§ 558.485 [Amended]

4. Section 558.485 Pyrantel tartrate is amended by removing and reserving paragraph (a)(14).

§ 558.625 [Amended]

5. Section 558.625 Tylosin is amended by removing and reserving paragraphs (b)(49) and (b)(56).

§ 558.630 [Amended]

6. Section 558.630 *Tylosin and sulfamethazine* is amended in paragraph (b)(8) by removing the number", 026848".

Dated: July 12, 1990.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 90-17314 Filed 7-24-90; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 175

[Docket No. 87F-0327]

Indirect Food Additives: Adhesives and Components of Coatings

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 ethylene-acrylic acid-carbon monoxide copolymer as an adhesive in multilayer structures intended for use in contact with food. This action is in response to a petition filed by The Dow Chemical Co.

DATES: Effective July 25, 1990; written objections and requests for a hearing by August 24, 1990.

ADDRESSES: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, 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, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of October 29, 1987 (52 FR 41628), FDA announced that a food additive petition (FAP 7B4037) had been filed by The Dow Chemical Co., 1803 Bldg., Door 7, Midland, MI 48674, proposing that § 175.105 Adhesives (21 CFR 175.105) be amended to provide for the safe use of ethylene-acrylic acid-carbon monoxide copolymer as an adhesive in multilayer structures intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that these data establish the safe use of the food additive, ethylene-acrylic acid-carbon monoxide copolymer, and that § 175.105 (21 CFR 175.105) should be amended by alphabetically adding it as a new entry in the table in paragraph (c)(5).

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.

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.

Any person who will be adversely affected by this regulation may at any time on or before August 24, 1990, file with the Dockets Mangement 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 the 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 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 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 175.105 is amended in paragraph (c)(5) by alphabetically adding a new entry in the table to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * *	
Ethylene-acrylic acid-carbon monoxide copolymer (CAS Reg. No. 97756-27-9).	
* * * * *	

Dated: July 12, 1990.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90-17316 Filed 7-24-90; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 178

[Docket No. 89F-0157]

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 2-methyl-4,6-bis[(octylthio)methyl]phenol as a stabilizer for polymers used as components of adhesives, gaskets, cements, repeat-use rubber articles, and paper in contact with food. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective July 25, 1990; written objections and requests for a hearing by August 24, 1990.

ADDRESSES: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 4–62, 5600 Fishers Lane, 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, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 1, 1989 (54 FR 23540), FDA announced that a food additive petition (FAP 9B4144) had been filed by Ciba Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532–2188, proposing that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the safe use of 2-methyl-4,6-bis[(octylthio)methyl]phenol as a stabilizer for polymers used as adhesives, gaskets, cements, repeat-use rubber articles, and paper additives in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive 2-methyl-4,6-bis[(ocylthio)methyl]phenol is safe, and that the regulations should be amended by alphabetically adding a new entry in the table in paragraph (b) of § 178.2010.

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.

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.

Any person who will be adversely affected by this regulation may at any time on or before August 24, 1990, 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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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 178.2010 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
2-methyl-4,6-bis-[(octylthio)methyl] phenol (CAS Reg. No. 110553–27–0)	For use only: 1. In adhesives complying with § 175.105 of this chapter. 2. At levels not to exceed 0.25 percent by weight of can-end cements and side-seam cements complying with § 175.300(b)(3)(xxxi) and (xxxii) of this chapter. 3. At levels not to exceed 1 percent by weight of pressure-sensitive adhesives complying with § 175.125 of this chapter, petroleum alicyclic hydrocarbon resins complying with § 176.170 of this chapter, resins and polymers complying with § 176.180 of this chapter, and closures with sealing gaskets complying with § 177.1210 of this chapter. 4. At levels not to exceed 0.5 percent by weight of finished rubber products complying with § 177.2600 of this chapter.

Dated: July 12, 1990.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90–17317 Filed 7–24–90; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 178

[Docket No. 88F–0442]

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*-methyl-*N*-(1-oxo-9-octadecenyl) glycine as a corrosion inhibitor for lubricants with incidental food contact. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective July 25, 1990; written objections and requests for a hearing by August 24, 1990.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas C. Brown, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 26, 1989 (54 FR 3852), FDA announced that a food additive petition (FAP 9B4124) had been filed by Ciba-Geigy Corp., Three Skyline Dr., Hawthorne, NY 10532, proposing that § 178.3570 Lubricants with incidental food contact (21 CFR 178.3570) be amended to provide for the safe use of *N*-methyl-*N*-(1-oxo-9-octadecenyl) glycine as a corrosion inhibitor for lubricants with incidental food contact.

I. The Additive

In its evaluation of the safety of this additive, FDA reviewed the safety of both the additive and the starting materials used to manufacture the additive. The agency is not aware of any data that show *N*-methyl-*N*-(1-oxo-9-octadecenyl) glycine to be a cancer-causing chemical. However, nitrilotriacetic acid (NTA), which could be present as an impurity in the additive, has been shown to cause cancer in test animals. Residual amounts of reactants and byproducts, such as NTA, are commonly found as contaminants in chemical products, including food additives.

II. Prior Action

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 Amendments 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. No. 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 Food Additives Amendment (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A))) further provides 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. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make is 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 the color additive, 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.

The agency now considers the Delaney anticancer clause to be applicable only when the food additive as a whole has been found to cause cancer. An additive that has not been shown to cause cancer, but that contains a carcinogenic impurity, is properly 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 was 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.

III. Safety of Petitioned Use

FDA estimates that the petitioned use of *N*-methyl-*N*-(1-oxo-9-octadecenyl)glycine will result in extremely low levels of exposure to this additive. The agency calculated the estimated 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 daily intake for the additive would not exceed 150 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 has not required such testing here. However, the agency has reviewed available data from acute studies and mutagenicity tests with the additive. No adverse effects were observed in these studies. On the basis of this information and in view of the low level of exposure to the additive, the agency concludes that there is an adequate margin of safety for the proposed use of the additive.

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, NTA, which 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). This risk evaluation of the carcinogenic impurity NTA 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. Exposure to NTA

Based on the fraction of the daily diet that may be in contact with surfaces containing *N*-methyl-*N*-(1-oxo-9-octadecenyl)glycine and on the level of NTA that may be present in the additive, FDA estimates the hypothetical worst-case exposure to NTA from the petitioned use of this additive to be 0.003 μg per person per day (Ref. 4). The agency used data from carcinogenesis bioassays on NTA, conducted for the National Cancer Institute (NCI) (Ref. 3), to estimate the upper-bound level of lifetime human risk from exposure to this chemical resulting from the proposed use of the additive. The data reported in the NCI report described three Fischer 344 rat and two B6C3F1 mouse chronic bioassays on either NTA or its trisodium salt. The NCI studies provide substantial evidence of the association of urinary tract neoplasia in rats and mice with NTA treatment at the higher dosage levels.

B. Risk Assessment

FDA reviewed the data in the NCI bioassays and other relevant data available in the literature and concluded that the findings of carcinogenicity were

supported by this information on NTA. FDA has concluded that NTA is carcinogenic to rats and mice, producing primarily tumors of the urinary tract including kidney, ureter, and bladder. The agency further concluded that the NTA bioassay provides an appropriate basis on which to calculate an estimate of the upper-bound level of lifetime human cancer risk from potential exposure to NTA resulting from the proposed use of *N*-methyl-*N*-(1-oxo-9-octadecenyl)glycine.

In calculating this risk, the agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the study with male rats (the most sensitive animals) to the very low doses encountered under the proposed conditions of use. This procedure is not likely to underestimate the actual risk from very low doses 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 the additive.

Based on a worst-case exposure to NTA of 0.003 μg per person per day, FDA estimates that the upper-bound limit of individual lifetime risk from potential exposure to this carcinogenic impurity from the proposed use of *N*-methyl-*N*-(1-oxo-9-octadecenyl)glycine is 1.4×10^{-11} based on the mouse studies, and 6×10^{-12} based on the rate studies (Ref. 5).

Because of numerous conservatisms in the exposure estimates, lifetime-averaged individual exposure to NTA is expected to be substantially less than the estimated daily intake, and therefore, the calculated upper-bound risks would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from exposure to NTA that might result from the proposed use of the additive.

C. Specifications

The agency has also considered whether specifications are necessary to control the amount of NTA in the food additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which NTA may be expected to remain as an impurity following production of the additive, the agency would not expect this impurity to become a component of food at other than extremely low levels; and (2) the upper-bound limit of lifetime risk from exposure to NTA even under worst-case assumptions, is very low, less than 1.4 in 100 billion.

IV. Conclusion of Safety

FDA has evaluated the available data and other relevant material and concludes that the proposed use of the additive is safe, and that 21 CFR 178.3570 should be amended in the table in paragraph (a)(3) 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 Assessment

FDA has carefully considered the potential environmental effects of this action. The agency 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., "Carcinogenicity Testing Programs" in "Food Safety: Where Are We?", Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, p. 59, July 1979.

2. Kokoski, C.J., "Regulatory Food Additive Toxicology," in "Chemical Safety Regulations and Compliance," F. Homburger and J.K. Marquis, Eds., S. Karger, New York, pp. 24–33, 1985.

3. National Cancer Institute Technical Report Series No. 6.

4. Memorandum dated June 23, 1989, from Food and Color Additives Review Section to Indirect Additives Branch, FAP 9B4124—Ciba-Geigy Co., "*N*-methyl-*N*-(1-oxo-9-octadecenyl)glycine as a corrosion inhibitor in lubricants contacting food."

5. Memorandum dated February 16, 1990, report of the Quantitative Risk Assessment Committee, "Upper Bound Risk for the Carcinogenic Impurity Nitrilotriacetic Acid (NTA) in FAP 9B4124-Sarkosyl O-Ciba Geigy Co."

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before August 24, 1990 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 178.3570 is amended in the table in paragraph (a)(3) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.3570 Lubricants with incidental food contact.

* * * * *

(a) * * *

(3) * * *

Substances	Limitations
* * * * *	
N-Methyl-*N*-(*1-oxo-9-octadecenyl*)glycine (*CAS Reg. No. 110-25-8*).	For use as a corrosion inhibitor at levels not to exceed 0.5 percent by weight of the lubricant.
* * * * *	

* * * * *

Dated: July 18, 1990.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90-17313 Filed 7-24-90; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[Amdt. No. 36]

Ohio Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval of a proposed amendment to the Ohio regulatory program (hereinafter referred to as the Ohio program) approved under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment modifies Ohio rules concerning release of performance bonds, lands unsuitable petitions, permit reviews, bond release conferences, and design standards for valley and head-of-hollow fills. The purpose of the amendment is to clarify the way Ohio implements its program, to adopt language comparable to the Federal regulations, and to incorporate the additional flexibility afforded by the revised Federal rules.

EFFECTIVE DATE: July 25, 1990.

FOR FURTHER INFORMATION CONTACT: Ms. Nina Rose Hatfield, Director, Columbus Field Office, Office of Surface Mining Reclamation and Enforcement, Room 202, 2242 South Hamilton Road, Columbus, Ohio 43232; Telephone: (614) 866-0578.

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Program

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Information on the general background of the Ohio program submission, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Ohio program, can be found in the August 10, 1982, **Federal Register** (47 FR 34688). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 935.11, 935.12, 935.15, and 935.16.

II. Submission of Amendment

By letter dated October 20, 1988 (Administrative Record No. OH-1110), Ohio submitted Program Amendment Number 36 to modify the following rules of chapter 1501 of the Ohio Administrative Code (OAC): 13-3-07(B)(8); 13-4-01(B); 13-7-01(A)(6)(c)(ii); 13-7-05 (A)(3), (A)(5)(b)(i), and (B)(2)(e); and 13-9-07(K)(1)(b).

The proposed amendment is the result of a State initiated revision of its rules and is intended to clarify Ohio rules for filing of incremental bond, to adopt language comparable to the Federal regulations for processing of lands unsuitable petitions, coordination of permit review with certain Federal laws, requests for bond release conferences, and design standards for valley and head-of-hollow fills, and to incorporate the additional flexibility afforded by the revised Federal rules.

OSM announced receipt of the proposed amendment in the November 22, 1988, **Federal Register** (53 FR 47225) and, in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendments.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.17, are the Director's findings concerning the proposed amendment.

1. OAC 1501:13-3-07 Lands Unsuitable Petitions

Paragraph OAC 1501:13-3-07(B)(6) of this rule provides the regulatory authority with discretion in the processing of lands unsuitable petitions received after the complete permit application has been filed. The proposed amendment deletes the existing language and adds language substantively identical to the counterpart Federal rule at 30 CFR 764.15(a)(6). The Director finds that the amendment is no less effective than the Federal rules.

2. OAC 1501:13-4-01 Permit Applications; General Requirements

This rule concerns the general contents of the requirements for permit applications and, specifically, the coordination with requirements under other laws. The proposed amendment modifies paragraph OAC 1501:13-4-01(B) by adding punctuation, a period and a comma, to the text. The added punctuation corrects omissions that were cited by the Director concerning Ohio Amendment No. 31 in a final rule published in the **Federal Register** on May 27, 1988 (53 FR 19283-86). In that notice, at Finding 4, the Director cited a punctuation error in the Amendment No. 31 which could be misinterpreted as limiting the applicability of the Bald Eagle Protection Act to Federal and Indian lands rather than being applicable to all lands. The Director also stated that the error should be corrected prior to promulgation of the rule, or in a subsequent rulemaking. This amendment corrects those punctuation errors. The Director finds that this provision is substantively identical to and no less effective than the counterpart Federal rule at 30 CFR 773.12.

3. OAC 1501:13-7-01 Bonding; General Requirements

Paragraph OAC 1501:13-7-01(A)(6)(c)(ii) of this rule requires the permittee to file, within thirty days after the end of the permit year, a performance bond concurrently with the submittal of the annual map if the number of acres shown as affected on the annual map exceeds the number of acres bonded. The purpose of this amendment is to reflect Ohio's current practice of billing operators for bond on incremental areas that they have not yet affected, but have proposed to be affected as indicated on the annual map.

On February 14, 1989, OSM informed Ohio that the language of the proposed amendment implied that an operator could affect an area and then post the bond at the end of the permit year to cover those acres not previously bonded. The previously approved language requires the permittee to consider the number of acres estimated to be affected when calculating annual bond adjustment, but that language is deleted by the proposed amendment.

Ohio responded to OSM's concern in a letter dated February 24, 1989 (Administrative Record No. OH-1164), and asserted that rule OAC 1501:13-7-01, read in its entirety, makes it clear that operators are not authorized to affect unbonded acreage. The approved