.

EFFECTIVE DATE: April 19, 1983.

FOR FURTHER INFORMATION CONTACT: Bob G. Griffith, Bureau of Veterinary Medicine (HFV-112), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Bolar Pharmaceutical Co., Inc., 130 Lincoln St., Copiague, NY 11726, filed NADA 125-329 providing for use of 12.5 and 50 milligram furosemide tablets for oral treatment of dogs for edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

The sponsor of this NADA submitted studies to demonstrate that the drug is safe and effective for its intended uses. Based on the data and information submitted, the NADA is approved and the regulations are amended to reflect the 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 520

Animal drugs, oral.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

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 520 is amended in § 520.1010a by revising paragraph (b), to read as follows:

§ 520.1010a Furosemide tablets or boluses.

(b) *Sponsor.* See No. 012799 in § 510.600(c) of this chapter for use in dogs, cats, and cattle; see No. 000725 and 013983 in § 510.600(c) of this chapter for use in dogs.

Effective date. April 18, 1983.

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

Dated: April 8, 1983.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 83-10160 Filed 4-18-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 211 and 700

[Docket No. 82N-0330]

Tamper-Resistant Packaging Requirements for Certain Over-the-Counter Human Drug and Cosmetic Products

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its tamper-resistant packaging regulations for over-the-counter (OTC) drug and cosmetic products to clarify certain sections of the preamble and to specify in the regulations those products that the agency has exempted from these regulations. This action is taken in response to comments received on the final rule and to citizens' petitions seeking exemptions from the final rule.

EFFECTIVE DATE: April 19, 1983.

FOR FURTHER INFORMATION CONTACT: Eileen R. Hodkinson, 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 regulations (corrected in the Federal Register of January 14, 1983; 48 FR 1706) establishing tamper-resistant packaging and labeling requirements for certain OTC human drug and cosmetic products in response to seven deaths linked to Extra-Strength Tylenol capsules found to be contaminated with cyanide and to other tampering incidents nationwide. This action was taken to provide safeguards against the future occurrence of such incidents. The OTC drug products covered by these regulations include oral drug products (except dentifrices) and nasal, otic, ophthalmic, rectal, and vaginal drug products. Cosmetic products covered by these regulations are liquids that are used orally, such as mouthwashes, gargles, breath fresheners, etc., and vaginal cosmetic products. The regulations require that the packaging of these products be capable of providing consumers with visible evidence if package tampering has occurred. In addition, the final rule requires the labeling of the affected products to bear

a statement describing the tamper-resistant feature of the package.

Compliance with these regulations becomes effective in steps. The requirements that a tamper-resistant package be used became effective February 7, 1983, for OTC drug products and cosmetics that are considered the most vulnerable to tampering. These products are oral, vaginal, and rectal drug products (other than oral and vaginal tablets and vaginal and rectal suppositories), otic drug products, nasal drug products, and ophthalmic drug products. A later effective date of May 5, 1983, is provided for oral and vaginal tablets and for vaginal and rectal suppositories because they are considered less susceptible to known methods of tampering. For all products, the label statement requirement and the requirement that the barrier to entry be distinctive are effective May 5, 1983. The agency also established a retail level effective date of February 6, 1984, by which time all stocks held for retail sale (including stocks in retail stores), no matter when packaged, must be in compliance with the tamper-resistant packaging requirements of the regulations.

As discussed in the preamble to the final rule, the agency recognizes that certain packaging or marketing practices for some products or classes of products may already provide adequate protection for consumers. For such instances, the agency established in the regulations (§§ 211.132(d) and 700.25(d) (21 CFR 211.132(d) and 21 CFR 700.25(d))) a procedure whereby a manufacturer or packer may request an exemption from the tamper-resistant packaging requirements or the labeling requirements, or both. The agency further set forth the procedure for manufacturers who are unable to meet the effective date provisions to request a stay of the effective date.

The final rule provided a 30-day comment period for interested persons to submit written comments on these regulations. Based on these comments and a further review of the regulations, the agency has decided that certain provisions of both the regulations and the preamble need clarification.

The agency received approximately 375 comments concerning the episodes of malicious tampering that occurred in Chicago and elsewhere in the nation. Of these comments, approximately 100 were directly in response to the final rule. The following is a summary of the substantive comments on the final rule and the agency's responses to them.

I. Concepts of Tamper Resistance

1. The agency received 18 comments, mainly from organizations of health care professionals and organized consumer groups, expressing concern that the tamper-resistant packaging would be too difficult for the elderly and the manually impaired to open. The comments stressed that, because the elderly are the largest group of consumers of OTC medications, the agency should have considered this segment of the population when preparing the final rule. Several of these comments suggested that either FDA or the Consumer Product Safety Commission (CPSC) should test packaging designs currently in use or as they are developed to determine whether the tamper-resistant products can be opened by this segment of the population. Most of the comments recommended that drug manufacturers and packagers should consider the following when designing tamper-resistant packaging:

a. Directions for opening the tamper-resistant package should be in large print, in contrasting colors, and placed on both sides of the product.

b. Tamper-resistant packaging should be clearly visible and should be manufactured in a color and design scheme that is distinct from the rest of the container.

c. Component parts of the tamper-resistant packaging that need to be manipulated to break the barrier should be clearly visible and easy to grasp.

d. There should be standards for minimum break strength so that persons with physical disabilities are able to open the packages.

e. There should be uniformity of tamper-resistant directions and mechanisms so that ability to open one type of tamper-resistant packaging increases the likelihood of being able to open other packaging of the same type.

The agency agrees that tamper-resistant packaging must be accessible to the elderly and the manually impaired. In the preamble to the final rule, FDA urged manufacturers devising new packaging to take the needs of this segment of the population into account. The agency is concerned, however, that many of these comments misunderstand the concept of tamper-resistance, apparently based on a belief that a product cannot be resistant to tampering, unless it requires extra strength or dexterity to open it. This is not the case and was not the agency's intent in using the term "tamper-resistant." In fact, a packaging system that may be very easy to open, such as one using a pull tab or a fragile paper seal over the mouth of a container, may

still be tamper-resistant because it would be obvious to the consumer if the package had been opened.

Since the publication of the final rule, the agency has met with officials of CPSC and, in conjunction with CPSC, is planning to study whether opening tamper-resistant packaging presents problems for the elderly or the manually impaired. The agency has developed a draft protocol for a study that is being reviewed by several consumer groups and health care organizations. In addition, on January 3, 1983, the agency met with representatives of consumer groups and various health organizations to hear their views on this issue and on January 31, 1982, the agency held a meeting for these organizations to present their views to industry representatives.

2. One trade association and two firms involved in the packaging of OTC drug products criticized the use of the term "tamper resistant," stating that it is unclear and confusing. Two of these comments argued that the term "tamper indicating" would be more appropriate than "tamper resistant," while the other comment argued that the term "tamper control packaging" would be more appropriate. Several other comments suggested the use of the term "tamper evident."

The agency understands the concern voiced by these comments but believes the term "tamper-resistant" packaging is more appropriate than any of the three suggested alternative terms. Although most of the technologies discussed in the preamble to the final rule are systems that can be expected to provide visible evidence to consumers if tampering has occurred, this is not the case with every system. For example, aerosol containers are always tamper-resistant but not always tamper-evident. Therefore, because the agency contends that tamper-resistant packaging is a term encompassing a greater number of possible technologies that would resist tampering, the agency does not plan to amend the regulations to change the terminology.

3. Several comments from a trade association and producers of packaging systems stated that some of the definitions of packaging technologies used in the preamble are inaccurate and misleading. These comments claimed that FDA's use of these terms is inconsistent with industry practice and argued that the agency should revise them.

The agency agrees that there are various ways of defining some of the packaging technologies listed in the preamble. The definitions used, however, were submitted by the

Proprietary Association and are basically the same as those contained in the *Glossary of Packaging Terms* that was compiled and published by both The Packaging Institute, U.S.A., and the Packaging Machinery Manufacturers Institute and accepted by the American National Standards Institute. Although the definitions selected differ from those suggested by the comments, the agency believes that the terms, as currently defined in the preamble, are widely used in, and understood by, the manufacturing industry. Furthermore, the agency points out that the packaging systems listed in the preamble are included there as examples only and not as regulatory requirements. Thus, how a type of packaging is described in the preamble has no bearing on compliance with the regulations, which set forth performance criteria to be met.

4. Several designers and manufacturers of packaging systems and individual consumers claimed to have devised new methods of packaging that were "tamper-proof" or "tamper-resistant." Many of these comments requested that their packaging systems be included in the FDA list of acceptable technologies in the final rule (47 FR 50444). These comments contended that their packaging systems would be recognized as acceptable by industry only if included in FDA's list of acceptable tamper-resistant packaging. The agency also received two comments from manufacturers of drug packaging systems claiming that their systems are tamper-resistant by design and thus, like aerosol containers, should be cited as such in the preamble.

The agency emphasizes, as it did in the preamble to the final rule, that the list of current technologies was never intended to be complete, but was intended only to provide examples of currently available packaging systems capable of meeting the tamper-resistant requirements of the final rule. The agency reemphasizes that it does not intend to preclude technological innovation that may create totally different systems for providing consumers with protection against product tampering. As was expected, since the publication of the final rule, the agency has become aware of numerous other available tamper-resistant packaging options. The agency again states that manufacturers and packagers are free to adopt any packaging system, whether or not listed in the preamble to the final rule, if it is tamper-resistant. The examples given in the preamble to the final rule have no special status.

Furthermore, the agency points out that the use of a technology listed in the preamble does not, by itself, constitute compliance with the requirement for the use of a tamper-resistant packaging system, because the performance characteristics of some technologies vary widely. For instance, although shrink seals are listed as a technology capable of meeting the tamper-resistant packaging requirement of the final rule, the agency does not believe the cellulose wet shrink seal, as currently manufactured, will meet the requirements of the regulations. The agency believes, however, that the heat shrink band does meet these requirements. The agency considers cellulose seals to be unacceptable because of the widespread knowledge, even among people outside of the packaging industry, that the currently available cellulose wet band can be removed and reapplied without evidence of tampering. The process for removing the heat shrink band, however, is not well known to the public and could not be accomplished by someone unfamiliar with commercial packaging techniques. The agency points out that at least one manufacturer of wet shrink bands is investigating ways to improve the characteristics of the bands so that they will meet the requirements of the regulations.

In addition, the agency will use its regulatory discretion in evaluating the compliance of firms. If a firm has made a good-faith effort to comply with the effective dates but has used a technology that is not completely satisfactory, the agency does not intend to take regulatory action until the firm has been duly notified and been given a reasonable time to correct any deficiencies.

5. Many comments from consumers commended the agency's immediate response to a serious public health problem, but thought that the final regulations should have covered additional products, pointing out that there have already been several cases of tampering involving food products. A pharmacist thought the final regulations also should have covered prescription drug products.

The agency has considered the possibility of extending tamper-resistant packaging and labeling requirements to other products generally, but believes at this time the scope of the current regulations should not be broadened. In regard to prescription drug products, FDA believes that tamper-resistant packaging is unnecessary. The objective of the regulation is to prevent the malicious tampering that can occur

when products are accessible to the public. Because prescription drug products are under the control of a health professional upon receipt at a retail establishment, they are not accessible to the public before they are dispensed. Tampering with such products, therefore, seems a remote possibility.

6. Another comment asserted that the agency failed to state the reason for exempting both dentifrices and insulin products from the tamper-resistant packaging and labeling regulations. The comment suggested that, to avoid public confusion, any products exempted from the packaging requirements should be required to bear a statement to that effect.

As stated in the preamble, the agency did not include dentifrices and insulin in the final rule because tampering with them is less probable. Also, the consequences of tampering with dentifrices are less severe than with those products that are ingested, inserted, inhaled, or intended for ophthalmic use. Furthermore, insulin is usually kept behind the pharmacy counter in a refrigerator and is packaged in a multiple-dose vial that is already tamper-resistant.

The agency believes it is unnecessary and would be unduly burdensome to manufacturers and packagers to require them to place a statement on their product labels merely because they are exempt from these regulations. The public will, through direct observation of products on the market, be able to ascertain which are subject to the regulations and which are not.

II. Provisions of the Rule

7. Comments from drug manufacturers and trade associations criticized FDA for using the terms "distinctive by design" and "identifying characteristic" without defining them. These comments stressed that both of these terms have varying possible interpretations and are causing confusion among manufacturers and packagers.

The agency agrees that it should clarify these terms. Under §§ 211.132(b) and 700.25(b) of the final rule, the agency defines a tamper-resistant package as one having an indicator or barrier to entry, which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. The rule further states that "to prevent the substitution of the tamper-resistant feature after tampering, the indicator or barrier to entry is required to be distinctive by design or by the use of an identifying characteristic." Although the agency did not define the term

"distinctive by design," it stated clearly in the preamble to the final rule that a tamper-resistant feature designed from material that is generally "not readily available" is "distinctive by design." By not readily available, the agency means materials that are not generally available for purchase by consumers at a variety of retail stores. Most packaging materials are generally available only in very large quantities and are sold primarily to manufacturers and packagers. Packaging systems, therefore, which use materials such as bubble packs, aerosol containers, or individual foil pouches, which are not readily available to the public and which would not be easy to duplicate, are considered distinctive by design and do not require an identifying characteristic. So as to clarify this point further, however, the agency has amended the regulations to define "distinctive by design" as meaning that "the packaging cannot be duplicated with commonly available materials or through commonly available processes."

Materials such as plain tape, clear plastic, or paper seals are obviously readily available to those who might tamper with products. Therefore, for barriers using these materials, the agency is requiring that an identifying characteristic be placed on them so that the substitution of a plain tape, clear plastic, or paper seal can be easily detected. The preamble to the final rule (47 FR 50444) listed 4 packaging systems, among the 11 cited, that would require an identifying characteristic.

The agency intentionally did not give specific examples of identifying characteristics so as to allow manufacturers and packagers flexibility in designing their tamper-resistant features. To clarify the regulations, however, the agency has added examples of kinds of identifying characteristics that would comply with this requirement. Although the agency realizes that many manufacturers and packagers are planning to imprint their company logo on their tamper-resistant feature to distinguish it from other designs, an individual specific identifying characteristic is not required. In fact, several manufacturers may use packaging technologies with the same identifying characteristic. The agency does not believe that such multiple use will cause a problem, because manufacturers will closely control their supplies of these imprinted packaging systems to be certain they are not generally available to the public.

8. Another comment questioned the assumption contained in §§ 211.132(b) and 700.25(b) that an indicator or barrier

to entry that is distinctive by design or has an identifying characteristic will "prevent the substitution of the tamper-resistant feature after tampering." The comment argued that tamper-resistant packaging cannot "prevent" the substitution of a tamper-resistant feature after tampering, but can only reduce its likelihood. The comment further suggested that for clarification the regulations should specifically include the concept that commonly available processes or materials would not be distinctive by design.

The agency agrees with this comment and has revised §§ 211.132(b) and 700.25(b) accordingly.

9. The agency has also received several comments from manufacturers and packagers questioning the requirement contained in §§ 211.132(c) and 700.25(c) that the labeling statement must be "prominently placed so that consumers are alerted to the specific tamper-resistant feature of the package." The comments asked whether this requirement means that the manufacturer or packager must describe specifically the tamper-resistant feature and its position on the package.

The agency believes that the labeling statement should identify the place on the package that has the tamper-resistant feature, and, where a packaging feature incorporates an identifying characteristic, that characteristic should be referred to in the labeling statement. For example, the labeling statement on a container with a shrink band that has a logo could say "For your protection, this bottle has an imprinted seal around the neck." The regulations have been amended to clarify this point.

10. One comment expressed the view that for any tamper-resistant packaging to be truly effective, visual indication of package integrity must be apparent at the point of retail purchase. The comment contended that, under the current regulations, consumers would be required to open some packages to discover evidence of tampering.

The agency agrees that some, but not all, of the currently acceptable tamper-resistant packaging technologies require that an outer container closure be opened before the tamper-resistant feature is evident to consumers. However, the agency disagrees that point-of-purchase evidence of tampering is necessary for the tamper-resistant packaging to be effective. The agency considered imposing a point-of-purchase requirement when the regulations were written and rejected such a requirement for several reasons. First, such a requirement would severely limit the numbers and kinds of packaging

technology that could be employed to fulfill the function of tamper-resistant packaging. Thus, such a requirement would increase the costs of complying with the regulations and undermine significantly the ability of packagers to comply within the short timeframes dictated by the risk of tampering episodes and by public's concern. In addition, the agency believes that, for affected products, consumers will come to expect tamper-resistant packaging as a matter of course and will not feel compelled to open packages while in the store. In the rare instances in which tampering or mishandling has compromised the tamper-resistant feature, the consumer will not be greatly inconvenienced by having to return the product to the store after having taken it home. Such an occasional inconvenience to consumers cannot justify imposing a requirement of point-of-purchase tamper-resistant packaging on all affected products, with the resultant additional cost to consumers, and the additional delay before packaging could be in full compliance with the regulations. Further, the agency notes that a number of the more popular tamper-resistant packaging technologies already provide point-of-purchase evidence of tampering.

11. Several comments asserted that there is an inconsistency between a statement in the preamble and a provision in the regulations. The preamble states at 47 FR 50445 that the labeling of products affected by this regulation must "contain a statement describing the tamper-resistant feature of the package and advising consumers that, if the feature is breached or missing when the product is purchased, tampering may have occurred." The regulations, however, state only that the labeling must alert the consumer to the specific tamper-resistant feature of the package.

The agency agrees that this point needs clarification, and although the agency strongly urges manufacturers to use a labeling statement that informs consumers not to purchase products if the tamper-resistant feature is breached or missing, it is not requiring such a statement on the labeling.

12. The agency received several comments suggesting that the term "retail sale" as used in the regulations should be defined. In addition, several requests for exemptions concerned products that are distributed in a manner in which the public has no access to them while they are held for sale. These requests asked that the following categories of drug products be exempted from the regulation: (1) OTC drug products that are controlled drugs

and are required to be dispensed by a pharmacist; (2) OTC human drug and cosmetic products distributed directly to hospitals, nursing homes, and health care clinics; (3) first-aid kits containing OTC human drug products sold directly to industrial users; (4) OTC human drug products sold directly to physicians or dentists for subsequent distribution to patients; and (5) products sold to pharmacists that are maintained under the pharmacists' control. Other comments questioned whether OTC products sold in vending machines, through the mail, or sold door-to-door would require tamper-resistant packaging.

The agency agrees that the term "retail sale," for purposes of these regulations, should be clarified and defined and that those products not held for "retail sale," as defined, should not be subject to the tamper-resistant packaging and labeling regulations. The purpose of the regulations is to reduce the risk of malicious tampering with OTC drug products for retail sale and related cosmetic products for retail sale by requiring that their packaging have a distinctive indicator or barrier to entry that would provide the consumer with visible evidence that the package has been tampered with or opened.

Malicious tampering has occurred with products that were accessible to the public, generally on a shelf in a retail establishment before purchase by the ultimate consumer. Prescription drugs were not included in the regulations because they are maintained under a pharmacist's control and are not accessible to the public before they are dispensed. For the same reason, the agency has concluded that those OTC human drug and cosmetic products that are distributed in a manner that does not afford the public access to them while they are held for sale were never intended to come within the scope of these regulations. Such restricted or controlled distribution does not constitute "retail sale" as that term is used in these regulations. Thus, the agency interprets "held for retail sale" under these regulations more narrowly than it interprets "held for sale" in enforcement actions under sections 301 through 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331 through 334).

In view of this interpretation of "retail sale," OTC drug products sold directly to a hospital, an institution, a medical or first aid unit, or a health professional for dispensing directly to patients need not be packaged or labeled as required by the tamper-resistant regulations. Likewise, the agency has concluded that

first-aid kits that are sold directly to organizations and that are not accessible to the general public are not held for "retail sale" for purposes of these regulations. Also, products sold in vending machines or through the mail directly from a firm representative to an individual user, as well as products sold in the same manner but door-to-door, are not considered held for "retail sale." Of course, if any of these products were in fact held for retail sale in a retail establishment where the public would have access to them, they would be subject to regulatory action if they were not in compliance with applicable tamper-resistant packaging and labeling requirements of the regulations.

13. Two consumers questioned the agency's policy of allowing plastic bottles to be used in tamper-resistant systems. They argued that a tamperer could easily inject a substance into a plastic bottle without visible evidence of tampering.

The agency does not agree with this argument. Although it may be possible to penetrate some plastic containers with a needle, the agency believes that most plastic containers are sufficiently strong that either a needle will not penetrate the container, or such a large needle would have to be used that the hole would not be resealed. In an event, most plastic containers would be tamper-evident under these conditions. A liquid injected into a plastic container of tablets or capsules would result in obvious damage to the contents, and, were a liquid injected into a liquid drug or cosmetic product, the hole in the bottle would result in leakage.

14. Two comments questioned the agency's timetable for implementing the packaging requirement. Specifically, these comments criticized the retail level effective date of February 6, 1984, as too late and therefore not responsive to the urgent need to respond to the tampering problem. One such comment contended that the 1984 compliance date for shelf drugs was not instituted to protect the public, but rather to minimize the losses to the drug industry.

The agency disagrees with these comments and believes that the sequential effective dates established by these regulations are both reasonable and responsive to the urgent need to protect the public against the tampering problem. It must be kept in mind that the regulations required that by February 7, 1983, tamper-resistant packaging must be used in the manufacturing of those OTC drug products and cosmetics most vulnerable to tampering (oral liquids and capsules). By May 5, 1983, tamper-resistant packaging must be used in the manufacture of all other products

subject to these regulations. In view of these two effective dates, which apply when the affected products are packaged, the agency believes that by the retail level effective date of February 6, 1984, the stock of products in non-tamper-resistant packaging will be significantly depleted.

The agency agrees that, under normal circumstances, substantial stocks of products with old packaging might remain on retail shelves by the February 6, 1984, date. However, because of consumers' extraordinary awareness of the tampering problem, and their strong demand for tamper-resistant packaging, the agency believes that manufacturers and retailers will attempt to replace old stocks with products in tamper-resistant packaging as soon as they become available. Setting an earlier date by which replacement of stocks is required, however, might create shortages of needed OTC drugs and, as a result, greatly increased prices. FDA believes it is appropriate to rely on the manufacturing effective dates and let the forces of the marketplace encourage the replacement of shelf stocks, with a February 6, 1984, date as a final regulatory target for completing that process. Further, as stated in the preamble to the regulations, because the agency is uncertain as to the circumstances that will prevail at the time of the retail level effective date, the agency plans to review the need for such a date and whether the date should be changed based on an assessment of the situation when more information is available.

III. Legal Authority

15. Two comments asserted that FDA lacks the legal authority to set an effective date after which all products that are subject to these regulations and that are on retail shelves must be in compliance with the tamper-resistant packaging requirements. These comments argued that FDA lacked authority on two grounds: (1) to set such a date was to enact an *ex post facto* requirement, and (2) based on the decision of the court in *United States v. An Article of Drug*, 484 F.2d 748 (7th Cir. 1973), products produced in accordance with current good manufacturing practice could not be proceeded against after shipment for failure to follow safety practices that were not recognized prior to the production of the products.

The agency does not agree, on either ground, that it lacks the legal authority to set a retail level effective date. The constitutional prohibition against *ex post facto* application of the law relates only to criminal penalties, not to civil

legislation or regulation. See *Harisiades v. Shaughnessy*, 342 U.S. 580, 594-595 (1952); *Agustin v. Quern*, 461 F. Supp. 441, 443 (N.D. Ill. 1978); aff'd 611 F.2d 206 (7th Cir. 1979); *United States v. An Article of Food*, 395 F. Supp. 1184, 1187 (S.D.N.Y. 1975); *United States v. Great Atlantic and Pacific Tea Co.*, 342 F. Supp. 272, 281 (D. Md. 1972). Cf. *Springdale Convalescent Center v. Mathews*, 545 F.2d 943, 955 (5th Cir. 1977) (regulation attaching new legal obligations to completed transaction will be upheld where court finds a rational basis). Because the provisions challenged here are regulatory and not necessarily penal in nature, the *ex post facto* prohibition does not apply. *United States v. An Article of Food*, 395 F. Supp. 1184, 1187.

The agency also does not agree that the *dicta* quoted from the *White Quadrisept* case, *supra*, compels the result asserted. The court in *White Quadrisept* was not faced with a situation analogous to that faced here by FDA. Here, the agency has responded to a problem not previously foreseen and has set forth a reasonable timetable during which affected manufacturers may achieve compliance. The court in *White Quadrisept* was faced with a challenge to the current good manufacturing practice regulations based on the argument that the regulations were void because they were too vague. The court rejected the challenge, finding, among other things, that the term "current" fixes the point in time when the acceptability of the relevant production practices may be determined. *White Quadrisept*, *supra*, at 749. Here, the date fixed for total compliance is more than 1 year from the date the regulation was published, and the agency believes that such a date is both reasonable and legally supportable. As noted in the preamble to the final regulations (47 FR 50446), the agency has promised to review the need for such an effective date after there has been an opportunity to determine the effects of the regulations on the marketplace (*id.*).

The argument based on the *White Quadrisept* case also ignores the fact that the tamper-resistant packaging requirements are not based solely on the current good manufacturing practice provisions contained in 21 U.S.C. 351(a)(2)(B). As discussed in the preamble to the regulations, the provisions are also based on other provisions of the act that relate to the adulteration of the affected OTC products.

The agency again points out that the purpose of the retail level effective date requirements of the regulations is to

assure that, at a defined time, all products covered by the rule will be contained in tamper-resistant packaging. Although the agency is sympathetic to the fact that the effective date requirements may impose some difficulties on manufacturers, the agency believes that in providing more than 1 year in which to comply, it has acted both reasonably and responsibly. Further, the agency has provided in §§ 211.132(d) and 700.25(d) a mechanism whereby any manufacturer or packer who can demonstrate a need for an exemption or stay from the packaging or labeling requirements can obtain one.

A final retail level effective date is, nonetheless, necessary and within the agency's authority to require. The date, therefore, remains February 6, 1984. Should the agency's review of the effects of the regulations on the marketplace indicate that a different date would be more appropriate, FDA will publish amended regulation in the Federal Register.

16. Two consumers suggested that the agency should use its authority to make tampering with drug products a crime punishable by death. If this were the case, the comments argued, drug product tampering would cease.

The provisions of the Federal Food, Drug, and Cosmetic Act do not provide the agency with the authority to make tampering with drug products a crime punishable by death. Legislation that would make the tampering with food, drug, cosmetic, and other products with intent to cause personal injury, death, or harm a felony punishable by a sentence of up to life in prison passed both houses of Congress last year. This bill, HR 3963, was vetoed by the President, however, because of other provisions, unrelated to the tampering provisions, that were in the bill. Anti-tampering bills have been reintroduced into both houses of the 98th Congress and have been referred to the appropriate committees for consideration.

17. Two manufacturers of packaging believed that the agency should not have mentioned the costs of specific systems when discussing the cost range of the various packaging technologies. They stressed that mentioning only two such systems was misleading and that any reference to specific systems should be deleted.

The agency disagrees with this comment. In the preamble to the final rule, the agency attempted to give examples of the most and the least expensive packaging system known at the time. Such examples were necessary as part of the agency's estimation of the economic impact of the regulations and were not intended to reflect upon the

merits of one system over another. Manufacturers and packagers consider a variety of factors in selecting packaging systems, including the suitability of their products, the availability of packaging supplies, and the design and capability of their existing production equipment. The agency does not believe that any manufacturer will select a packaging system based on the unit-cost data in FDA's economic analysis.

IV. Exemptions Granted

Section 211.132(d) and 700.25(d) of the tamper-resistant packaging and labeling regulations set forth a procedure whereby a manufacturer or packer may request an exemption from the labeling and packaging requirements of the regulations. In response to this provision, the agency has received many petitions requesting that various OTC human drug and cosmetic products be exempted from these regulations.

In the Federal Register of February 25, 1983 (48 FR 8137), the agency announced the availability of the agency's responses to these requests for exemptions. The exemptions are now being incorporated into the regulations.

A. Lozenges

1. One petition was received requesting that lozenges be exempt from the labeling provisions of the regulations.

After considering this request, the agency concluded that all lozenges (i.e., candy-like solids containing a medicinal agent in a suitably flavored base) should be exempted from both the packaging and labeling requirements of the tamper-resistant packaging regulations. The likelihood of successful tampering with lozenges is remote. The lozenges flavored base may be a hard sugar candy, glycerinated gelatin, or a combination of sugar with sufficient mucilage to give it form. Because lozenges are generally distinctive in appearance, the successful substitution of another product would be unlikely. Lozenges are placed in the mouth where they dissolve, liberating the active ingredient. In addition, the agency believes that it would be extremely difficult to counterfeit or tamper with such a dosage form, and that if physical tampering were attempted, it would be readily visually detectable.

B. Ammonia Inhalant Ampules

2. One petition was received requesting that an alcoholic ammonia solution in a crushable glass ampule be exempt from the labeling requirements of the regulations.

The agency granted this exemption because any malicious tampering with

such a product would not only be evident, but would also release the ammonia, precluding any further use.

C. Aerosol Products and Compressed Medical Oxygen

3. Although the agency did not receive any petitions requesting that aerosol containers be exempted from the labeling requirements, it did receive three such comments from manufacturers and packagers of OTC drug products urging the agency to amend the labeling requirements under §§ 211.132(c) and 700.25(c) to exclude aerosol containers. In addition, a distributor of compressed medical oxygen requested an exemption from the labeling requirements.

The agency concluded that aerosol OTC human drug and cosmetic products and compressed medical oxygen should be exempt from the labeling requirements of the tamper-resistant regulations. The reason for these exemptions is that such containers are tamper-resistant but are not always "tamper evident," so that in the unlikely event that someone had tampered with the contents of an aerosol container or a container of medical oxygen, a labeling statement could not inform the consumer how to detect the occurrence of tampering. For purposes of this exemption, the term "aerosol" product means a product that depends upon the power of a liquified or compressed gas to expel the contents from the container.

D. One-Piece Soft Gelatin Capsules

4. In the Federal Register of January 4, 1983 (48 FR 334), the agency announced its advisory opinion that OTC drugs in one-piece soft gelatin capsules belong to the category of products that must comply with the regulations by May 5, 1983. That opinion and the ones set forth in the Federal Register notice of February 25, 1983 (48 FR 8137) and in this document constitute all the exemptions granted to date from the tamper-resistant packaging and labeling regulations.

V. Economic Considerations

In the preamble to the November 5, 1982 final rule, the agency discussed the economic considerations of the rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (47 FR 50449). The agency concluded that the costs of conversion to tamper-resistant packaging would not be sufficient to warrant designation of the rule as a major rule under Executive Order 12291 and, further, certified under the Regulatory Flexibility Act that the rule will not have a significant economic

impact on a substantial number of small entities.

These amendments to the final rule are for clarification. The agency finds that the regulatory impacts previously considered are not changed to any measurable degree and, accordingly, reexamination of the economic impacts under Executive Order 12291 and the Regulatory Flexibility Act is not necessary.

VI. Environmental Impact

The agency has determined pursuant to 21 CFR 25.24(d) (12) and (13) (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

21 CFR Part 211

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

21 CFR Part 700

Cosmetics, Definitions, Prohibited cosmetic ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 501, 502, 505, 506, 507, 601, 602, 701, 52 Stat. 1041 as amended, 1049-1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 321(n), 351, 352, 355, 356, 357, 361, 362, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 211 and 700 are amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. Part 211 is amended in § 211.132 by revising paragraphs (a), (b), and (c), by revising the introductory text of paragraph (g), and by revising paragraph (g)(1), to read as follows:

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

(a) *General.* Because most over-the-counter (OTC) human drug products are not now packaged in tamper-resistant retail packages, there is the opportunity for the malicious adulteration of OTC drug products with health risks to individuals who unknowingly purchase adulterated products and with loss of consumer confidence in the security of OTC drug product packages. The Food and Drug Administration has the authority and responsibility 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 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 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 an indicator or barrier 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 substitution of a tamper-resistant feature after tampering, the indicator or barrier to entry is required to be distinctive by design (e.g., an aerosol product container) or by the use of 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.

(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."

(g) *Effective date.* OTC drug products, except dermatological, dentifrice, insulin, and lozenge products, are required to comply with the requirements of this section on the dates listed below except to the extent that a product's manufacturer or packer has obtained an exemption from a packaging or labeling requirement.

(1) *Initial effective date for packaging requirements.* (i) The packaging requirement in paragraph (b) of this section is effective on February 7, 1983 for each affected OTC drug product (except oral and vaginal tablets, vaginal and rectal suppositories, and one-piece soft gelatin capsules) packaged for retail sale on or after that date, except for the requirement in paragraph (b) of this section for a distinctive indicator or barrier to entry.

(ii) The packaging requirement in paragraph (b) of this section is effective on May 5, 1983 for each OTC drug product that is an oral or vaginal tablet, a vaginal or rectal suppository, or one-piece soft gelatin capsules packaged for retail sale on or after that date.

PART 700—GENERAL

2. Part 700 is amended in § 700.25 by revising paragraphs (b) and (c), to read as follows:

§ 700.25 Tamper-resistant packaging requirements for cosmetic products.

(b) *Requirement for tamper-resistant package.* Each manufacturer and packer who packages a cosmetic liquid oral hygiene product or vaginal 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 an indicator or barrier 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 substitution of a tamper-resistant feature after tampering, the indicator or barrier to entry is required

to be distinctive by design (e.g., an aerosol product container) or by the use of 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.

(c) *Labeling.* Each retail package of a cosmetic product covered by this section, except aerosol products as defined in paragraph (b) of this section, 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."

EFFECTIVE DATE: April 19, 1983.

(Secs. 201(n), 501, 502, 505, 506, 507, 601, 602, 701, 52 Stat. 1041 as amended, 1049-1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 321(n), 351, 352, 355, 356, 357, 361, 362, 371))

Dated: March 17, 1983.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 83-10280 Filed 4-18-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Virginiamycin

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 Cadco, Inc., providing for use of a 50 percent virginiamycin premix to make a 2.2 percent (10 grams per pound) intermediate premix used to make complete swine feeds.

EFFECTIVE DATE: April 19, 1983.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Bureau of Veterinary Medicine (HFV-128), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4317.

SUPPLEMENTARY INFORMATION: Cadco, Inc., P.O. Box 3599, 10100 Douglas Ave., Des Moines, IA 50322, is sponsor of NADA 133-334 filed on its behalf by SmithKline Animal Health Products. The NADA provides for use of a 50-percent virginiamycin premix to make a 2.2-percent (10 grams per pound) intermediate premix used to make a complete swine feed. The feed is used as in § 558.635(f)(1)(iv) and (v) (21 CFR 558.635(f)(1)(iv) and (v)) for increased rate of weight gain and improved feed efficiency. The NADA is approved and § 558.635 is amended to reflect the approval.

Approval of this application is based on safety and effectiveness data contained in SmithKline's approved NADA's 91-467 and 91-513. SmithKline has authorized use of the data in its NADA's to support approval of this NADA. This approval does not change the approved use of the drug. Consequently, approval of this NADA poses no increased human risk of exposure to residues of the animal drug nor does it change the conditions of the drug's safe use in the target animal species. Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), this is equivalent to a Category II supplemental approval which does not require reevaluation of the safety and effectiveness data in the parent NADA's 91-467 and 91-513.

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 Docket 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.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMALS 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), § 558.635 is amended by revising paragraph (b) to read as follows:

§ 558.635 Virginiamycin.

(b) *Approvals.* (1) Premix levels of 2.2 percent (10 grams per pound), 11 percent (50 grams per pound), and 50 percent (227 grams per pound) virginiamycin activity granted to No. 000007 in § 510.600(c) of this chapter for use as in paragraph (f) of this section.

(2) Premix level of 2.2 percent (10 grams per pound) virginiamycin activity granted to No. 011490 in § 510.600(c) of this chapter for use as in paragraph (f)(1)(iv) and (v) of this section.

Effective date, April 19, 1983.

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

Dated: April 13, 1983.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 83-10281 Filed 4-18-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 800

[Docket No. 82N-0332]

Tamper-Resistant Packaging Requirements for Contact Lens Solutions and Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its tamper-resistant packaging and labeling regulations for contact lens solutions and for tablets and other dosage forms used to make such solutions. The amendments clarify the regulation and conform it to amendments made elsewhere in this issue of the Federal Register to the tamper-resistant