The agency has examined the economic impact of this rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96-354). Specifically, the agency has determined that because the effect of this final rule is to remove sections of a regulation which have never become effective and have been stayed, no economic impact will result. Therefore, the agency concludes that this rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

**List of Subjects in 21 CFR Part 201**

Drugs, Labeling.

## PART 201—LABELING

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 502, 701(a), 52 Stat. 1050-1051 as amended, 1055 (21 U.S.C. 352, 371(a)) and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), Part 201 is amended in § 201.1 by revising paragraphs (c)(4), (e)(3), (f), and (g) to read as follows:

**§ 201.1 Drugs; name and place of business of manufacturer, packer, or distributor.**

* * * * *

(c) * * *

(4) If the person performs all applicable operations listed in paragraph (b) of this section except for those operations listed in paragraph (d) of this section. For purposes of this paragraph, person, when it identifies a corporation, includes a parent, subsidiary, or affiliate company where the related companies are under common ownership and control.

* * * * *

(e) * * *

(3) On equipment that is continuously owned or leased by the person. As used in this paragraph, person, when it identifies a corportion, includes a parent, subsidiary, or affiliate company where the related companies are under common ownership and control.

(f) The name of the person represented as manufacturer under paragraph (b) or (c) of this section must be the same as either (1) the name of the establishment (as defined in § 207.3(b) of this chapter) under which that person is registered at the time the labeled product is produced or (2) the registered establishment name of a parent, subsidiary, or affiliate company where the related companies are under common ownership and control. In addition, the name shall meet the requirements of paragraph (g) of this section.

(g) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporate person, only by the actual corporate name, except that the corporate name may be the name of a parent, subsidiary, or affiliate company where the related companies are under common ownership and control. The corporate name may be preceded or followed by the name of the particular division of the corporation. "Company," "Incorporated," etc., may be abbreviated or omitted and "The" may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

*Effective date:* September 19, 1983.

(Secs. 502, 701(a), 52 Stat. 1050-1051 as amended, 1055 (21 U.S.C. 352, 371(a)))

Dated: July 29, 1983.

**Arthur Hull Hayes, Jr.,**

*Commissioner of Food and Drugs.*

**Margaret M. Heckler,**

*Secretary of Health and Human Services.*

[FR Doc. 83-22467 Filed 8-18-83; 8:45 am]

BILLING CODE 4160-01-M

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**21 CFR Part 558**

## New Animal Drugs for Use in Animal Feeds; Tylosin

**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 supplemental new animal drug application (NADA) filed for Growmark, Inc., providing for the manufacture of a 40-gram-per-pound tylosin premix. The premix is used to make complete feeds for swine, beef cattle, and chickens.

**EFFECTIVE DATE:** August 19, 1983.

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

**SUPPLEMENTARY INFORMATION:** Growmark, Inc., 1701 Towanda Ave., Bloomington, IL 61701, is the sponsor of a supplement to NADA 99-098 submitted on its behalf by Elanco Products Co. This supplement provides for the manufacture of 40-gram-per-pound premixes subsequently used to make complete feeds for swine, beef cattle, and chickens for use as in 21 CFR 558.625(f)(1)(i) through (vi). The basis for approval of this supplement is discussed in the freedom of information (FOI) summary. Based on the data and information submitted, the supplement 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 558**

Animal drugs, Animal feeds.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.625 is amended by revising paragraph (b)(27) to read as follows:

**§ 558.625 Tylosin.**

* * * * *

(b) * * *

(27) To 020275: 8 and 10 grams per pound, paragraph (f)(1)(i), (iii), (iv), and (vi) of this section; 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

* * * * *

*Effective date.* August 19, 1983.

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

Dated: August 11, 1983.

**Robert A. Baldwin,**

*Associate Director for Scientific Evaluation.*

[FR Doc. 83-22579 Filed 8-18-83 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

## New Animal Drugs for Use in Animal Feeds; Tylosin

**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 supplemental new animal drug application (NADA) filed for Ag-Mark, Inc., providing for the manufacture of a 40-gram-per-pound tylosin premix. The premix is used to make complete feeds for swine, beef cattle, and chicken.

**EFFECTIVE DATE:** August 19, 1983.

**FOR FURTHER INFORMATION CONTACT:** Benjamin A. Puyot, Bureau of Veterinary Medicine (HFV–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4913.

**SUPPLEMENTARY INFORMATION:** Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464, is the sponsor of a supplement to NADA 121–147 submitted on its behalf by Elanco Products Co. This supplement provides for the manufacture of 40-gram-per-pound premixes subsequently used to make complete feeds for swine, beef cattle, and chickens for use as in 21 CFR 558.625(f)(1)(i) through (vi). The basis for approval of this supplement is discussed in the freedom of information (FOI) summary. Based on the data and information submitted, the supplement 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 Part 558

Animal drugs, Animal feeds.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.625 is amended by revising paragraph (b)(66) to read as follows:

**§ 558.625 Tylosin**

* * * * *

(b) * * *

(66) To 024174: 10 grams per pound, paragraph (f)(2)(vi)(*a*) of this section; 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

* * * * *

*Effective date.* August 19, 1983.

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

Dated: August 11, 1983.

**Robert A. Baldwin,**

*Associate Director for Scientific Evaluation.*

[FR Doc. 83-22560 Filed 8-18-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

## New Animal Drugs for Use in Animal Feeds; Tylosin

**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 supplemental new animal drug application (NADA) filed for Webel Feeds, Inc., providing for the manufacture of a 40-gram-per-pound tylosin premix. The premix is used to make complete feeds for swine, beef cattle, and chickens.

**EFFECTIVE DATE:** August 19, 1983.

**FOR FURTHER INFORMATION CONTACT:** Benjamin A. Puyot, Bureau of Veterinary Medicine (HFV–130), Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857, 301–443–4913.

**SUPPLEMENTARY INFORMATION:** Webel Feeds, Inc., R.R. 3, Pittsfield, IL 62363, is the sponsor of a supplement to NADA 116–196 submitted on its behalf by Elanco Products Co. This supplement provides for the manufacture of a 40-gram-per-pound premix subsequently used to make complete feeds for swine, beer cattle, and chickens for use as in 21 CFR 558.625(f)(1)(i) through (vi). The supplement is approved and the regulations are amended accordingly. The basis for approval of this supplement is discussed in the freedom of information (FOI) summary.

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

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Therefore, under the Federal Foods, 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), § 558.625 is amended by revising paragraph (b)(73) to read as follows:

**§ 558.625 Tylosin.**

* * * * *

(b) * * *

(73) To 035096: 0.33 and 0.67 gram per pound, paragraph (f)(1)(vi) (*a*) of this section; 0.8, 1, 2, and 10 grams per pound, paragraph (f)(1)(i) and (vi) (*a*), (*b*) and (*d*) of this section; 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

* * * * *

*Effective date.* August 19, 1983.

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

Dated: August 11, 1983.

**Robert A. Baldwin,**

*Associate Director for Scientific Evaluation.*

[FR Doc. 83-22577 Filed 8-18-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

## New Animal Drugs for Use in Animal Feeds; Tylosin

**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 supplemental new animal drug application (NADA) filed for Seeco, Inc., providing for the manufacture of a 40-gram-per-pound tylosin premix. The premix is used to make complete feeds for swine, beef cattle, and chickens.

**EFFECTIVE DATE:** August 19, 1983.

**FOR FURTHER INFORMATION CONTACT:** Benjamin A. Puyot, Bureau of Veterinary Medicine (HFV–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4913.

**SUPPLEMENTARY INFORMATION:** Seeco, Inc., Box 1014, North Highway 71, Willmar, MN 56201, is the sponsor of a supplement to NADA 100–352 submitted on its behalf by Elanco Products Co. This supplement provides for the manufacture of 40-gram-per-pound premixes subsequently used to make complete feeds for swine, beef cattle, and chickens for use as in 21 CFR 558.625(f)(1) (i) through (vi). The basis for approval of this supplement is discussed in the freedom of information (FOI) summary. Based on the data and information submitted, the supplement 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 558**

Animal drugs, Animal feeds.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.625 is amended by revising paragraph (b) (38) to read as follows:

**§ 558.625 Tylosin.**

* * * * *

(b) * * *

(38) To 011749: 1 and 10 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 40 grams per pound, paragraph (f)(1) (i) through (vi) of this section.

* * * * *

*Effective date.* August 19, 1983.

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

Dated: August 11, 1983.

**Robert A. Baldwin,**

*Associate Director for Scientific Evaluation.*

[FR Doc. 83-22578 Filed 8-18-83; 8:45 am]

**BILLING CODE 4160-01-M**

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**21 CFR Part 558**

**New Animal Drugs for Use in Animal Feeds; Tylosin**

**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 supplemental new animal drug application (NADA) filed for I.M.S., Inc., providing for the manufacture of a 40-gram-per-pound tylosin premix. The premix is used to make complete feeds for swine, beef cattle, and chickens.

**EFFECTIVE DATE:** August 19, 1983.

**FOR FURTHER INFORMATION CONTACT:** Benjamin A. Puyot, Bureau of Veterinary Medicine (HFV–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4913.

**SUPPLEMENTARY INFORMATION:** I.M.S., Inc., 13619 Industrial Rd., Omaha, NE 68137, is the sponsor of a supplement to NADA 127–195 submitted on its behalf by Elanco Products Co. This supplement provides for the manufacture of a 40-gram-per-pound premix subsequently used to make complete feeds for swine, beef cattle, and chickens for use as in 21 CFR 558.625(f)(1)(i) through (vi). The supplement is approved and the regulations are amended accordingly. The basis for approval of this supplement is discussed in the freedom of information (FOI) summary.

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

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

**§ 558.625 Tylosin.**

* * * * *

(b) * * *

(77) To 050639: 10 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

* * * * *

*Effective date.* August 19, 1983.

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

Dated: August 11, 1983.

**Robert A. Baldwin,**

*Associate Director for Scientific Evaluation.*

[FR Doc. 83-22576 Filed 8-18-83; 8:45 am]

**BILLING CODE 4160-01-M**

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**21 CFR Part 558**

**New Animal Drugs for Use in Animal Feeds; Tylosin**

**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 supplemental new animal drug application (NADA) submitted by Ralston-Purina Co. providing for use of a 40-gram-per-pound tylosin premix. The premix is used to make complete feeds for chickens.

**EFFECTIVE DATE:** August 19, 1983.

**FOR FURTHER INFORMATION CONTACT:** Benjamin A. Puyot, Bureau of Veterinary Medicine (HFV–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4913.

**SUPPLEMENTARY INFORMATION:** Ralston Purina Co., Checkerboard Square, St. Louis, MO 63199, has submitted a supplement to its previously approved NADA 43–387 for tylosin premix. The supplement provides for the use of a 40-gram-per-pound tylosin premix for making complete chicken, layer, broiler, and replacement chicken feed. The chicken feed is used for increased rate

of weight gain and improved feed efficiency, the layer feed for improved feed efficiency, and the broiler and replacement chicken feed for control of chronic respiratory disease. The supplement is approved and the regulations are amended accordingly. The basis for approval is discussed in the freedom of information (FOI) summary.

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

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360(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), § 558.625 is amended by revising paragraph (b)(5) to read as follows:

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

**§ 558.625 Tylosin.**

* * * * *

(b) * * *

(5) To 017800: 0.4, 0.8, 1, and 8 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 10 grams per pound, paragraph (f)(1)(i) and (vi)(*a*) of this section; 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

* * * * *

*Effective date:* August 19, 1983.

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

Dated: August 15, 1983.

**Robert A. Baldwin,**

*Associate Director for Scientific Evaluation.*

[FR Doc. 83-22796 Filed 8-18-83; 8:45 am]

BILLING CODE 4160-01-M

**21 CFR Part 555**

## Chloramphenicol Drugs for Animal Use; Chloramphenicol Oral Solution

**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 supplemental new animal drug application (NADA) filed by Philips Roxane, Inc., et al., providing for a change of pH specifications for chloramphenicol oral solution for treating bacterial pulmonary and urinary tract infections, enteritis, and infections associated with canine distemper.

**EFFECTIVE DATE:** August 19, 1983.

**FOR FURTHER INFORMATION CONTACT:** Patricia N. Cushing, Bureau of Veterinary Medicine (HFV-143), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1788.

**SUPPLEMENTARY INFORMATION:** Philips Roxane, Inc., 2621 North Belt Highway, St. Joseph, MO 64502, filed a supplement to NADA 65-477 providing for a change of pH specifications for chloramphenicol oral solution (100 and 250 milligrams per milliliter) from pH 6.5 to 8.5 to pH 5.0 to 8.5. The product is used for treating bacterial pulmonary and urinary tract infections, enteritis, and infections associated with canine distemper. The Bureau of Veterinary Medicine (BVM) evaluted finished product specifications for chloramphenicol oral solution in § 555.110c(a) (21 CFR 555.110c(a)) and reviewed the pH specifications of various chloramphenicol products in 21 CFR Parts 455 and 555. Those products reviewed were:

| Human drug product | 21 CFR reference (section) | pH specifications |
|---|---|---|
| Bulk | 455.10(a)(1)(iii) | 4.5-7.5 |
| Bulk sterile | 455.10a(a)(1)(vi) | 4.5-7.5 |
| Sterile sodium succinate. | 45512a(a)(1)(vii) | 6.4-7.0 |
| Palmitate oral suspension. | 455.111(a)(1) | 4.5-7.0 |
| Injection | 455.210(a)(1) | 4.7-5.0 |
| Ophthalmic solution | 455.310a(a)(1) | 3.0-6.0 |
| Ophthalmic | 455.310b(a)(1) | 7.1-7.5 |
| Otic | 455.410(a)(1) | 4.0-8.0 |

| Animal drug product | 21 CFR reference (section) | pH specifications |
|---|---|---|
| Oral solution | 555.110c(a)(1) | 6.5-8.5 |
| Palmitate oral suspension. | 555.111(a)(1) | 4.5-7.0 |
| Injection | 555.210(a)(1) | 6.5-8.5 |
| Ophthalmic | 555.310a(a)(1) | 7.1-7.5 |
| | 455.310b(a)(1) (cross reference). | |
| Topical | 555.310b(a)(1) | 4.0-8.0 |
| | 455.410(a)(1) (cross reference). | |
| Ophthalmic solution | 555.310d(a)(1) | 3.0-6.0 |
| Otic | 555.410 | 4.0-8.0 |
| | 455.410(a)(1) (cross reference). | |

Although potency is the primary indicator of a product's stability, a product's pH is also an indicator of its stability. Based on a BVM review of pH specifications and product potency and on stability data submitted by Philips Roxane, the Bureau has concluded that the pH of chloramphenicol oral solution in 21 CFR 555.110c(a) should be 5.0 to 8.5. Accordingly, the regulation is amended to reflect that conclusion. Those other firms holding NADA's whose approval is reflected in § 555.110c have filed supplemental NADA's to reflect the change. The firms and NADA's affected are:

| Sponsor | NADA |
|---|---|
| John D. Copanos & Co., Inc | 65-364 |
| International Multifoods Corp. (formerly Tevcon) | 55-003 |
| Medico Industries, Inc. (A Tech-America Co.) | 65-487 |
| Michael Gordon, Inc | 65-484 |
| Philips Roxane, Inc | 65-477 |
| Pfizer, Inc | 65-464 |

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 555**

Animal drugs, Antibiotics, chloramphenicol.

## PART 555—CHLORAMPHENICOL DRUGS FOR ANIMAL USE

**§ 555.110c [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), § 555.110c *Chloramphenicol oral solution* is amended by revising the fourth sentence in paragraph (a)(1) to read "The pH is 5.0 to 8.5."

*Effective date.* August 19, 1983.

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

Dated: August 15, 1983.

Robert A. Baldwin,

*Associate Director for Scientific Evaluation.*

[FR Doc. 83-22767 Filed 8-18-83; 8:45 am]

BILLING CODE 4160-01-M

## 21 CFR Parts 211, 700, and 800

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

## Tamper-Resistant Packaging Requirements for Certain Over-the-Counter Human Drug and Cosmetic Products and Contact Lens Solutions and Tablets; Stay of Effective Date

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule; stay of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) announces that, in response to a citizen petition, the provision of the tamper-resistant packaging regulations that requires a specific label reference to any identifying characteristic that is incorporated into the tamper-resistant feature of a particular product is stayed until February 6, 1984. Elsewhere in this issue of the **Federal Register**, the agency announces the availability of the advisory opinion, issued in response to the citizen petition, and also advises that as part of its Tamper-Resistant Packaging Compliance Program, it plans to maintain a current list of acceptable technologies and those packaging technologies that the agency believes are unacceptable and have problems.

**DATE:** The amendments are effective August 19, 1983. The provisions in §§ 211.132(c), 700.25(c), and 800.12(c) that require that a label reference any identifying characteristic that is incorporated into the tamper-resistant feature are stayed until February 6, 1984.

**FOR FURTHER INFORMATION CONTACT:** Paul O. Fehnel, 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 establishing tamper-resistant packaging and labeling requirements for certain over-the-counter (OTC) human drug and cosmetic products. In the same issue of the **Federal Register** (47 FR 50452), the agency also published tamper-resistant regulations for contact lens solutions and tablets. In the **Federal Register** of April 19, 1983 (48 FR 16658), the agency amended its tamper-resistant packaging and labeling regulations for OTC drug and cosmetic products to clarify certain sections of the preamble and to specify in the regulations those products that the agency had exempted from those regulations. In the same issue of the **Federal Register** (48 FR 16665), the agency made similar clarifying amendments for contact lens solutions and tablets. One of the clarifying labeling amendments added by the April 19, 1983 rule was the statement, "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."

The agency received a petition from The Proprietary Association (PA) requesting a stay of the effective date of a portion of the tamper-resistant packaging and labeling regulations. Specifically, PA sought a stay of that provision of the regulations that requires a specific label reference to any identifying characteristic that is incorporated into the tamper-resistant feature of a particular product. For OTC drugs, this statement is required by 21 CFR 211.132(c); and for cosmetic products and contact lens solutions and tablets, 21 CFR 700.25(c) and 800.12(c), respectively, as amended April 19, 1983.

The agency agreed with the petitioner that additional time should be provided to comply with the requirement that any identifying characteristic of the tamper-resistant feature be specifically referred to in the labeling and stayed the effective date for this requirement until February 6, 1984. The petition response was made an advisory opinion. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the advisory opinion and also of information on packaging technologies.

### List of Subjects

*21 CFR Part 211*

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

*21 CFR Part 700*

Cosmetics, Definitions, Prohibited cosmetic ingredients.

*21 CFR Part 800*

Administrative detention, Administrative practice and procedure, Medical devices.

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, 700, and 800 are amended as follows:

### PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. Part 211 is amended in § 211.132 by revising paragraph (g)(2), to read as follows:

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

* * * * *

(g) * * *

(2) *Initial effective date for labeling requirements.* The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each affected OTC drug product packaged for retail sale on or after that date, except that the requirement for a specific label reference to any identifying characteristic is effective on February 6, 1984 for each affected OTC drug product packaged for retail sale on or after that date.

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### PART 700—GENERAL

2. Part 700 is amended in § 700.25 by revising paragraph (e)(2), to read as follows:

**§ 700.25 Tamper-resistant packaging requirements for cosmetic products.**

* * * * *

(e) * * *

(2) *Initial effective date for labeling requirements.* The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each affected cosmetic product packaged for retail sale on or after that date, except that the requirement for a specific label reference to any identifying characteristic is effective on February 6, 1984 for each affected cosmetic product packaged for retail sale on or after that date.

* * * * *

### PART 800—GENERAL

3. Part 800 is amended in § 800.12 by revising paragraph (f)(2), to read as follows:

§ 800.12 **Contact lens solutions and tablets; tamper-resistant packaging.**

* * * * *

(f) * * *

(2) *Initial effective date for labeling requirements.* The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each product subject to this section packaged for retail sale on or after that date, except that the requirement for a specific label reference to any identifying characteristic is effective on February 6, 1984 for each affected product subject to this section packaged for retail sale on or after that date.

* * * * *

*Effective date.* August 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: August 11, 1983.

**Joseph P. Hile,**

*Associate Commissioner for Regulatory Affairs.*

[FR Doc. 83-22581 Filed 8-18-83; 8:45 am]

BILLING CODE 4160-01-M

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## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

### 30 CFR Part 913

### Extension of Deadline for Satisfaction of Conditions of Approval of the Illinois Permanent Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

**ACTION:** Final rule.

**SUMMARY:** OSM is announcing its decision to extend the deadline for Illinois to meet two conditions of approval of its State permanent regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The conditions concern sediment ponds and covering coal seams with water.

**EFFECTIVE DATE:** August 19, 1983.

**FOR FURTHER INFORMATION CONTACT:** Mr. James Fulton, Field Office Director, Springfield Field Office, 600 E. Monroe Street, Room 20, Springfield, Illinois 62701; Telephone: (217) 492–4495.

**SUPPLEMENTARY INFORMATION:** The Illinois program was conditionally approved June 1, 1982 (47 FR 23858). In that document, the Secretary published a schedule for the State to meet each of the five conditions on the State program.

On May 23, 1983, Illinois requested an extension of the deadline to satisfy conditions (b) and (c), as listed at 30 CFR 913.11 (b) and (c), from June 1, 1983 to December 1, 1983.

The State noted, in its May 23, 1983 request, that the Illinois Department of Mines and Minerals (IDMM) had filed a notice of proposed rulemaking in the Illinois Register to amend its permanent program rules to meet the two conditions due June 1, 1983. However, the IDMM received little public comment on the proposed rulemaking. In order to stimulate the fullest public participation in the rulemaking process, the IDMM wishes, by direct mailing to interested persons, to give further notice of the proposed rulemaking. Under Illinois administrative procedures, this process should be complete within six months.

Therefore, the State requested a six-month extension of the June 1, 1983 deadline. As the State noted in its letter, since Illinois agreed to operate its program in conformance with the terms of the conditions until such time as its rules are amended, there will be no substantive difference in the field.

On June 2, 1983, OSM published a notice in the **Federal Register** (48 FR 24741) to propose an extension of the deadline to meet conditions (b) and (c) to December 1, 1983. Comment on the proposal was solicited for 30 days, ending July 5, 1983.

#### Public Comment

1. The Illinois South Project, Inc. (ISP), objected that OSM should have requested comment on the proposed extension of the June 1, 1982 deadline well in advance of that date rather than on June 2, and asked OSM to explain how this action is consistent with the Administrative Procedure Act (APA).

OSM did not receive the extension request from the IDMM until May 23, 1983. OSM acted promptly to prepare and publish the **Federal Register** notice on June 2, only six working days later.

Section 553 of the APA requires an agency to give notice and an opportunity to be heard on any proposed action by publishing a notice in the **Federal Register.** OSM has provided both notice and the opportunity to be heard in accordance with the APA.

2. ISP commented that, according to the Secretary's decision on the Illinois program, the program should have terminated on June 2, because OSM's rules at 30 CFR 913.11 (b) and (c) state that "The approval found in § 913.10 will terminate unless Illinois submits to the Secretary by June 1, 1983" the required changes. Termination of a State program is not automatic. The Secretary's regulations at 30 CFR 732.13(j) provide that the Director has a number of options if the State fails to correct the deficiencies by the deadline. However, Illinois' good faith request for an extension of the deadline is not equivalent to a failure to meet its deadline. Illinois requested, prior to that deadline, that an extension be granted. The Secretary has determined that an extension is warranted and will not result in any substantive difference in the environmental protection standards of the Illinois program.

3. ISP commented that soliciting additional public participation on this matter is unnecessary since the Illinois program has already gone through two years of development and public comment. In addition, ISP noted that Illinois went through its standard rulemaking procedures on these conditions and questions whether this procedure is adequate, whether it will work in the future, and whether it will be biased in favor of industry rather than citizens. ISM believes the Illinois rulemaking procedure is adequate. If Illinois believes additional public involvement is necessary on these critical issues and granting the extension would not lessen environmental protection, OSM does not believe that the request for an extension is unreasonable. The Illinois rulemaking procedure requires careful consideration of all comments, from whatever viewpoint.

4. ISP asked for assurances that the extension is not merely an attempt by the State and OSM to obtain additional time to work out an out-of-court settlement in *Illinois Department of Mines and Mineral* v. *Watt* (C.A. No. 82–3152), since the two conditions for which the extension is being sought are the subject of that suit by the State. The fact that these conditions are the subject of litigation has no bearing on the extension of the deadline. There is another condition on the Illinois program that is subject to the same litigation but Illinois did not seek an extension of the deadline for meeting that condition.

#### Secretary's Determination

The Secretary has determined that an extension of the deadline for Illinois to satisfy conditions (b) and (c) is warranted. As noted above, since Illinois has agreed to operate its program in accordance with the terms of the conditions until such time as its

rules are amended, there will be no substantive effect in the field.

**Procedural Matters**

1. *Compliance with the National Environmental Policy Act:* The Secretary has determined that, pursuant to Section 702(d) of SMCRA, 30 U.S.C. 1292(d), no environmental impact statement need be prepared on this rulemaking.

2. *Executive Order No. 12291 and the Regulatory Flexibility Act:* On August 28, 1981, the Office of Management and Budget (OMB) granted OSM an exemption from Sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs. Therefore, this action is exempt from preparation of a Regulatory Impact Analysis and regulatory review by OMB.

The Department of the Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibilitiy Act (5 U.S.C. 601 *et seq.*). This rule will not impose any new requirements; rather, it will ensure that existing requirements established by SMCRA and the Federal rules will be met by the State.

3. *Paperwork Reduction Act:* This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3507.

**List of Subjects in 30 CFR Part 913**

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Accordingly, Part 913 of Title 30 is amended as set forth herein.

Dated: August 12, 1983.

**W. L. Dare,**

*Acting Deputy Assistant Secretary for Energy and Minerals.*

## PART 913—ILLINOIS

**§ 913.11 [Amended]**

1. Section 913.11 is amended in paragraphs (b) and (c) by substituting "December 1, 1983" for "June 1, 1983" each time it appears.

(Pub. L. 95–87, 30 U.S.C. 1201 *et seq.*)

[FR Doc. 83–22867 Filed 8–18–83; 8:45 am]
BILLING CODE 4310–05–M

**30 CFR Part 914**

## Approval and Disapproval of Permanent Program Amendments From the State of Indiana Under the Surface Mining Control and Reclamation Act of 1977

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

**ACTION:** Final rule.

**SUMMARY:** OSM is announcing the approval and disapproval of certain amendments to the Indiana permanent regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). In addition, the remaining conditions of the Secretary of the Interior's approval of the Indiana program are being removed.

On April 19, 1983, OSM received a set of regulation amendments from the Indiana Department of Natural Resources (IDNR). Also, on April 28, 1983, OSM received a set of statutory amendments from IDNR. Both sets of amendments were intended, in part, to meet the conditions of the Secretary's approval of the Indiana permanent program. The conditions of approval concern (1) design criteria for stream channel diversions, (2) requirements for each permit application to contain a list of all other licenses and permits needed by the applicant to conduct the proposed surface or underground mining activities, (3) requirements that a petitioner would only have to present evidence which would tend to establish allegations of fact in a petition to designate lands as unsuitable for mining, (4) the award of attorney and expert witness fees in surface mining related common law damage actions, and (5) administrative review of a permit or any final decision of the regulatory authority.

In addition to meeting the remaining conditions of approval, both sets of amendments proposed modifications to other provisions of the Indiana law and rules. Details of these modifications are discussed below under "Supplementary Information".

After providing opportunity for public comment and conducting a thorough review of the program amendments, the Secretary has determined that the modifications to the Indiana program satisfy the remaining conditions of approval, and that, except as noted under "Secretary's Findings" below, the additional modifications meet the requirements of SMCRA and the Federal permanent program regulations. Accordingly, the Secretary is removing the remaining conditions of approval of the Indiana program, is approving the additional modifications that meet the requirements of SMCRA and the Federal rules, and is advising the State of his disapproval of one proposed modification that does not meet the requirements of SMCRA or the Federal rules.

The Federal rules codifying Secretarial decisions concerning the Indiana permanent program are being amended to implement these actions.

**EFFECTIVE DATE:** August 19, 1983.

**FOR FURTHER INFORMATION CONTACT:** Mr. Richard D. McNabb, Director, Indianapolis Field Office, Office of Surface Mining, Federal Building and U.S. Courthouse, Room 522, 46 East Ohio Street, Indianapolis, Indiana 46204. Telephone: (317) 269–2600.

**SUPPLEMENTARY INFORMATION:**

### I. Background on the Indiana State Program

Information regarding the general background on the Indiana State program, including the Secretary's Findings, the disposition of comments and a detailed explanation of the conditions of approval of the Indiana program, can be found in the July 26, 1982, **Federal Register** (47 32071–32108).

At the time of the Secretary's conditional approval, Indiana agreed to meet nine minor conditions, many of which contained several parts. Most of the conditions and their parts have been removed through the approval of amendments to the Indiana program. For additional information on the prior removal of conditions, see the December 17, 1982, **Federal Register** at 47 FR 56493, and the March 4, 1983, **Federal Register** at 48 FR 9248.

The remaining conditions on the Indiana program are as follows:

Condition (a)(2) requires Indiana to develop design criteria for stream channel diversions as required by 30 CFR 816.44 and 817.44.

Condition (b)(3) requires Indiana to provide that each permit application contain a list of all other licenses and permits needed by the applicant to conduct the proposed surface or underground mining activities indicating all the information required by 30 CFR 782.19

The deadline for Indiana to address two conditions was July 1, 1983.

Condition (g)(1) requires Indiana to amend its statute to provide that a petitioner would only have to present evidence which would tend to establish allegations of fact in a petition to designate lands as unsuitable for mining in accordance with the provisions of