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 Center for Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(ii) (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

§ 558.550 [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 Center for Veterinary Medicine (21 CFR 5.83), § 558.550 *Salinomycin* is amended in paragraph (c)(1)(iv)(*a*) by changing "30 grams" to read "50 grams."

Effective date. April 5, 1985.

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

Dated: March 27, 1985.

Marvin A. Norcross,

Acting Associate Director for Scientific Evaluation.

[FR Doc. 85-8135 Filed 4-4-85; 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 Music City Supplement Co., providing for manufacturing a 40-gram-per-pound tylosin premix. The premix is used to make finished feeds for swine, beef cattle, and chickens.

EFFECTIVE DATE: April 5, 1985.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3410.

SUPPLEMENTARY INFORMATION: Music City Supplement Co., 401 Cowan St., Nashville, TN 37202, is sponsor of a supplement to NADA 107-958 submitted on its behalf by Elanco Products Co. This supplement provides for the manufacture of a 40-gram-per-pound tylosin premix subsequently used to make finished 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 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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

The Center for 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 Center for Veterinary Medicine (21 CFR 5.83), Part 558 is amended in § 558.625 by revising paragraph (b)(51) to read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(51) *To 017519:* 10 grams per pound, paragraph (f)(1)(i), (iii), (iv), and (vi) of this section; 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

* * * * *

Effective date: April 5, 1985.

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

Dated: March 26, 1985.

Richard A. Carnevale,

Acting Associate Director for Scientific Evaluation, Center for Veterinary Medicine.

[FR Doc. 85-8140 Filed 4-4-85; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 1010

[Docket No. 85N-0033]

Performance Standards for Electronic Products; Number of Copies of an Exemption Application

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reducing the required number of copies of applications that must be submitted to obtain exemptions from one or more provisions of a standard for electronic products. The agency has determined that it currently is receiving more copies of such applications than the agency needs.

DATES: Comments by May 6, 1985. The final rule is effective June 4, 1985.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Tracy Summers, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION: Under section 358 of the Radiation Control for Health and Safety Act of 1968 (the RCHSA) (42 U.S.C. 263f), FDA is required to establish performance standards for electronic products to control the emission of radiation from such products. Section 1010.5 of the regulations governing the establishment of performance standards (21 CFR 1010.5) under the RCHSA provides the basis on which a manufacturer of an electronic product intended for U.S. Government use may apply for exemption from one or more provisions of a standard. Section 1010.5(c) requires that applications for exemption or for amendments or extensions thereof be submitted in quintuplicate (OMB control number 0910-0025).

In the Federal Register of March 31, 1983 (48 FR 13666), the Office of Management and Budget (OMB) published a final rule (5 CFR Part 1320) implementing the Paperwork Reduction Act of 1980 (Pub. L. 96-511), which established policies and procedures for

controlling paperwork burdens imposed by Federal agencies on the public. Section 1320.6(c) of OMB's general information collection guidelines, which are codified as part of its final rule, provides that an agency should not require submission to it of more than one original and two copies of any document, unless the agency demonstrates that the requirement is necessary to satisfy a statutory requirement or some other substantial need.

FDA has reexamined § 1010.5(c) and has concluded that its existing requirement that a manufacturer applying for an exemption, or an amendment, or an extension of an existing exemption submit five copies of the application is not necessary to satisfy any requirement of the RCHSA. Furthermore, there is not any substantial need for the agency to receive more than three copies of such documents.

Therefore, FDA is changing its procedure to conform to OMB's guidelines by requiring an applicant to submit only an original and two copies of any application for exemption or for amendments or extensions of an existing exemption.

In accordance with the Administrative Procedures Act (5 U.S.C. 553(b)(B)), the Commissioner of Food and Drugs finds for good cause that notice and public procedure are unnecessary. This is because reducing the number of copies required to be submitted to FDA of an application for exemption or for amendments or extensions thereof will not affect the public health and will be less burdensome on, and less costly for, applicants. The agency, nevertheless, providing a 30-day period during which it will accept comments on this procedural change. If FDA decides on the basis of comments received that the change should be modified or revoked, it will provide further notice in the **Federal Register**.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this final rule and has determined that the final rule will not be a major rule as defined by the Order. The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because it was not subject to a notice of proposed rulemaking under 5 U.S.C. 553.

List of Subjects in 21 CFR Part 1010

Administrative practice and procedure, Electronic products, Exemptions, Exports, Radiation protection, Standards, Variances.

Therefore, under the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177–1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 1010 is amended in § 1010.5 by revising the first sentence of paragraph (c), to read as follows:

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

§ 1010.5 Exemptions for products intended for United States Government use.

* * * * *

(c) *Application for exemption.* An original and two copies of any application for exemption, or for amendment or extension thereof, shall be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. * * * * * * * * *

Interested persons may, on or before May 6, 1985, submit to the Dockets Management Branch (address above) written comments on this final rule. Such comments will be considered in determining whether further amendments, modifications, or revisions to the final rule are warranted. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective June 4, 1985.

(Sec. 358, 82 Stat. 1177–1179 (42 U.S.C. 263))

Dated: March 12, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85–8143 Filed 4–4–85; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 1010

[Docket No. 85N–0013]

Performance Standards for Electronic Products; Number of Copies of an Application for Variance

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reducing the required number of copies of applications that must be submitted in order to obtain variances from provisions of performance standards for electronic products. FDA has determined that it currently is receiving more copies of such applications than the agency needs.

DATES: Comments by May 6, 1985. The final rule is effective June 4, 1985.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Tracy Summers, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4874.

SUPPLEMENTARY INFORMATION: Under section 358 of the Radiation Control for Health and Safety Act of 1968 (the RCHSA) (42 U.S.C. 263f), FDA is required to establish performance standards for electronic products to control the emission of radiation from such products. Section 1010.4 of the regulations governing establishment of performance standards (21 CFR 1010.4) under the RCHSA provides the basis on which a manufacturer of an electronic product may apply for a variance or for amendments or extension of an existing variance from one or more provisions of a standard. Section 1010.4(b) requires that applications for variances or for amendments or extensions thereof be submitted in quintuplicate (OMB approval number 0910–0025).

In the **Federal Register** of March 31, 1983 (48 FR 13666), the Office of Management and Budget (OMB) published a final rule (5 CFR Part 1320) implementing the Paperwork Reduction Act of 1980 (Pub. L. 96–511), which established policies and procedures for controlling paperwork burdens imposed by Federal agencies on the public. Section 1320.6(c) of OMB's general information collection guidelines, which are codified as part of its final rule, provides that an agency should not require submission to it of more than one original and two copies of any document, unless the agency demonstrates that the requirement is necessary to satisfy a statutory requirement or some other substantial need.

FDA has reexamined § 1010.4(b) and has concluded that its existing requirement that a manufacturer applying for a variance or an amendment or extension of an existing variance must submit five copies of the application is not necessary to satisfy any requirement of the RCHSA. Furthermore, there is not any substantial need for the agency to receive more than three copies of variance requests.

Therefore, FDA is changing its procedure to conform to OMB's guidelines by requiring an applicant to submit only an original and two copies of any application for variance or for amendments or extensions of an existing variance.

In accordance with the Administrative Procedure Act (5 U.S.C. 553(b)(B)), the Commissioner of Food and Drugs finds for good cause that notice and public procedure are unnecessary. This is because reducing the number of copies required to be submitted to FDA of an application for variance or for amendments or extensions thereof will not affect the public health and will be less burdensome on, and less costly for, applicants. The agency, nevertheless, is providing a 30-day period during which it will accept comments on this procedural change. If FDA decides on the basis of comments received that the change should be modified or revoked, it will provide further notice in the **Federal Register.**

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this final rule and has determined that the final rule will not be a major rule as defined by the Order. The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because it was not subject to a notice of proposed rulemaking under 5 U.S.C. 553.

Lists of Subjects in 21 CFR Part 1010

Administrative practice and procedure, Electronic products, Exemptions, Exports, Radiation protection, Standards, Variances.

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

Therefore, under the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177–1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 1010 is amended in § 1010.4 by revising the introductory text of paragraph (b), to read as follows:

§ 1010.4 Variances.

* * * * *

(b) *Applications for variances.* Applications for variances or for amendments or extensions thereof shall be submitted in an original and two copies to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm 4–62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

* * * * *

Interested persons may, on or before May 6, 1985, submit to the Dockets Management Branch (address above) written comments on this final rule. Such comments will be considered in determining whether further amendments, modifications, or revisions to the final rule are warranted. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective June 4, 1985.

(Sec. 358, 82 Stat. 1177–1179 (42 U.S.C. 263f)).

Dated: March 12, 1985

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85–8145 Filed 4–4–85; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 1030

[Docket No. 85N–0005]

Performance Standards for Microwave and Radio Frequency Emitting Products; Number of Copies of an Exemption Application

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reducing the required number of copies of applications that must be submitted to obtain exemptions from one or more of the requirements to post radiation safety warnings on microwave ovens. FDA has determined that it currently is receiving more copies of such applications than the agency needs.

DATES: Comments by May 6, 1985. The final rule is effective June 4, 1985.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Tracy Summers, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4874.

SUPPLEMENTARY INFORMATION: Under section 358 of the Radiation Control for Health and Safety Act of 1968 (the RCHSA) (42 U.S.C. 263f), FDA is required to establish performance standards for electronic products to control the emission of radiation from such products. The performance standard for microwave and radio frequency emitting products is found in Part 1030 of the regulations governing establishment of performance standards under the RCHSA (21 CFR Part 1030). Section 1030.10(c)(6)(iv) of the standard provides the basis on which a manufacturer of a microwave oven may apply for exemption from one or more of the microwave oven radiation safety warnings specified in § 1030.10(c)(6)(i). Section 1030.10(c)(6)(iv) requires that applications for exemption be submitted in quintuplicate (OMB approval number 0910–0025).

In the **Federal Register** of March 31, 1983 (48 FR 13666), the Office of Management and Budget (OMB) published a final rule (5 CFR Part 1320) implementing the Paperwork Reduction Act of 1980 (Pub. L. 96–511), which established policies and procedures for controlling paperwork burdens imposed by Federal agencies on the public. Section 1320.6(c) of OMB's general information collection guidelines, which are codified as part of its final rule, provides that an agency should not require submission to it of more than one original and two copies of any document, unless the agency demonstrates that the requirement is necessary to satisfy a statutory requirement or some other substantial need.

FDA has reexamined § 1030.10(c)(6)(iv) and has concluded that its existing requirement that a manufacturer applying for an exemption submit five copies of the exemption application is not necessary to satisfy any requirement of the RCHSA. Furthermore, there is not any substantial need for the agency to receive more than three copies of such documents.

Therefore, FDA is changing its procedure to conform to OMB's guidelines by requiring an applicant to submit only an original and two copies of any application for exemption from one or more of the radiation safety warnings specified in § 1030.10(c)(6)(i).

In accordance with the Administrative Procedure Act (5 U.S.C. 553(b)(B)), the Commissioner of Food and Drugs finds for good cause that notice and public procedure are unnecessary. This is because reducing the number of copies required to be submitted to FDA of an application for exemption from one or more provisions of the radiation safety warnings will not affect the public health and will be less burdensome on, and less costly for, applicants. The