

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(vi) * * *		Replacement chickens; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration..	046573
(ix) * * *		Replacement chickens; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Start at first clinical signs of disease, vary dosage based on severity of infection, administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce medication to prevention level (50 g/t).	046573

\* \* \* \* \*

Dated: July 10, 1998.

**Margaret Ann Miller,**

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.  
[FR Doc. 98-20466 Filed 7-30-98; 8:45 am]

BILLING CODE 4160-01-F

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 814**

[Docket No. 98N-0171]

**Medical Devices; Humanitarian Use of Devices**

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) published, in the **Federal Register** of April 17, 1998 (63 FR 19185), a direct final rule to implement the amendments to the humanitarian use devices provision of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). The comment period closed July 1, 1998. FDA is withdrawing the direct final rule because the agency received significant adverse comment.

**DATES:** The direct final rule published at 63 FR 19185, April 17, 1998, is withdrawn effective July 31, 1998.

**FOR FURTHER INFORMATION CONTACT:** Joanne R. Less, Center for Devices and Radiological Health (HFZ-403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20857, 301-594-1190.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on April 17, 1998, at 63 FR 19185 is withdrawn.

Dated: July 29, 1998.

**William K. Hubbard,**

Associate Commissioner for Policy Coordination.

[FR Doc. 98-20594 Filed 7-30-98; 8:45 am]

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**DEPARTMENT OF THE INTERIOR**

**Office of Surface Mining Reclamation and Enforcement**

**30 CFR Part 917**

[KY-217-FOR]

**Kentucky Regulatory Program**

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

ACTION: Final rule; approval of amendment.

**SUMMARY:** OSM is approving a proposed amendment to the Kentucky regulatory program (hereinafter referred to as the "Kentucky program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Kentucky requested the removal of 30 CFR 917.17(a) which disapproved Kentucky's proposed revision to its staffing and budget levels (49 FR 50718, December 31, 1984). The amendment is intended to revise the Kentucky program to be consistent with the Federal regulations and SMCRA.

**EFFECTIVE DATE:** July 31, 1998.

**FOR FURTHER INFORMATION CONTACT:** William J. Kovacic, Director, Lexington Field Office, 2675 Regency Road, Lexington, Kentucky 40502. Telephone: (606) 233-2494.

**SUPPLEMENTARY INFORMATION:**

- I. Background on the Kentucky Program
- II. Submission of the Proposed Amendment
- III. Director's Findings
- IV. Summary and Disposition of Comments
- V. Director's Decision
- VI. Procedural Determinations

**I. Background on the Kentucky Program**

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. Background information on the Kentucky program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the May 18, 1982 **Federal Register** (47 FR 21404). Subsequent actions concerning conditions of approval and program amendments can be found at

30 CFR 917.11, 917.13, 917.15, 917.16, and 917.17.

## II. Submission of the Proposed Amendment

By letter dated November 3, 1997 (Administrative Record No. KY-1418), Kentucky submitted a proposed amendment to its program pursuant to SMCRA requesting the removal of 30 CFR 917.17(a), which disapproved revisions to its approved staffing and budget levels.

Specifically, Kentucky requested removal of the requirement that the Kentucky Department for Surface Mining Reclamation and Enforcement (DSMRE) maintain a staffing level of 156 field inspectors. This specific requirement is codified at 30 CFR 917.16(b)(2).

OSM announced receipt of the proposed amendment in the December 10, 1997, **Federal Register** (62 FR 65044), and in the same document opened the public comment period and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on January 9, 1998. OSM reopened the comment period on April 27, 1998 (63 FR 20561), because OSM requested and Kentucky subsequently provided certain documents containing evidence that it has sufficient inspection and enforcement staffing levels to regulate mining in accordance with SMCRA. Those documents are: "Historical Information on Kentucky's Surface Mining Primacy Program," compiled by Kentucky, July 1997 (Administrative Record No. KY-1424); "Review of Current Staffing and Funding Levels," prepared by the OSM Lexington Field Office (LFO), December 1997 (Administrative Record No. KY-1420); and "Inspection Resources Study," prepared by OSM and Kentucky, August 1989 (Administrative Record No. KY-1418). The comment period closed on May 12, 1998. OSM reopened the comment period a second time on May 18, 1998 (63 FR 27229).

## III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment.

Kentucky is requesting the removal of 30 CFR 917.17(a) which disapproved a revision to its approved staffing and budget levels. One effect of the disapproval was that Kentucky was required to maintain a staffing level of 156 field inspectors (49 FR 50718, December 31, 1984). In its submission letter dated November 3, 1997,

Kentucky provided the following information:

- field inspector staffing levels are no longer based on 1984 inspection numbers and budgetary needs,
- a study pursuant to the settlement agreement between Kentucky and the National Wildlife Federation [*National Wildlife Federation v. Miller*, No. 86-99 (E.D. Ky. 1986)] determined that a cap of 24 inspectable units per field inspector should be established. See August 1989, "Inspection Resources Study" which concluded that 176 inspectors were needed to adequately conduct the monthly and quarterly inspections needed for 4,260 permanent program sites (Administrative Record No. KY-1418),
- OSM has accepted the limits set by the study in determining inspection staff levels as indicated by the approval of Title V administrative and enforcement grants,
- OSM's annual reports indicate that Kentucky's Title V regulatory program meets high inspection frequency levels. See July 1997, document "Historical Information on Kentucky's Surface Mining Primacy Program," prepared by the Kentucky Natural Resources and Environmental Protection cabinet, DSMRE (Administrative Record No. KY-1424).

Kentucky also asserts that using a fixed number of field inspectors fails to provide the latitude necessary to adapt its inspection force to changing conditions in the coal industry. Further, the number of inspectors Kentucky maintains is based on the current and ever-changing number of inspectable units.

In December 1997, OSM's LFO prepared a summary of current staffing and funding levels at the DSMRE (Administrative Record No. KY-1420). That summary reported that the number of inspectable units in Kentucky had been steadily declining for several years. Specifically, since the 1993 evaluation period, the total number of inspectable units had declined from 3,799 to 2,832. During that same period, the number of inspection and enforcement staff dropped from 156 to 123. However, even with 123 inspectors, the ratio of inspectable units to inspectors stood at 23 units per inspector, as of December 1997. This ratio is actually slightly better than the ratio of 24 units per inspector agreed upon in the settlement in *National Wildlife Federation, supra*.

In 1984, when the Director disapproved Kentucky's proposal to reduce its inspection staff below the

mandated number of 156, he cited the lack of thorough complete inspections and the failure to consistently cite all violations as the grounds for disapproval (49 FR 50720). However, in its December 1997, "Review of Staffing and Funding Levels," LFO reported the DSMRE inspectors had made at least 97 percent of all required inspections over the last five evaluation periods, averaging 98.3 percent over that same period. Moreover, LFO found that 76 percent of all mines were in complete compliance with applicable performance standards over the last five years, and that over half of the mines not in full compliance had only one violation per year. Finally, over the last two evaluation periods, only 4 percent and 8 percent of mines, respectively, had violations which caused off site impacts. Thus, LFO concluded, not only are DSMRE's 123 inspectors making an adequate number of inspections, the inspections are also serving as a deterrent to violations (Administrative Record No. KY-1420).

LFO also noted that, while permitting staff had dropped from 52 to 38 over the five year period prior to December, 1997, the permitting workload had dropped even faster. Since the 1993 evaluation period, new permit approvals had dropped from 142 per year to 99.

Therefore, based on the new evidence discussed in the preceding paragraphs, the Director finds that Kentucky has demonstrated that it has sufficient staffing levels to regulate mining in accordance with SMCRA. He finds that the Kentucky program is consistent with the provisions of section 503(a)(3) of SMCRA and is therefore removing the required amendment at 30 CFR 917.16(b), which requires Kentucky to maintain a minimum permanent program staff of 408, including a minimum of 156 inspection and enforcement personnel. The disapproval codified at 30 CFR 917.17(a) is also being removed, since Kentucky will no longer be required to maintain a permanent program staff of 408.

## IV. Summary and Disposition of Comments

### Public Comments

The Director solicited public comments and provided an opportunity for a public hearing on the proposed amendment submitted on November 3, 1997. One comment was received in support of the amendment. The commentor stated that the coal industry has witnessed a dramatic decline in the number of coal mines in Kentucky. To support this statement, the commentor

also submitted a "Survey of Active Coal Mining Operations in Kentucky (June 1–July 31, 1997)" reflecting a total of 353 active mines in the State. By comparison, the number of licensed mines in 1984 was 2,063.

#### Federal Agency Comments

Pursuant to 30 CFR 732.17(h)(11)(i), the Director solicited comments on the proposed amendment submitted on November 3, 1997, from various Federal agencies with an actual or potential interest in the Kentucky program. No comments were received.

#### Environmental Protection Agency (EPA)

Pursuant to 30 CFR 732.17(h)(11)(ii), OSM is required to obtain the written concurrence of the EPA with respect to those provisions of the proposed program amendment that relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*).

None of the revisions that Kentucky proposed to make in its amendment pertains to air or water quality standards. Therefore, OSM did not request EPA's concurrence.

#### V. Director's Decision

Based on the above findings, the Director approves the proposed amendment as submitted by Kentucky on November 3, 1997.

The Federal regulations at 30 CFR Part 917, codifying decisions concerning the Kentucky program, are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

#### VI. Procedural Determinations

##### Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

##### Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such

program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

#### National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

#### Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

#### Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 6501 *et seq.*) The State submittal which is the subject of this rule is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

#### Unfunded Mandates

This rule will not impose a cost of \$100 million or more in any given year on any governmental entity or the private sector.

#### List of Subjects in 30 CFR Part 917

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 16, 1998.

**Allen D. Klein,**

*Regional Director, Appalachian Regional Coordinating Center.*

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

#### PART 917—KENTUCKY

1. The authority citation for part 917 continues to read as follows:

**Authority:** 30 U.S.C. 1201 *et seq.*

2. Section 917.15 is amended in the table by adding a new entry in chronological order by "Date of Final Publication" to read as follows:

#### § 917.15 Approval of Kentucky regulatory program amendments.

\* \* \* \* \*

Original amendment submission date	Date of final publication	Citation/description
* November 3, 1997.	* July 31, 1998	* Staffing and budget levels.

#### § 917.16 [Amended]

3. Section 917.16 is amended by removing and reserving paragraph (b).

#### § 917.17 [Amended]

4. Section 917.16 is amended by removing and reserving paragraph (a). [FR Doc. 98–20468 Filed 7–30–98; 8:45 am]

BILLING CODE 4310–05–M

## POSTAL SERVICE

### 39 CFR Part 111

#### Elimination of Mixed BMC/ADC Pallets of Packages of Flats

**AGENCY:** Postal Service.

**ACTION:** Final rule; correction.

**SUMMARY:** The Postal Service published a document in the **Federal Register** of July 10, 1998, concerning revisions to Domestic Mail Manual (DMM) sections M020, M041, and M045, eliminating options for mailers to place packages and bundles of Standard Mail (A) and Standard Mail (B) on mixed BMC pallets. The document contained an incorrect date.

**FOR FURTHER INFORMATION CONTACT:** Cheryl Beller, (202) 268–5166.