by the licensee that may have caused or threatens to cause:

* * * * *

(d) Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees that have an installed Emergency Notification System shall make the reports required by paragraphs (a) and (b) of this section to the NRC Operations Center in accordance with § 50.72 of this chapter.

(2) All other licensees shall make the reports required by paragraphs (a) and (b) of this section by telephone and by telegram, mailgram, or facsimile to the Administrator of the appropriate NRC Regional Office listed in Appendix D of this part.

5. In § 20.405, paragraphs (a) and (c) are revised, and new paragraphs (d) and (e) are added to read as follows:

§ 20.405 Reports of overexposures and excessive levels and concentrations.

(a)(1) In addition to any notification required by § 20.403 of this part, each licensee shall make a report in writing concerning any one of the following types of incidents within 30 days of its occurrence:

(i) Each exposure of an individual to radiation in excess of the applicable limits in §§ 20.101 or 20.104(a) of this part, or the license;

(ii) Each exposure of an individual to radioactive material in excess of the applicable limits in §§ 20.103(a)(1), 20.103(a)(2), or 20.104(b) of this part, or in the license;

(iii) Levels of radiation or concentrations of radioactive material in a restricted area in excess of any other applicable limit in the license;

(iv) Any incident for which notification is required by § 20.403 of this part; or

(v) Levels of radiation or concentrations of radioactive material (whether or not involving excessive exposure of any individual) in an unrestricted area in excess of ten times any applicable limit set forth in this part or in the license.

(2) Each report required under paragraph (a)(1) of this section must describe the extent of exposure of individuals to radiation or to radioactive material, including:

(i) Estimates of each individual's exposure as required by paragraph (b) of this section;

(ii) Levels of radiation and concentrations of radioactive material involved;

(iii) The cause of the exposure, levels or concentrations; and

(iv) Corrective steps taken or planned to prevent a recurrence.

* * * * *

(c)(1) In addition to any notification required by § 20.403 of this part, each licensee shall make a report in writing of levels of radiation or releases of radioactive material in excess of limits specified by 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations," or in excess of license conditions related to compliance with 40 CFR Part 190.

(2) Each report submitted under paragraph (c)(1) of this section must describe:

(i) The extent of exposure of individuals to radiation or to radioactive material;

(ii) Levels of radiation and concentrations of radioactive material involved;

(iii) The cause of the exposure, levels, or concentrations; and

(iv) Corrective steps taken or planned to assure against a recurrence, including the schedule for achieving conformance with 40 CFR Part 190 and with associated license conditions.

(d) For holders of an operating license for a nuclear power plant, the incidents included in paragraphs (a) or (c) of this section must be reported in accordance with the procedures described in paragraphs 50.73 (b), (c), (d), (e), and (g) of this chapter and must also include the information required by paragraphs (a) and (c) of this section. Incidents reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraphs (a) or (c) of this section.

(e) All other licensees who make reports under paragraphs (a) or (c) of this section shall, within 30 days after learning of the overexposure or excessive level or concentration, make a report in writing to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of this part.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

6. In § 50.36, new paragraphs (c)(6) and (7) are added to read as follows:

§ 50.36 Technical specifications.

* * * * *

(c) * * *

(6) *Initial Notification.* Reports made to the Commission by licensees in response to the requirements of this section must be made as follows:

(i) Licensees that have an installed Emergency Notification System shall make the initial notification to the NRC Operations Center in accordance with § 50.72 of this part.

(ii) All other licensees shall make the initial notification by telephone to the Administrator of the appropriate NRC Regional Office listed in Appendix D, Part 20, of this chapter.

(7) *Written reports.* Holders of an operating license for a nuclear power plant shall submit a written report to the Commission concerning the incidents included in paragraphs (c) (1) and (2) of this section in accordance with the procedures described in § 50.73 (b), (c), (d), (e), and (g) of this part. Incidents reported in accordance with §50.73 of this part need not also be reported under paragraphs (c) (1) or (2) of this section.

Dated at Washington, D.C. this 20th day of July 1983.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 83-20168 Filed 7-25-83; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 134

[T.D. 83-155]

Customs Regulations Amendments Relating to Country of Origin Marking

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations to establish certification requirements for importers with respect to the country of origin marking of certain articles repacked in the United States after release from Customs custody. This change requires importers to certify to the district director having custody of the articles that: (a) If the importer does the repacking, the new container must be marked in accordance with applicable law and regulations; or (b) if the article is sold or transferred, the importer must notify the subsequent purchaser or repacker, in writing, at the time of sale or transfer, that any repacking of the article must conform to the marking requirements. The purpose of this change is to ensure that an ultimate purchaser in the United States is aware of the country of origin of the imported article.

EFFECTIVE DATE: October 24, 1983.

FOR FURTHER INFORMATION CONTACT:
Anthony L. Piazza, Entry Procedures and Penalties Division, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229 (202–566–8468).

SUPPLEMENTARY INFORMATION:

Background

Section 304, Tariff Act of 1930, as amended (19 U.S.C. 1304), provides that, unless expressly excepted, every article of foreign origin (or its container) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the article or container will permit, in such manner as to indicate to an ultimate purchaser, the English name of the country of origin of the article.

Part 134, Customs Regulations (19 CFR Part 134), sets forth the country of origin marking requirements and the exceptions of 19 U.S.C. 1304. The general exceptions to marking are contained in 19 U.S.C. 1304(a)(3) and § 134.32, Customs Regulations.

Among the exceptions to the country of origin marking requirements are: (1) Articles which the Secretary of the Treasury, pursuant to public notice published in the Treasury Decisions before July 1, 1937, determined "were imported in substantial quantities during the 5-year period immediately preceding January 1, 1937, and were not required during such period to be marked to indicate their origin" * * * (19 U.S.C. 1304(a)(3)(j)). The full list of articles excepted from the marking requirements under 19 U.S.C. 1304(a)(3)(j) is set forth in section 134.33, Customs Regulations, referred to as the "J-list"; and (2) articles which are incapable of being marked (19 CFR 134.32(a)).

Generally, whenever an article is excepted from the marking requirements, the container or holder in which the article reaches the ultimate purchaser is required to be marked to indicate the country of origin of the article whether or not the article itself is marked (19 U.S.C. 1304(b)).

The "ultimate purchaser", as defined in § 134.1, Customs Regulations, is generally the last person in the United States who will receive the article in the form in which it was imported. It is not feasible to state who will be the ultimate purchaser in every circumstance. However, the following examples may be helpful:

(1) If an imported article will be used in manufacture, the manufacturer may be the ultimate purchaser if he subjects the imported article to a process which results in a substantial transformation of the article, even though the process may not result in a new or different article.

(2) If the manufacturing process is merely a minor one which leaves the identity of the imported article intact, the consumer or user of the article, who obtains it after the processing, will be regarded as the ultimate puchaser.

(3) If an article is to be sold at retail in its imported form, the purchaser at retail is the ultimate purchaser.

When an article is imported in the container in which it will reach the ultimate purchaser it is relatively simple for Customs to determine the sufficiency of the country of origin marking. However, a problem exists with J-list articles, and articles incapable of being marked, which are imported in bulk and repacked in the United States by the importer or a subsequent purchaser after release from Customs custody. In these cases, while the container in which the article is imported is usually marked, the container in which the article is repacked for sale to an ultimate purchaser is frequently not. Although the problem appears to be greatest involving steel wire rope, it also involves numerous other articles whose containers are required to be marked.

To minimize the practice of not disclosing country of origin information on the new containers, by notice published in the **Federal Register** on September 10, 1982 (47 FR 39866), Customs proposed a procedure to require importers of repacked J-list articles, and articles incapable of being marked, to certify to the district director having custody of the articles that: (a) If the importer repacks the article, he shall do so in accordance with the marking requirements; or (b) if the article is sold or transferred, the importer shall notify the subsequent purchaser or repacker, in writing, at the time of sale or transfer, that any repacking must conform to these requirements.

At present, repacked articles do not come under Customs scrutiny because Customs and the Treasury Department have taken the position (based on a restrictive interpretation of 19 U.S.C. 1304) that the statute applies only to articles or their containers at the time of importation. However, this position, and Customs lack of enforcement of the marking requirements after articles are released from Customs custody, has resulted in many articles reaching the ultimate purchaser in unmarked containers, which otherwise should have been marked. Rather than permitting the repacking rationale to serve to frustrate the clear intent of the statute (ie., to notify an ultimate purchaser of an article's foreign origin), Customs seeks to enforce the statute with respect to repacked articles by applying the rationale in *U.S. Wolfson Bros. Corp.* v. *United States*, 52 CCPA 46, C.A.D. 856 (1965). In that case the court held that if the article will not reach the ultimate purchaser in the container in which it is imported, then Customs cannot find the marking of the imported container to satisfy the requirement of the statute.

Discussion of Comments

Over twelve hundred and fifty (1250) comments were received in response to the notice of September 10, 1982. Approximately twelve hundred (1200) commenters favored the proposal; fifty (50) or so opposed it on various grounds. Several commenters made suggestions that Customs believes would increase the effectiveness of the proposal and reduce the administrative burden for Customs and importers.

The commenters favoring the proposal argued that the present regulations fail to implement effectively the purpose of 19 U.S.C. 1304. They commented that if the change is adopted it will be of paramount importance in providing country of origin information to ultimate purchasers, and will reduce the incidences of fraudulent and deceptive practices which have led to unfair competition in many cases.

A commenter representing the Hand Tools Institute, an association consisting of domestic producers of hand tools, suggested that the proposal not be limited to overcoming difficulties which have attended the repacking of unmarked articles, but should also resolve marking problems with respect to the packing and repacking of marked articles, especially where the marking on the article is concealed. For example, various foreign-made tools are entering the United States in bulk, properly marked with the country of origin marking. Once in the United States however, these tools are repacked in such a way to conceal the country of origin marking by placing the items face down in sealed, unmarked blister packs. To correct this problem, the commenter suggested that the certification include language that "any packing or repacking must not obscure or conceal the country of origin information appearing on the articles, or else the outermost container must be marked in accordance with the applicable law or regulation."

Customs believes that this suggestion constitutes a major change to the proposal, which is limited to unmarked articles. Such a change would require additional notice to the public and an opportunity to comment before being adopted. Accordingly, a separate notice will be published in the **Federal Register** soliciting public comment on the

concealment of marking problem as it relates to the repacking of marked articles.

A second commenter suggested allowing the importer to file with the district director at each port where the article is entered a blanket certification to cover all importations of that article for a given period (e.g., calendar year), rather than requiring a certification for each entry filed.

Customs has adopted this modification because it will greatly reduce the paperwork burden for importers.

A third commenter argued that to require a certification broadly for every repacked article would sweep in many products not intended to be covered by the law and regulations. Therefore, it was suggested that the words "and not subject to an exemption under the act or regulations" be inserted after the word "possession" in the first sentence of the proposed certification, to minimize this situation.

Customs also agrees with this suggestion and has modified the certification to include similar exempting language.

Certain opposing commenters apparently misinterpreted the proposal. They stated that it requires the importer "to ensure that repackers correctly mark each individual package."

The only obligation that an importer has with respect to repackers is to notify them that the country of origin information is required on the new package.

Other opposing commenters claimed that the proposal involves the establishment of a non-tariff trade barrier.

The mere certification that an importer will abide by the marking law, which binds the importer in any event, does not prevent or otherwise restrict importations. It merely ensures an importer's compliance with a rule that now imposes sanctions for its violation.

One commenter opposed the proposal upon grounds that similar requirements are not imposed on domestic industry and its products. The Congress in its wisdom saw fit to require country of origin marking only on articles that are produced in foreign countries. The fundamental objective of country of origin marking legislation, since the first enactment appeared as section 6 of the Tariff Act of 1890, has been to notify an ultimate purchaser of an article's foreign origin before determining whether to buy the article or its domestic counterpart. This choice was provided in large part because Congress recognized that if given a choice, consumers prefer domestic goods. The failure to provide country of origin information on foreign articles or their containers prevents consumers from exercising this right.

Many domestic food processors objected that labeling requirements would be prohibitive. Customs believes that most of the products concerned will be substantially transformed and therefore will not be subject to the rule. The regulation is intended to apply to articles which are repacked after importation but not to articles substantially changed by manufacture or processing which results in an article having a name, character, or use differing from that to the imported article. For example, meat imported in 60-pound boxes would have to carry country of origin labeling as long as it remained physically in the form in which it is imported, even if repacked in smaller size containers. However, if such meat is further processed or combined with other products to make ground beef or other consumer meat products, the processor, as the ultimate purchaser of the meat in the form in which it was imported, would not be responsible for continued country of origin labeling.

Another commenter opposed the certification requirement upon grounds that the Federal Trade Commission (FTC) has the authority to compel marking after articles are imported.

Customs does not believe the rule impinges upon the authority of the FTC. Nothing in the law or regulations should be construed as excepting any particle (or its container) from the particular requirements of marking provided for in any other provision of law, such as those of the FTC, Food and Drug Administration, and other such agencies. The certification merely attaches sanctions to obligations which already exist under 19 U.S.C. 1304 and Part 134, Customs Regulations. The case cited by the commenter, *L. Heller & Son v. Federal Trade Commission*, 191 F. 2d 954 (7th Cir. 1951), is inapposite for the proposition that seeks to bar Customs from promulgating the rule. The court recognized that the two statutes, 19 U.S.C. 1304 and section 5 of the Federal Trade Commission Act, are not repugnant. The court stated that 19 U.S.C. 1304 was "concerned solely with the extent to which the Treasury Department, incidentally to its collection of Customs duties, should regulate the labeling of imported goods."

A commenter for the steel importing community challenged the measure as beyond the jurisdiction of Customs. The point is made that articles entering the domestic commerce after clearing Customs are not susceptible to continuing regulation by Customs.

Clearly, the Secretary of the Treasury has power to attach conditions to any exemption in order to carry out Congressional intent and prevent subversion of the marking statute. As such, the Secretary has announced the certification process as a framework for obtaining compliance with the statute.

A commenter representing a foreign meat producer claimed that the proposed rule is inconsistent with the General Agreement on Tariffs and Trade (GATT).

This is incorrect as the marking statutes antidated the GATT and were not repealed thereby.

Section 134.34, Customs Regulations, provides that an exception from marking under section 134.32(d), Customs Regulations, may be authorized in the discretion of the district director for articles which are repacked after leaving Customs custody and the containers will be marked. One commenter believed that the proposal, if adopted, should supersede the discretionary exemption in § 134.34.

Customs agrees. Since, unless expressly excepted, the marking of the new containers will be mandatory, § 134.34 will be removed.

Customs recognizes that the change will not eliminate all marking problems. However, we are convinced that it is a proper response to an increasing administrative burden. We are hopeful that it will strike a balance between administrative concern for compliance with the marking statute and the desire of interested parties to understand the parameters of their responsibility for satisfying country of origin marking requirements.

Many commenters stated their views on the rule's applicability to specific articles. However, Customs obviously cannot in this document answer all of the questions raised in this context. Such questions should be submitted to the Director, Entry, Procedures and Penalties Division, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229, in accordance with the ruling procedures set forth in Part 177, Customs Regulations (19 CFR Part 177).

After consideration of the comments and further review of the matter, it has been determined to adopt the proposal, with the changes noted above. However, rather than amending § 134.22 as proposed, a new § 134.25 is being added to Part 134 to deal more specifically with the marking of containers of repacked articles which are the subject of this rule.

Executive Order 12291

It has been determined that this document does not contain a "major rule" requiring preparation of a regulatory impact analysis under Executive Order 12291.

Regulatory Flexibility Act

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

Drafting Information

The principal author of this document was Jesse V. Vitello, Regulations Control Branch, Office of Regulations and Rulings, U.S. Customs Service (202-566-8237). However, personnel from other Customs offices participated in its development.

Lists of Subjects in 19 CFR Part 134

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

Amendments to the regulations

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

Alfred R. De Angelus,
Acting Commissioner of Customs

Approved:

Robert E. Powis,
Acting Assistant Secretary of the Treasury.
July 18, 1983.

PART 134—COUNTRY OF ORIGIN MARKING

1. Part 134, Customs Regulations (19 CFR Part 134), is amended by adding a new § 134.25 to read as follows:

§ 134.25 Containers or holders for repacked J-list articles and articles incapable of being marked.

(a) *Certification requirements.* If an article subject to these requirements is intended to be repacked in new containers for sale to an ultimate purchaser after its release from Customs custody, or if the district director having custody of the article, has reason to believe such article will be repacked after its release, the importer shall certify to the district director that: (1) If the importer does the repacking, the new container shall be marked to indicate the country of origin of the article in accordance with the requirements of this Part; or (2) if the article is intended to be sold or transferred to a subsequent purchaser or repacker, the importer shall notify such purchaser or transferee, in writing, at the time of sale or transfer, that any repacking of the article must conform to these requirements. The importer, or his authorized agent, shall sign the following statement.

Certificate of Marking—Repacked J-List Articles and Articles Incapable of Being Marked

(Port of entry) _____

I, _____ of _____, certify that if the article(s) covered by this entry (entry no.(s) _____ dated _____), is (are) repacked in a new container(s), while still in my possession, the new containers, unless excepted, shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the container(s) will permit, in such manner as to indicate the country of origin of the article(s) to the ultimate purchaser(s) in accordance with the requirements of 19 U.S.C. 1304 and 19 CFR Part 134. I further certify that if the article(s) is (are) intended to be sold or transferred by me to a subsequent purchaser or repacker, I will notify such purchaser or transferee, in writing, at the time of sale or transfer, of the marking requirements.

Date _____

Importer _____

The certification statement may appear as a typed or stamped statement on an appropriate entry document or commercial invoice, or on a preprinted attachment to such entry or invoice; or it may be submitted in blanket form to cover all importations of a particular product for a given period (e.g., calendar year). If the blanket procedure is used, a certification must be filed at each port where the article is entered.

(b) *Facsimile signatures.* The certification statement may be signed by means of an authorized facsimile signature.

(c) *Time of filing.* The certification statement shall be filed with the district director at the time of entry summary. If the certification is not available at that time, a bond shall be given for its production in accordance with § 141.66, Customs Regulations (19 CFR 141.66). In case of repeated failure to timely file the certification required under this section, the district director may decline to accept a bond for the missing document and demand redelivery of the merchandise under § 134.51, Customs Regulations (19 CFR 134.51).

(d) *Notice to subsequent purchaser or repacker.* If the article is sold or transferred to a subsequent purchaser or repacker the following notice shall be given to the purchaser or repacker:

Notice to Subsequent Purchaser or Repacker

These articles are imported. The requirements of 19 U.S.C. 1304 and 19 CFR Part 134 provide that the articles or their containers must be marked in a conspicuous place as legibly, indelibly and permanently as the nature of the article or container will permit, in such a manner as to indicate to an ultimate purchaser in the United States, the English name of the country of origin of the article.

(e) *Duties and Penalties.* Failure to comply with the certification requirements in paragraph (a) may subject the importer to a demand for liquidated damages under section 134.54(a) and for the additional duty under 19 U.S.C. 1304. Fraud or negligence by any person in furnishing the required certification may also result in a penalty under 19 U.S.C. 1592.

§ 134.34 [Removed]

2. Part 134 is further amended by removing § 134.34.

(R.S. 251, as amended (19 U.S.C. 66), section 304, 624, 46 Stat. 731 as amended, 759, (19 U.S.C. 1304, 1624), 77A Stat. 14 (19 U.S.C. 1202))

[FR Doc. 83-20136 Filed 7-25-83; 8:45 am]
BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 83C-0041]

2-[[2,5-Diethoxy-4-[(4-Methylphenyl)Thio]Phenyl]AZO]-1,3,5-Benzenetriol; Listing as a Color Additive For Use in Soft (Hydrophilic) Contact Lenses; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of June 21, 1983, for a regulation that provides for the safe use of 2-[[2,5-diethoxy-4-[(4-methylphenyl)-thio]phenyl]azo]-1,3,5-benzenetriol as a color additive in marking soft (hydrophilic) contact lenses with the letter R or the letter L for identification purposes. The agency is taking this action in response to a petition filed by Precision-Cosmet Co., Inc.

DATE: Effective date confirmed: June 21, 1983.

FOR FURTHER INFORMATION CONTACT: George C. Murray, National Center for Devices and Radiological Health (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7940.

SUPPLEMENTARY INFORMATION: In a final rule published in the **Federal Register** of May 20, 1983 (48 FR 22705), FDA amended the color additive regulations

to provide for the safe use of 2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol as a color additive in marking soft (hydrophilic) contact lenses with the letter R or the letter L for identification purposes. The final rule added new Subpart D, consisting of § 73.3115, to 21 CFR Part 73 to provide for the listing of color additives that are exempt from certification for use in medical devices.

In the final rule, FDA gave interested persons until June 20, 1983, to file objections. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA has concluded that the final rule published in the **Federal Register** of May 20, 1983, for 2-[[2,5-diethoxy-4-[(4-methylphenyl)-thio]phenyl]azo]-1,3,5-benzenetriol should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371(e), 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the final rule of May 20, 1983. Accordingly, the final rule adding § 73.3115 *2-[[2,5-diethoxy-4-[(4-methylphenyl)-thio]phenyl]azo]-1,3,5-benzenetriol* to provide for the safe use of 2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol as a color additive in marking soft (hydrophilic) contact lenses with the letter R or the letter L for identification purposes became effective June 21, 1983.

Dated: July 14, 1983.

William F. Randolph, ,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-19967 Filed 7-25-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 510

New Animal Drugs; Change of ZIP Code

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of zip code for Elanco Products Co.

EFFECTIVE DATE: July 26, 1983.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Bureau of Veterinary Medicine (HFV–238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6243.

SUPPLEMENTARY INFORMATION: Elanco Products Co., Division of Eli Lilly & Co., 740 South Alabama St., Indianapolis, IN 46285, has informed FDA of a change in its postal zip code number. This is an administrative change which does not in any other way affect sponsor name and address nor the approval of any NADA. The agency is amending the regulations to reflect the change.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

PART 510—NEW ANIMAL DRUGS

§ 510.600 [Amended]

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), § 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended by changing the zip code to "46285" in the entry for "Elanco Products Co." in paragraph (c)(1) and in the entry for No. "000986" in paragraph (c)(2).

Effective date. July 26, 1983.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(1)))

Dated: July 20, 1983.

Max L. Crandall,

Associate Director for Surveillance and Compliance.

[FR Doc. 83-20032 Filed 7-25-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 540

Penicillin Antibiotic Drugs for Animal Use; Amoxicillin Trihydrate Tablets; Clarification

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is clarifying a regulation published in the **Federal Register** of May 10, 1983 (48 FR 20901) reflecting approval of NADA 65–492 sponsored jointly by A. H. Robins Co., Inc., and Biocraft Laboratories, Inc. This document amends the regulation to properly reflect certain conditions of use.

EFFECTIVE DATE: May 10, 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: In the **Federal Register** of May 10, 1983 (48 FR 20901), FDA published a document reflecting approval of A. H. Robins Co.'s and Biocraft Laboratories' NADA 65–492 for amoxicillin trihydrate tablets (Robamox®–V). The drug is for oral treatment of dogs for soft tissue infections and bacterial dermatitis. In that document, the limitations stated "use for 5 to 7 days for 48 hours after" rather than "use for 5 to 7 days or 48 hours after." This document amends the regulation to reflect this change.

List of Subjects in 21 CFR 540

Animal drugs, Antibiotics, penicillin.

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

§ 540.103f [Amended]

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), § 540.103f *Amoxicillin trihydrate tablets* is amended in paragraph (c)(3)(i)(*c*) by revising the phrase "5 to 7 days for 48 hours" to read "5 to 7 days or 48 hours."

Effective date. May 10, 1983.

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

Dated: July 20, 1983.

Max L. Crandall,

Associate Director for Surveillance and Compliance.

[FR Doc. 83-20033 Filed 7-25-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 555

Chloramphenicol Drugs for Animal Use; Chloramphenicol 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) sponsored by Pfizer, Inc., providing for safe and effective oral use of chloramphenicol