the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Drafting Information

The principal author of this document was Harold M. Singer, Regulations and Disclosure Law Branch, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 4

Customs duties and inspection, Cargo vessels, Maritime carriers, Vessels.

Amendment to the Regulations

Part 4 of the Customs Regulations (19 CFR part 4) is amended as set forth below:

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

1. The general authority for part 4 continues to read as follows and the specific authority for § 4.69 is added:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1624; 46 U.S.C. App. 3.

* * * * *

Section 4.69 also issued under 46 U.S.C. 10301, 10302, 10314, and 10315.

* * * * *

2. Section 4.69 is revised to read as follows:

§ 4.69 Shipping articles.

No vessel of the U.S. on a voyage between a U.S. port and a foreign port (except a port in Canada, Mexico, or the West Indies), or if of at least 75 gross tons, on a voyage between a U.S. port on the Atlantic Ocean and a U.S. port on the Pacific Ocean, shall be granted clearance before presentation, to the appropriate Customs officer, of the shipping articles agreements, including any seaman's allotment agreement, required by 46 U.S.C. chapter 103, in the form provided for in 46 CFR 14.05–1.

Editorial Note: This document was received at the Office of the Federal Register on June 1, 1992.

Carol Hallett,

Commissioner of Customs.

Approved: January 22, 1992.

Peter K. Nunez,

Assistant Secretary of the Treasury.

[FR Doc. 92–13129 Filed 6–4–92; 8:45 am]

BILLING CODE 4820–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 404

[Regulation No. 4]

RIN 0960–None Assigned

Federal Old-Age, Survivors and Disability Insurance Determining Disability and Blindness; Extension of Expiration Date for Cardiovascular System Listing

AGENCY: Social Security Administration, HHS.

ACTION: Final rule.

SUMMARY: We are extending the date on which part A of the cardiovascular system listings found in appendix 1 of part 404, subpart P, will no longer be effective from June 6, 1992, to January 5, 1993. We have made no revisions in the medical criteria in the cardiovascular listings; they remain the same as they now appear in the Code of Federal Regulations. We are presently considering comments we received on a proposed rule to update the medical criteria contained in Part A and Part B of the listings. When we have completed our review, and revised criteria will be published as final regulations.

EFFECTIVE DATE: This final rule will be effective June 5, 1992.

FOR FURTHER INFORMATION CONTACT: Irving Darrow, Esq., Legal Assistant, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 966–0512.

SUPPLEMENTARY INFORMATION: On December 6, 1985, a revised Listing of Impairments in appendix 1 to subpart P of part 404 was published in the **Federal Register** (50 FR 50068). The Listing of Impairments describes, for each of the 13 major body systems, impairments that are considered severe enough to preclude a person from engaging in any gainful activity (Part A), or in the case of a child under the age of 18, impairments that are severe enough to prevent the child from functioning independently, appropriately, and effectively in an age-appropriate manner (Part B). The Listing of Impairments is used for evaluating disability and blindness under the Social Security disability program and the supplemental security income program.

When the revised Listing of Impairments was published in 1985, we indicated that disability evaluation and treatment and program experience would require that the listing be periodically reviewed and updated. Accordingly, expiration dates were established ranging from 4 to 8 years for each of the specific body systems. A date of December 6, 1989, was established for the cardiovascular system listings in Part A to no longer be effective. A date of December 6, 1993, was established for Part B of the listings to no longer be effective.

The potential program impact of the changes to update the listings required careful analysis and consideration within the Agency. As our study and analysis continued, it became evident that we would be unable to publish a proposed and then a final regulation containing revised criteria for Part A of the cardiovascular listings by December 6, 1989. We published in the **Federal Register** of December 5, 1989 (54 FR 50233), a final regulation extending the current cardiovascular listings for a period of 18 months through June 5, 1991. The cardiovascular listings were again extended an additional 12 months through June 5, 1992, by final regulation published in the **Federal Register** on June 6, 1991 (56 FR 26030).

Proposed revisions to the medical criteria contained in Parts A and B of the cardiovascular system listings were published in the **Federal Register** on July 9, 1991 (56 FR 31266), with provisions for a 60-day comment period. Because the issues raised by the comments have required careful consideration, we find that we will not have sufficient time to publish a final regulation in the **Federal Register** by June 6, 1992. We have, therefore, decided to extend the date on which the current cardiovascular system listings in Part A will no longer be effective for an additional 7 months—from June 6, 1992, to January 5, 1993.

Regulatory Procedures

The Department, even when not required by statute, as a matter of policy, generally follows the Administrative Procedure Act notice of proposed rulemaking and public comment procedures specified in 5 U.S.C. 553 in the development of its regulations. The Administrative Procedure Act provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that, under 5 U.S.C. 553(b)(B), good cause exists for waiver of notice of proposed rulemaking and public comment procedures on this rule because it only extends the expiration date of Part A of the cardiovascular

listings and makes no substantive changes to these listings. The current regulations expressly provide that the listings may be extended by the Secretary, as well as revised and promulgated again.

Because we are not making any revisions to the current listings, use of public comment procedures is not contemplated by the existing regulations and is unnecessary under the Administrative Procedure Act. After our review of comments submitted with respect to the proposed revisions to the existing criteria, a final regulation will be published.

Executive Order 12291

The Secretary has determined that this is not a major rule under Executive Order 12291 because this regulation does not meet any of the threshold criteria for a major rule. Therefore, a regulatory impact analysis is not required.

Regulatory Flexibility Act

We certify that this regulation will not have a significant economic impact on a substantial number of small entities because it only affects disability claimants under titles II and XVI of the Act.

Paperwork Reduction Act

This regulation imposes no reporting or recordkeeping requirements necessitating clearance by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.802, Social Security Disability Insurance; No. 93.807, Supplemental Security Income Program)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: April 14, 1992.

Gwendolyn S. King,

Commissioner of Social Security.

Approved: May 21, 1992.

Louis W. Sullivan,

Secretary of Health and Human Services.

For the reasons set forth in the preamble, part 404, title 20 of the Code of Federal Regulations is amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950-)

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 1102 of the Social Security Act; 42 U.S.C. 402, 405(a), (b) and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 1302.

Appendix 1 to Subpart P—[Amended]

2. Appendix 1 to Subpart P is amended by revising the fourth paragraph of the introductory text to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

* * * * *

The cardiovascular system (4.00) will no longer be effective on January 5, 1993.

* * * * *

[FR Doc. 92–13279 Filed 6–4–92; 8:45 am]

BILLING CODE 4190–29–M

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20 CFR Part 404

RIN 0960–None Assigned

Federal Old-Age, Survivors and Disability Insurance; Determining Disability and Blindness; Extension of Expiration Date for Musculoskeletal System Listings

AGENCY: Social Security Administration, HHS.

ACTION: Final rule.

SUMMARY: We are extending the date on which Part A of the musculoskeletal system listings found in appendix 1 of part 404, subpart P, will no longer be effective from June 6, 1992, to December 6, 1993. We have made no revisions in the medical criteria in the musculoskeletal listings; they remain the same as they now appear in the Code of Federal Regulations. We are presently considering revisions to update the medical criteria contained in the listings, and any revised criteria will be published as proposed rules when we have completed our review. Under this final rule extending the expiration date of the musculoskeletal system listings, we will continue to use the existing criteria until any revised criteria are published as final rules.

EFFECTIVE DATE: This final rule will be effective June 5, 1992.

FOR FURTHER INFORMATION CONTACT: Irving Darrow, Esq., Legal Assistant, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 966–0512.

SUPPLEMENTARY INFORMATION: On December 6, 1985, a revised Listing of Impairments in appendix 1 to subpart P of part 404 was published in the **Federal Register** (50 FR 50068). The Listing of Impairments describes, for each of the 13 major body systems, impairments that are considered severe enough to prevent an adult from performing any gainful activity (part A), or in the case of a child under the age of 18, impairments which are severe enough to prevent the child from functioning independently, appropriately, and effectively in an age-appropriate manner (part B). The Listing of Impairments is used for evaluating disability and blindness under the Social Security disability program and the supplemental security income program.

When the revised Listing of Impairments was published in 1985, we indicated that disability evaluation and treatment and program experience would require that the listing be periodically reviewed and updated. Accordingly, expiration dates were established ranging from 4 to 8 years for each of the specific body systems. A date of December 6, 1990, was established for the musculoskeletal system listings in part A to no longer be effective. A date of December 6, 1993, was established for part B of the listings to no longer be effective.

The potential program impact of the changes to update the listings required careful analysis and consideration within the Agency. As our study and analysis continued, it became evident that we would be unable to publish a proposed and then a final regulation containing revised criteria for part A of the musculoskeletal system listings by December 6, 1990. We, therefore, published in the **Federal Register** of December 12, 1990 (55 FR 51100), a final regulation extending the current musculoskeletal system listings for a period of 18 months through June 5, 1992.

Before proposing revisions to the current musculoskeletal listings, we must consider and resolve a variety of medical issues affecting both adults and children. We also want to give special attention to ensuring consistency between the proposed adult and childhood listings, while also recognizing the particular considerations appropriate to children. Because of the complexity of these medical and technical tasks, we find that we will not have sufficient time to publish a notice of proposed rulemaking setting out any proposed revisions to the current listings that may be necessary and then publish a final regulation in the **Federal Register** by June 6, 1992. We have, therefore, decided to extend the date on which the current musculoskeletal system listings in part A will no longer be effective for an additional period of 18 months—from June 6, 1992, to December 6, 1993.

Regulatory Procedures

The Department, even when not required by statute, as a matter of policy, generally follows the Administrative Procedure Act notice of proposed rulemaking and public comment procedures specified in 5 U.S.C. 553 in the development of its regulations. The Administrative Procedure Act provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that, under 5 U.S.C. 553(b)(B), good cause exists for waiver of notice of proposed rulemaking and public comment procedures on this rule because it only extends the expiration date of Part A of the musculoskeletal system listings and makes no substantive changes to these listings. The current regulations expressly provide that the listings may be extended by the Secretary, as well as revised and promulgated again. Because we are not making any revisions to the current listings, use of public comment procedures is not contemplated by the existing regulations and is unnecessary under the Administrative Procedure Act. After our review of the existing musculoskeletal system listings is completed, any proposed revisions to the existing criteria will be published for public comment.

Executive Order 12291

The Secretary has determined that this is not a major rule under Executive Order 12291 because this regulation does not meet any of the threshold criteria for a major rule. Therefore, a regulatory impact analysis is not required.

Regulatory Flexibility Act

We certify that this regulation will not have a significant economic impact on a substantial number of small entities because it only affects disability claimants under titles II and XVI of the Act.

Paperwork Reduction Act

This regulation imposes no reporting or recordkeeping requirements necessitating clearance by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.802, Social Security Disability Insurance; No. 93.807, Supplemental Security Income Program)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: April 14, 1992.

Gwendolyn S. King,

Commissioner of Social Security.

Approved: May 21, 1992.

Louis W. Sullivan,

Secretary of Health and Human Services.

For the reasons set forth in the preamble, part 404 of title 20 of the Code of Federal Regulations is amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950-)

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205 (a), (b), and (d)–(h), 216(i), 221 (a) and (i), 222(c), 223, 225, and 1102 of the Social Security Act; 42 U.S.C. 402, 405 (a), (b) and (d)–(h), 416(i), 421 (a) and (i), 422(c), 423, 425, and 1302.

Appendix 1 to Subpart P—[Amended]

2. Appendix 1 to subpart P is amended by revising the second paragraph of the introductory text to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

* * * * *

The musculoskeletal system (1.00) will no longer be effective on December 6, 1993.

* * * * *

[FR Doc. 92–13281 Filed 6–4–92; 8:45 am]

BILLING CODE 4190–29–M

Food and Drug Administration

21 CFR Part 176

[Docket No. 87F–0239]

Indirect Food Additives: Paper and Paperboard Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a polyamide-epichlorohydrin resin prepared by reacting *N*-methyl-bis (3-aminopropyl) amine with oxalic acid and urea to form a basic polyamide and further reacting the polyamide with epichlorohydrin. The polyamide-epichlorohydrin resin will be used to impart wet strength to paper and paperboard in contract with aqueous and fatty foods. This action is in response to a petition filed by Hercules, Inc.

DATES: Effective June 5, 1992; written objections and requests for a hearing by July 6, 1992.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 205–254–9511.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 17, 1987 (52 FR 30740), FDA announced that a food additive petition (FAP 7B3986) had been filed by Hercules, Inc., Hercules Plaza, Wilmington, DE 19894, proposing that Section 176.170 *Components of Paper and Paperboard in Contact With Aqueous and Fatty Foods* (21 CFR 176.170) be amended to provide for the safe use of polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting *N*-methyl-bis (3-aminopropyl) amine with oxalic acid and urea or dimethylglutarate to form a basic polyamide and further reacting the polyamide with epichlorohydrin. The polyamide-epichlorohydrin resins will be used to impart wet strength to paper and paperboard in contact with aqueous and fatty foods.

Since publication of the filing notice, the petitioner has withdrawn a request to list the proposed use of the polyamide-epichlorohydrin resin prepared by reacting *N*-methyl-bis (3-aminopropyl) amine with dimethylglutarate to form a basic polyamide and further reacting the polyamide with epichlorohydrin.

FDA, in the evaluation of the safety of the additive, reviewed the safety of the additive, the starting materials used to manufacture the additive, and manufacturing impurities that may be present in the additive. Although the additive itself has not been found to cause cancer, it has been found to contain minute amounts of epichlorohydrin as an impurity from its production. This chemical has been shown to cause cancer in test animals. Residual amounts of reactants, such as epichlorohydrin, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-

called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 (the amendment) is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. 2284, 85th Cong., 2d sess. 4 (1958)). This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the amendment (section 409(c)(3)(A) of the act) (21 U.S.C. 348(c)(3)(A)) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve the use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain carcinogenic chemicals but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic impurity. Since that decision, FDA has approved the use of other color additives and food additives on the same basis.

An additive that has not been shown to cause cancer, but that contains a carcinogenic impurity, may properly be evaluated under the general safety clause of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, 728 F. 2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the U.S. Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the polyamide-epichlorohydrin resin will result in extremely low levels of exposure to this additive. The agency estimated the probable daily intake of the additive based on considerations such as the migration of the additive under the most severe intended use conditions and the types of food-contact articles that may contain this substance. The agency estimated that the probable daily intake for the additive would not exceed 18 micrograms (μg) per person per day.

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2), and the agency has not required such testing here. However, the agency has reviewed other available toxicological data. On the basis of the agency's review of these data and of the low level of migration of the resin, the agency concludes that there is an adequate margin of safety for the proposed use of the additive.

As stated above, the additive may contain epichlorohydrin, a substance that has been shown to cause cancer in test animals. This impurity may be present as a residue from manufacturing the additive. However, because the additive itself has not been shown to cause cancer, the Delaney Clause (21 U.S.C. 348(c)(3)(A)) does not apply to it.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of risk presented by the carcinogenic chemical, epichlorohydrin, that may be present as an impurity in this additive. Based on this evaluation, the agency has concluded that the additive is safe under the proposed conditions of use.

The risk assessment procedures that FDA used in this evaluation are similar to the methods that the agency has used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities (see, e.g., 49 FR 13018 and 13019, April 2, 1984). The risk evaluation of the carcinogenic impurity has two aspects: (1) Assessment of the worst-case exposure to the impurity from the proposed use of the additive, and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

A. Epichlorohydrin

Based on the fraction of the daily diet that may be in contact with surfaces containing the polyamide-epichlorohydrin resin and on the level of epichlorohydrin that may be present in the additive, FDA estimated that the hypothetical worst-case exposure to epichlorohydrin from the use of the additive in paper and paperboard to be 0.15 μg per person per day (Refs. 3 and 4). The agency used data from a Japanese carcinogenesis bioassay (Ref. 5) on epichlorohydrin fed to rats in their drinking water to estimate the upper-bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of this resin. The results of the bioassay demonstrated that epichlorohydrin was carcinogenic for rats under the conditions of the study. The test material caused significantly increased incidences of stomach papillomas and carcinomas in the rats.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on epichlorohydrin. The committee further concluded that an estimate of the upper-bound limit of lifetime human risk from potential exposure to epicholorohydrin stemming from the proposed use of the resin could be calculated from the bioassay.

Based on a worst-case exposure of 0.15 μg per person per day, FDA estimates that the upper-bound limit of individual lifetime risk from potential exposure to epichlorohydrin from the use of this polyamide-epichlorohydrin water-soluble thermosetting resin is 7×10^{-9}, or less than 1 in 140 million (Ref. 6). Because of numerous conservatisms in the exposure estimate, actual lifetime-averaged individual exposure to epichlorohydrin is expected to be substantially less than the estimated daily intake, and, therefore, the actual risk would be less than the calculated upper-bound limit. Thus, the agency concludes that there is a reasonable certainty of no harm from exposure to epichlorohydrin that might result from the proposed use of the polyamide-epichlorohydrin resin.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of epichlorohydrin in

the food additive. The agency finds that specifications are not necessary for the following reasons: (1) Because the trace amounts of epichlorohydrin that might be present in the additive can be expected to be virtually eliminated from the paper during subsequent paper processing operations and by the heat during drying steps, the agency would not expect this impurity to become a component of food at other than extremely small amounts, and (2) the upper-bound limit of lifetime risk from exposure to epichlorohydrin, even under worst-case assumptions, is very low, less than 1 in 140 million.

C. Conclusion on Safety

FDA has evaluated the available toxicity data and the exposure calculation for the resin and has found it to be safe and effective for the intended use based upon the extremely low levels of exposure to the resin and upon evaluation of the data furnished in the petition. Accordingly, FDA concludes that the regulation in § 176.170 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

III. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Carr, G.M., "Carcinogen Testing Programs" in *Food Safety: Where Are We?*, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, pp. 59–67, July 1979.

2. Kokoski, C.J., "Regulatory Food Additive Toxicology," *Chemical Safety Regulation and Compliance*, edited by Homburger, F., and J.K. Marquis, New York, pp. 24–33, 1985.

3. Memorandum from the Food and Color Additives Review Section to the Indirect Additives Branch, "Polyamide-Epichlorohydrin Resin for Use in Paper and Paperboard," dated March 3, 1988.

4. Memorandum from the Food Additives and Animal Drug Chemistry Evaluation Branch to the Petitions Control Branch, "Consumption Estimates for Epichlorohydrin," dated October 15, 1982.

5. Konishi, Y. et al., "Forestomach Tumors Induced by Orally Administered Epichlorohydrin in Male Wistar Rats," *Gan No Rinsho (Japanese Journal of Cancer Clinics)*, 71:922–923, 1980.

6. Report of the Quantitative Risk Assessment Committee, "Upper Bound Risk Estimation for the Carcinogenic Impurity, Epichlorohydrin, in FAP 7B3966," dated October 27, 1988.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before July 6, 1992 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 176

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: Secs. 201, 402, 406, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 346, 348, 376).

2. Section 176.170 is amended in paragraph (a)(5) by alphabetically adding a new entry to the table to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(a) * * *

(5) * * *

List of substances	Limitations
* * * * * * * *	
Polyamide-epichlorohydrin water-soluble thermosetting resin (CAS Reg. No. 96387–48–3) prepared by reacting *N*-methyl-bis(3-aminopropyl) amine with oxalic acid and urea to form a basic polyamide and further reacting the polyamide with epichlorohydrin.	For use only as a wet strength agent and/or retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and used at a level not to exceed 1.5 percent by weight of dry paper and paperboard fibers.
* * * * * * * *	

* * * * *

Dated: May 28, 1992.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 92–13133 Filed 6–4–92; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 178

[Docket No. 89F–0156]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of *N,N*-bis (2-hydroxyethyl) butylamine; bis (hydrogenated tallow alkyl) aminoethanol; isotridecyl alcohol, ethoxylated; bis (hydrogenated tallow alkyl) amine; and diethylene glycol monobutylether as components of lubricants used in the manufacture of metallic articles for food-contact use. This action is in response to a petition filed by Berol (Suisse) S.A. Fribourg (formally Alunique S.A.).

DATES: Effective June 5, 1992; written objections and requests for a hearing by July 6, 1992.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 7, 1989 (54 FR 24425), FDA announced that a food additive petition (FAP 9B4145) had been filed by Alunique S.A., 56 Grand Rue, CH 1700 Fribourg, Switzerland, proposing that section 178.3910 *Surface Lubricants Used in the Manufacture of Metallic Articles* (21 CFR 178.3910) be amended to provide for the safe use of the following additives as components of lubricants in the manufacture of metallic articles for food-contact use:

(1) *N,N*-Di (2-hydroxyethyl) butylamine.

(2) Bis (hydrogenated tallow-alkyl) aminoethanol.

(3) Isotridecyl alcohol, ethoxylated.

(4) Bis (hydrogenated tallow-alkyl) amine.

(5) Diethyleneglycol monobutylether.

In the remainder of this preamble and in the rule set forth below, the agency refers respectively to the compounds listed above by their more appropriate chemical names: *N,N*-Bis (2-hydroxyethyl) butylamine; bis (hydrogenated tallow-alkyl) aminoethanol; isotridecyl alcohol, ethoxylated; bis (hydrogenated tallow alkyl) amine; and diethylene glycol monobutylether. The petitioner, Alunique S.A., has been replaced by Berol (Suisse) S.A. Fribourg, c/o Lenz, Schluep, Briner, & de Coulon, Grand Rue 25, 1211 Geneva 11 Switzerland.

FDA, in its evaluation of the safety of these additives, reviewed the safety of both the additives and the starting materials used to manufacture the additives. The additives themselves have not been found to cause cancer. However, all of the additives except bis (hydrogenated tallow alkyl) aminoethanol may contain minute amounts of ethylene oxide and 1,4 dioxane as byproducts of their production; these chemicals have been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as these chemicals, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance. (H. Rept. 2284, 85th Cong., 2d sess. 4 (1958).) This definition of safety has been incorporated into FDA's food additive regulations (§ 170.3(i)). The anticancer or Delaney clause of the Food Additives Amendment (section 409(c)(3)(A)) of the act provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA often refused to approve the use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures have made it possible for FDA to establish the safety of additives that contain carcinogenic impurities but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contained a carcinogenic impurity. Since that decision, FDA has approved the use of other color additives and food additives on the same basis. FDA fully explained the scientific, legal, and policy underpinnings for these decisions in the advance notice of proposed rulemaking on a policy for regulating carcinogenic chemicals in food and color additives, published in the **Federal Register** of April 2, 1982 (47 FR 14464).

The agency now believes that the Delaney or anticancer clause is applicable only when the food additive as a whole is found to cause cancer. An additive that has not been shown to cause cancer, but that contains a carcinogenic impurity, may properly be evaluated under the general safety provision of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the United States Court of Appeals for the Sixth Court rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use

FDA estimated that the petitioned use of the five additives will result in extremely low levels of exposure. The agency has calculated estimated daily intakes for these additives based on the potential residue levels of the additives on food contact surfaces under the most severe intended use conditions and the probable concentration of the additives in the daily diet from food-contact articles that may contain them as a consequence of having been manufactured by a process in which the

additives were used as components of lubricants. The maximum concentration of each additive in the daily diet and the estimated daily intake (EDI) for the additives are not expected to exceed the following:

Daily dietary intake		
Components	Concentration (parts per billion)	EDI (micrograms per day)
N,N-Bis(2-hydroxyethyl) butylamine	4	11
Bis (hydrogenated tallow alkyl) amine	0.03	0.08
Bis(hydrogented tallow alkyl) aminoethanol	0.11	0.32
Diethylene glycol monobutylether	6	18
Isotridecyl alcohol, ethoxylated	0.09	0.3

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2) and has not required such testing here. Because these additives have not been shown to cause cancer, the anticancer clause does not apply to them. However, the agency has reviewed data from acute oral toxicity studies on these lubricant formulation components and concludes that there is an adequate margin of safety for the proposed use of the additives.

For the four additives that may contain the carcinogenic impurities ethylene oxide and 1,4-dioxane, FDA has evaluated the safety of the additives under the general safety provision, using risk assessment procedures to estimate the upper-bound limit of risk presented by the two carcinogenic chemicals.

The risk assessment procedures that FDA used in this evaluation are similar to the methods that it has used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities (e.g., 49 FR 13018 at 13019, April 2, 1984). This risk evaluation of the carcinogenic impurities ethylene oxide and 1,4-dioxane has two aspects: (1) Assessment of the worst-case exposure to the impurities from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

A. The Impurity 1,4-Dioxane

Based on the fraction of the daily diet that may contact surfaces containing the four additives, the residue levels on these surfaces, as well as the level of 1,4-dioxane that may be present in the additives (Ref. 3), FDA estimated the hypothetical worst-case exposure to 1,4-dioxane from the use of these additives (in nanograms per person per day (ng/p/day)) to be as follows:

Components	1,4-dioxane (ng/p/day)
N,N-Bis(2-hydroxyethyl)butylamine	1.2
Bis(hydrogenated tallow alkyl)aminoethanol	0.016
Diethylene glycol monobutylether	0.18
Isotridecyl alcohol, ethoxylated	0.0027

The agency used data in a carcinogenesis bioassay on 1,4-dioxane conducted for the National Cancer Institute (Ref. 4) to estimate the upper-bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of the additives. The results of the bioassay on 1,4-dioxane demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas and hepatocellular tumors in female rats.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee (the CAC) reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on 1,4-dioxane. The Quantitative Risk Assessment Committee (the QRAC) concluded that an estimate of the upper-bound level of lifetime human risk from potential exposure to 1,4-dioxane stemming from the proposed use of these additives could be calculated from the bioassay (Ref. 5).

The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate to potential human exposure from the doses encountered under the proposed conditions of use. This procedure is not likely to underestimate the actual risk from very low exposures and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the proposed conditions and levels of use of these food additives. Based on worst-case exposures mentioned above, FDA estimates the upper-bound limit of individual lifetime risk from potential exposure to 1,4-dioxane (Ref. 5) from the use of these additives to be as follows:

Components	1,4-dioxane upper-bound lifetime risk
N,N-Bis(2-hydroxyethyl) butylamine.	4×10^{-11} (or 4 in 100 billion).
Bis(hydrogenated tallow alkyl)aminoethanol.	6×10^{-13} (or 6 in 10 trillion).
Diethylene glycol monobutylether.	6×10^{-12} (or 6 in 1 trillion).
Isotridecyl alcohol, ethoxylated.	1×10^{-13} (or 1 in 10 trillion).

Because of numerous conservatisms in the exposure estimate, lifetime-averaged individual exposure to 1,4-dioxane is expected to be substantially less than the estimated daily intake, and therefore the calculated upper-bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from exposure to 1,4-dioxane that may result from the proposed use of the above listed additives.

B. The Impurity Ethylene Oxide

Based on the fraction of the daily diet that may contact surfaces containing the four additives, the residue levels on these surfaces, as well as the level of ethylene oxide that may be present in the additives (Ref. 3), FDA also estimated the hypothetical worst-case exposure to ethylene oxide from the use of these additives to be as follows:

Components	Ethylene oxide (ng/p/day)
N,N-Bis(2-hydroxyethyl) butylamine	0.16
Bis(hydrogenated tallow alkyl)aminoethanol	0.016
Diethylene glycol monobutylether	0.090
Isotridecyl alcohol, ethoxylated	0.0054

The agency used data in a carcinogenesis bioassay on ethylene oxide conducted by the Institute of Hygiene, University of Mainz, Germany (Ref. 6), to estimate the upper-bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of these additives. The results of the bioassay on ethylene oxide demonstrated that this material was carcinogenic for female rats under the conditions of the study. The test material caused a significantly increased incidence of squamous cell carcinoma of the forestomach and carcinoma, in situ, of the glandular stomach.

The CAC reviewed this bioassay and other relevant data available in the literature and concluded that this information on ethylene oxide supported the finding of carcinogenicity. The QRAC further concluded that an estimate of the upper-bound limit of

lifetime human cancer risk from potential exposure to ethylene oxide could be made from the bioassay.

Based on worst-case exposures listed above, FDA estimates, using a linear proportional model, the upper-bound limit of individual lifetime risk from potential exposure to ethylene oxide (Ref. 5) from the use of these additives to be as follows:

Component	Ethylene oxide upper-bound lifetime risk
N,N-Bis(2-hydroxyethyl) butylamine.	3×10^{-10} (or 3 in 10 billion)
Bis(hydrogenated tallow alkyl) aminoethanol.	3×10^{-11} (or 3 in 100 billion)
Diethylene glycol monobutylether.	2×10^{-10} (or 2 in 10 billion)
Isotridecyl alchohol, ethoxylated.	1×10^{-11} (or 1 in 100 billion)

Because of numerous conservatisms in the exposure estimate, lifetime-averaged individual exposure to ethylene oxide is expected to be substantially less than the estimated daily intake, and therefore, the calculated upper-bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to ethylene oxide that may result from the use of these additives.

III. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of the ethylene oxide and 1,4-dioxane impurities in the food additives. The agency finds that specifications are not necessary for the following reasons: (1) Production specifications will control the levels of residual ethylene oxide and 1,4-dioxane, such that the agency would not expect these impurities to become components of food at other than extremely low levels; and (2) the upper-bound limit of lifetime risk from exposure to these impurities, even under a worst-case assumption, is very low.

IV. Conclusion on Safety

FDA has evaluated the available toxicity data and the estimated exposure for the additives and has determined that the additives are safe for their proposed use and that 21 CFR 178.3910(a)(2) be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

V. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Carr, G. M., "Carcinogen Testing Programs" in "Food Safety: Where Are We?," p. 59, Committee on Agriculture, Nutrition, and Forestry, United States Senate, July 1979.

2. Kokoski, C. J., "Regulatory Food Additive Toxicology," presented at the Second International Conference on Safety Evaluation and Regulation of Chemicals, Cambridge, MA, October 24, 1983.

3. Memorandum dated November 1, 1989, from Food and Color Additives Review Section (HFF-415), to Indirect Additives Branch, FAP 9B4145—Berol Nobel Stenungsund AB (formerly Berol Keni AB) (BNS), "Rolling Fluid Formation/Metal Foil," October 10, 1989.

4. "Bioassay of 1,4-Dioxane for Possible Carcinogenicity," National Cancer Institute, NCI-CG-TR-80, 1978.

5. Report of the Quantitative Risk Assessment Committee, "FAP 9B4145—Estimation of Upper-Bound Risk for Ethylene Oxide and 1,4-Dioxane in Rolling Fluid Formulation/Metal Foil (Berol Nobel Stenungsund AB)," February 4, 1991.

6. Dunkelberg, H., "Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide upon Intragastric Administration to Rats," British Journal of Cancer, 46:924, 1982.

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before July 6, 1992 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.3910 is amended in paragraph (a)(2) by alphabetically adding five new entries to the table to read as follows:

§ 178.3910 Surface lubricants used in the manufacture of metallic articles.

* * * * *

(a) * * *

(2) * * *

List of substances	Limitations
* * * * * * *	
Bis(hydrogenated tallow alkyl)amine (CAS Reg. No. 61789-79-5)	Not to be used in combination with sodium nitrite.
Bis(hydrogenated tallow alkyl)aminoethanol (CAS Reg. No. 116438-56-3)	
N,N-Bis(2-hydroxyethyl)butylamine (CAS Reg. No. 102-79-4)	
* * * * * * *	

List of substances	Limitations
Diethylene glycol monobutylether (CAS Reg. No. 112-34-5)	
* * * * * * *	
Isotridecyl alcohol, ethoxylated (CAS Reg. No. 9043-30-5)	
* * * * * * *	

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Dated: May 28, 1992.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 92-13134 Filed 6-4-92; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin

AGENCY: Food and Drug Administration, HHS.

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 Elanco Animal Health. The supplemental NADA provides for the use of an additional concentration of monensin Type A medicated article (80 grams of monensin sodium per pound of product) to be used as currently approved to make Type B and Type C medicated cattle and goat feeds.

EFFECTIVE DATE: June 5, 1992.

FOR FURTHER INFORMATION CONTACT: William G. Marnane, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8678.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, has filed a supplement to NADA 95-735, providing for the use of an 80-grams-per-pound monensin Type A medicated article in addition to the currently approved 20-, 30-, 45-, and 60-grams-per-pound articles. The Type A medicated article is to be used as currently approved in § 558.355 (f)(3) and (f)(6) (21 CFR 558.355 (f)(3) and (f)(6)) to make Type B and Type C medicated cattle and goat feeds, respectively.

The supplemental NADA is approved as of May 4, 1992, and the regulations are amended in paragraphs (b)(7) and (b)(14) of § 558.355 to reflect the approval.

Under 21 CFR 514.106(b)(2), this is a Category II supplement that did not require reevaluation of the underlying safety and effectiveness data in the parent application because the approved uses of the product have not been changed. Because the sponsor was not required to submit new safety and effectiveness data, a freedom of information summary was not required.

As provided in 21 CFR 558.4(a), monensin is a Category I, Type A medicated ariticle, which as the sole drug ingredient, does not require an approved Form FDA 1900 for making Type B and Type C medicated feeds as permitted under § 558.355 (f)(3) and (f)(6). Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplement does not qualify for marketing exclusivity because neither new clinical or field studies, nor human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant, were required for its approval.

The agency has determined under 21 CFR 25.24(d)(1)(iii) that this action is of a type that does not individually or cumulatively have a significant effect 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 and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.355 is amended by revising paragraphs (b)(7) and (b)(14) to read as follows:

§ 558.355 Monensin.

* * * * *

(b) * * *

(7) To 000986: 20, 30, 45, 60, and 80 grams per pound, as monensin sodium, paragraph (f)(3) of this section.

* * * * *

(14) To 000986: 60 and 80 grams per pound, as monensin sodium, paragraph (f)(6) of this section.

* * * * *

Dated: June 1, 1992.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 92-13188 Filed 6-4-92; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

24 CFR Part 901

[Docket No. R-91-1520; FR-2897-I-05]

RIN 2577-AA89

Public Housing Management Assessment Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of extension of time for submission of comments.