

Dated: September 7, 1989.

Sammie R. Young,

Deputy Director, Office of Compliance,
Center for Drug Evaluation and Research.

[FR Doc. 89-21870 Filed 9-15-89; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 448

[Docket No. 89N-0198]

Antibiotic Drugs; Polymyxin B Sulfate-Trimethoprim Hemisulfate Ophthalmic Solution

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new dosage form of polymyxin B sulfate, polymyxin B sulfate-trimethoprim hemisulfate ophthalmic solution. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective October 18, 1989; comments, notice of participation, and request for hearing by October 18, 1989; data information, and analyses to justify a hearing by November 17, 1989.

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

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new dosage form of polymyxin B sulfate, polymyxin B sulfate-trimethoprim hemisulfate ophthalmic solution. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended by adding new 21 CFR 448.330 to subpart D to provide for the inclusion of accepted standards for this product.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) 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.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, is effective October 18, 1989. However, interested persons may, on or before October 18, 1989, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before October 18, 1989, a written notice of participation and request for hearing, and (2) on or before November 17, 1989, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this order and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other

comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 448

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 448 is amended as follows:

PART 448—PEPTIDE ANTIBIOTIC DRUGS

1. The authority citation for 21 CFR part 448 continues to read as follows:

Authority: Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357); 21 CFR 5.10.

2. Section 448.330 is added to subpart D to read as follows:

§ 448.330 Polymyxin B sulfate-trimethoprim hemisulfate ophthalmic solution.

(a) *Requirements for certification.*—
(1) *Standards of identity, strength, quality, and purity.* Polymyxin B sulfate-trimethoprim hemisulfate ophthalmic solution contains, in each milliliter, 10,000 units of polymyxin B and 1.0 milligram of trimethoprim in a suitable and harmless isotonic aqueous vehicle. It may contain one or more suitable and harmless buffers and preservatives. Its polymyxin B content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. Its trimethoprim content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of trimethoprim that it is represented to contain. It is sterile. Its pH is not less than 3.0 and not more than 5.5. The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

- (i) Results of tests and assays on:
 - (A) The polymyxin B sulfate used in making the batch for potency, loss on drying, pH, and identity.
 - (B) The trimethoprim used in making the batch for all U.S.P. specifications.

(C) The batch for polymyxin B content, trimethoprim content, sterility, and pH.

(ii) Samples if required by the Director, Center for Drug Evaluation and Research:

(A) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(B) The trimethoprim hemisulfate used in making the batch: 10 packages, each containing approximately 500 milligrams.

(C) The batch:

(1) For all tests except sterility: A minimum of 7 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Polymyxin content*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with 10 percent potassium phosphate buffer, pH 6.0 (solution 10), to obtain a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

(2) *Trimethoprim content*. Proceed as directed in § 436.216 of this chapter, using ambient temperature, an ultraviolet detection system operating at a wavelength of 254 nanometers, and a column packed with octyl, octadecyl, or phenyl groups chemically bonded to porous silica ranging from 3 to 10 micrometers in particle size. Reagents, working standard solution, sample solution, resolution test solution, system suitability requirements and calculations are as follows:

(i) *Reagents*—(A) *Diluting fluid*. 13 percent acetonitrile in 0.01M hydrochloric acid.

(B) *Mobile phase*. Mix 0.015M ethanesulfonic acid in acetonitrile: water (130:870) and adjust to pH 3.5 with 50 percent w/w sodium hydroxide and hydrochloric acid solution. Filter the mobile phase through a suitable filter capable of removing particulate matter to 0.5 micron in diameter. Degas the mobile phase just prior to its introduction into the chromatograph.

(ii) *Preparation of working standard, sample, and resolution test solutions*—

(A) *Working standard solution*. Place approximately 40 milligrams of trimethoprim working standard, accurately weighed, into a 50-milliliter volumetric flask. Dissolve and dilute to volume with 13 percent acetonitrile in 0.01M hydrochloric acid, and mix. Transfer 5 milliliters of this solution to a

50-milliliter volumetric flask, and dilute to volume with 13 percent acetonitrile in 0.01M hydrochloric acid, and mix.

(B) *Sample solution*. Transfer 4.0 milliliters of the sample into a 50-milliliter volumetric flask and dilute to volume with 13 percent acetonitrile in 0.01M hydrochloric acid.

(C) *Resolution test solution*. Place approximately 40 milligrams of trimethoprim working standard and 15 milligrams of 2-amino-4-hydroxy-5-(3',4',5')-trimethoxybenzyl pyrimidine, accurately weighed, into a 50-milliliter volumetric flask. Dissolve and dilute to volume with 13 percent acetonitrile in 0.01M hydrochloric acid, and mix. Transfer 5 milliliters of this solution to a 50-milliliter volumetric flask, and dilute to volume with 13 percent acetonitrile in 0.01M hydrochloric acid, and mix. Prepare the resolution test solution just prior to its introduction into the chromatograph pumping system.

(iii) *System suitability requirements*—(A) *Asymmetry factor*. The asymmetry factor (A_s) is satisfactory if it is not more than 1.4 at 10 percent of peak height.

(B) *Efficiency of the column*. The efficiency of the column (n) is satisfactory if it is greater than 1,500 theoretical plates.

(C) *Resolution*. The resolution (R) between 2-amino-4-hydroxy-5-(3',4',5')-trimethoxybenzyl pyrimidine (AHTP) and trimethoprim is satisfactory if it is not more than 1.5.

(D) *Coefficient of variation*. The coefficient of variation (S_R in percent) of five replicate injections is satisfactory if it is not more than 2.0 percent. If the system suitability parameters have been met, then proceed as described in § 436.216(b) of this chapter.

(iv) *Calculations*. Calculate the milligrams of trimethoprim per milliliter of sample as follows:

$$\text{Milligrams of trimethoprim per milliliter} = \frac{A_u \times W_s \times 0.8555}{A_s \times 40}$$

where:

A_u = Area of the trimethoprim peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_s = Area of the trimethoprim peak in the chromatogram of the trimethoprim working standard;

W_s = Weight of the trimethoprim working standard in milligrams; and

0.855 = Gravimetric conversion factor trimethoprim hemisulfate to trimethoprim.

(3) *Sterility*. Proceed as directed in § 436.20 of this chapter, using the

method described in paragraph (e)(1) of that section.

(4) *pH*. Proceed as directed in § 436.202 of this chapter, using the undiluted sample.

Dated: September 7, 1989.

Sammie R. Young,

Deputy Director, Office of Compliance,
Center for Drug Evaluation and Research.
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DEPARTMENT OF THE INTERIOR

Bureau of Mines

30 CFR Part 652

RIN 1032-AA00

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 890

Mining and Mineral Resources Research Institute Program

AGENCY: Bureau of Mines, Interior.

ACTION: Final rule.

SUMMARY: This part sets forth the administrative policies and procedures for the Mining and Mineral Resources Research Institute Program. These rules are needed owing to the transfer of responsibility for the program to the Bureau of Mines, and the revised operation of the program.

EFFECTIVE DATE: October 18, 1989.

FOR FURTHER INFORMATION CONTACT:

Ronald Munson, Chief, Office of Mineral Institutes, Bureau of Mines, MS 1020, 2401 E Street NW., Washington, DC 20241. Phone (202) 634-1328.

SUPPLEMENTARY INFORMATION: This rulemaking redesignates the existing regulations found at 30 CFR part 890 as a new part 652 and revises and updates the regulations so they reflect the transfer of responsibility and revised operation of the program. By Secretarial Order No. 3073, dated February 1, 1982, the Secretary of the Interior transferred administrative responsibility for the Department's mineral institute program from the Office of Surface Mining Reclamation and Enforcement to the Bureau of Mines. These regulations contain mineral institute eligibility criteria and a description of the characteristics of generic mineral technology centers. A description of the specific responsibilities of mineral institute directors, rules for the transfer of funds between cooperating institutions, and an exposition of the

role of the Advisory Committee on Mining and Mineral Resources Research in making recommendations to the Secretary both on the operation of the program and in the determination of institute eligibility are included.

Descriptions of the types of reports required under the program and sample statements for crediting the program in the professional literature are provided.

The Department of the Interior has determined this document is not a major rule under E.O. 12291 and certifies this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

The information collection requirements contained in this rule have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*, and assigned clearance number 1032-0116.

The Department of the Interior has determined that this document does not constitute a major federal action significantly affecting the quality of the human environment under The National Environmental Policy Act of 1969.

Author: Dr. Ronald A. Munson, Chief, Office of Mineral Institutes, Bureau of Mines.

(Catalog of Federal Domestic Assistance Program No. 15.308, Grants for Mining and Mineral Resources and Research Institutes.)

Background and Discussion

A proposed rule was published in the *Federal Register* Vol. 53, No. 183, Wednesday, September 21, 1988, on pages 36582-36585. Written comments were solicited for 30 days. Two comments were received, both from mineral institute directors. One respondent stated satisfaction with the description and rules; the second respondent urged adoption of a preproposal system with responsibility placed on each generic center to screen the preproposals and recommend detailed proposals to the Bureau. The Bureau finds the present procedure to be satisfactory at this time in producing a research program having variety and quality.

No change in these rules would be required to adopt an alternative proposal selection system. The Bureau intends to continue to evaluate management options under this rule and could make changes similar to those proposed if conditions warrant.

Since the drafting of this rule Public Law 98-409 has been amended by Public Law 100-483, which extended authorization for the mineral institutes program through September 30, 1994, and made other clarifications. No

provisions of Public Law 100-483 required changes in this rule. References to Public Law 100-483 have been added.

List of Subjects in 30 CFR Parts 652 and 890

Grant program—natural resources, Mineral resources, Mines, Environmental protection, Research, Scholarships and fellowships.

Therefore, title 30 is amended by redesignating part 890 of chapter VII as part 652 of Chapter VI, removing and reserving subchapter S of chapter VII, and revising newly redesignated part 652 to read as follows:

PART 652—MINING AND MINERAL RESOURCES RESEARCH INSTITUTE PROGRAM

Sec.

- 652.1 Scope.
- 652.2 Objectives.
- 652.3 Authority.
- 652.4 Administration.
- 652.5 Definitions.
- 652.6 Eligibility.
- 652.7 Responsibilities of institutions designated as mineral institutes.
- 652.8 Applications for allotment grants.
- 652.9 Generic mineral technology centers.
- 652.10 Applications for research grants.
- 652.11 Transfers of research and allotment grant funds.
- 652.12 Governing provisions for grants.
- 652.13 Reports.
- 652.14 Information collection.
- 652.15 Advisory committee.
- 652.16 Site visits.
- 652.17 Grant modifications.
- 652.18 Grant reduction and termination.

Authority: 30 U.S.C. 1221-1230; Pub. L. 98-409; Public Law 100-483.

§ 652.1 Scope.

This part sets forth policies and procedures for the assistance of institutions of higher learning that have been designated as State Mining and Mineral Resources Research Institutes and for the support of mining and mineral resources research at these institutions through specialized generic mineral technology research centers.

§ 652.2 Objectives.

The objectives of the assistance provided by the Mining and Mineral Resources Research Institute program are:

(a) To support research and training in mining and mineral resources problems related to the mission of the Department of the Interior;

(b) To improve the advanced training of mineral scientists and engineers through grants which encourage State and industry support of mineral education;

(c) To support, and encourage support of, research centers of generic expertise in mineral technology;

(d) To assist the States in carrying on the work of competent and qualified mining and mineral resources research institutes; and

(e) To provide support for graduate and postdoctoral students in mining and mineral resources disciplines including mining engineering, extractive metallurgy, geology, reclamation, engineering, economics, chemistry, physics, biology, ecology, and others.

§ 652.3 Authority.

The authority for this program is the Mining and Mineral Resources Research Program Act of 1984 and the Mining and Mineral Resources Research Institute Amendments of 1988.

(30 U.S.C. 1221-1230; Pub. L. 98-409 and Pub. L. 100-483)

(a) 30 U.S.C. 1221 authorizes the Secretary to make grants to assist States on a matching basis in carrying on the work of competent and qualified mining and mineral resources research institutes.

(b) 30 U.S.C. 1222 authorizes the Secretary to make grants to the institutes for specific research and demonstration projects, and for research into any aspects of mining and mineral resources problems related to the mission of the Department of the Interior deemed desirable and not otherwise under study.

(c) 30 U.S.C. 1229 authorizes the Secretary to appoint an Advisory Committee on Mining and Mineral Resources Research jointly chaired by the Assistant Secretary of the Interior responsible for minerals and mining and a committee member elected by the Committee from among those members who are not Federal employees.

§ 652.4 Administration.

Responsibility for administration of the Mining and Mineral Resources Research Institute Program is assigned to the Director of the Bureau of Mines and subject to the supervisory authority of the Assistant Secretary to whom he/she reports.

§ 652.5 Definitions.

As used in this part, the term—

Act means the State Mining and Mineral Resources Research Program Act of 1984 and subsequent amendments.

(30 U.S.C. 1221-1230; Pub. L. 98-409, Pub. L. 100-483)

Advisory Committee means the Advisory Committee on Mining and

Mineral Resources Research appointed by the Secretary pursuant to 30 U.S.C. 1229.

Allotment grant means funds made available to a mineral institute for the support of mineral-related research and education on a matching (formula) basis in a particular fiscal year pursuant to 30 U.S.C. 1221 and under the regulations contained herein.

Bureau means the Bureau of Mines.

Call for proposals means a letter from the Director to eligible mineral institutes and generic mineral technology centers requesting proposals for allotment or research grants, and specifying the format and date for receipt at the Office and other conditions. Separate Calls for proposals are issued annually for allotment and research grants.

Applications for funds may be submitted only in response to a Call for Proposals.

Director means Director of the Bureau of Mines.

Generic mineral technology center means a cooperative mineral resources research effort in a specific area of broad applicability across the minerals industry headquartered in one institute with participation by one or more affiliate mineral institutes as authorized under 30 U.S.C. 1222.

Grant agreement means the legal document that sets forth the rules for the administration of the grant, including the responsibilities and privileges of the recipient, the amount of the award, reports required, and applicable rules and regulations.

Mineral institute means a competent and qualified mining and mineral resources research institute, department, or component of a college or university that conducts mineral resources research, which is determined to be eligible in accordance with the provisions of the Act, and which is designated by the Secretary as a State Mining and Mineral Resources Institute.

Mineral resources research means research, investigations, demonstrations, and experiments of a basic or practical nature relating to mineral exploration, extraction, processing, development, production, mining and technology, supply and demand, conservation and best use of available supplies, and the mineral-related aspects of other disciplines; and the training of mineral engineers and scientists through such activity; and the planning and coordination of such cooperative activity with other mineral institutes and those other agencies and individuals as may contribute to the solution of mining and mineral resources problems.

Office means Office of Mineral Institutes.

Secretary means the Secretary of the Interior or his authorized representative.

§ 652.6 Eligibility.

Only institutions of higher learning (post-secondary institutions having graduate research programs) designated by the Secretary, after consultation with, and upon the advice of the Advisory Committee, as a State Mining and Mineral Resources Research Institute are eligible to receive funds under this program. Only one institution may be designated per State. To qualify as a mineral institute, institutions must meet all the following criteria as determined by the Advisory Committee:

- (a) Be either a public college or university or, in a State not having an eligible public college or university, a private college or university in that State.
- (b) Be recommended by the Governor of the State, as eligible, in the absence of contrary act by the legislature of the State.
- (c) Have in existence a substantial program of graduate instruction and research in mining or mineral extraction or closely related fields which has a demonstrated history of achievement.
- (d) Evidence institutional commitment to the purposes of the Act.
- (e) Exhibit significant industrial cooperation in activities within the scope of the Act.
- (f) Have in existence an engineering program in mining or minerals extraction that is accredited by the Accreditation Board for Engineering and Technology, or show evidence of equivalent institutional capability.
- (g) Employ at least six full-time permanent faculty members in the department or component of the institution conducting instruction and research in mining and mineral extraction.
- (h) Meet such other criteria as the Advisory Committee shall deem necessary or desirable.

§ 652.7 Responsibilities of institutions designated as mineral institutes.

- (a) Each institution designated as mineral institute has the duty of planning and conducting mineral resources research. To carry out its responsibility, it shall appoint a mineral institute director from its faculty or staff, who is professionally qualified in minerals research and education.
- (b) Mineral institute directors shall be responsible for preparation of allotment grant proposals; for the technical administration of allotment grant agreements; for periodic reporting to the Bureau of Mines; for the preparation and transmission to the Bureau of Mines of

an annual institute status report; for providing such coordination as may be necessary between various departments, units, and individuals at that institution to achieve a focused minerals program of value to the mineral institute's State and region; for the coordination between and among the minerals programs of the several mineral institutes; for responding to requests for information regarding the minerals program at that institution from the Bureau of Mines, the Advisory Committee, and the public; and for the selection and transmission of the best research proposals from that institution for inclusion in the generic mineral technology center program.

§ 652.8 Applications for allotment grants.

Applications for annual allotment grants shall be submitted in response to an annual call for proposals issued by the Bureau of Mines to mineral institutes. To receive a new allotment grant, a mineral institute must have submitted all reports due and shall not have been found by the Secretary to have improperly diminished, lost, or misapplied funds previously received. Such funds shall be replaced by the State concerned and until so replaced no subsequent grant shall be allotted or paid to the institute of that State. Each allotment grant application shall be responsive to 30 U.S.C. 1221(b) and as a minimum shall consist of the following elements in duplicate:

- (a) A completed Standard Form 424.
- (b) A plan to provide for the training of individuals as mineral engineers and scientists under a curriculum appropriate to the field of mineral resources and mineral engineering and related fields.
- (c) A budget to support that plan.
- (d) Assurance that Federal funds will supplement and, to the extent practicable, increase the level of funds that would otherwise have been available for the purposes of the Act, and in no case supplant such funds.
- (e) Such other information as is requested in the Call for Proposals. The Secretary shall deny or reduce funds to mineral institutes where proposals or portions thereof are not complementary to the mission of the Department or the goals of this program.

§ 652.9 Generic mineral technology centers.

All research supported under this program, except for that funded through allotment grants, is funded through established generic mineral technology centers (generic centers). Each generic center provides a focus for mineral

research in a specific area of broad applicability across the minerals industry. Each generic center has the following characteristics:

(a) It is headquartered in one mineral institute with participation by one or more affiliate institutions.

(b) A generic center director supervises the operation of the center including the coordination of related projects; makes arrangements for an annual seminar; provides for operation of a reference center; makes recommendations to the Bureau of Mines on budget revisions, equipment purchases, and other grant modifications; and provides technical leadership for the center.

(c) A reference center serves as a centralized repository of literature concerning the generic research area and also is a repository of all periodic and final reports, dissertations, and contributions to the technical literature resulting from generic center research.

(d) An annual seminar provides opportunity for students and principal investigators to exchange ideas and present their latest research in the generic area.

(e) A Research Council, consisting of experts in the generic research area from industry, government and, where possible, academia, attends the annual seminars, receives periodic reports, evaluates research proposals, and provides recommendations to the Bureau of Mines on the program of the center.

(f) New proposals for research, submitted through generic center and mineral institute directors, are evaluated on a competitive basis, in writing, and through Council discussion.

§ 652.10 Application for research grants.

Proposals may be submitted to the Bureau of Mines in any of the generic mineral technology areas through mineral institute and generic mineral technology center directors in response to an annual call for proposals which describes the format of the proposals. Proposals shall address the requirements of 30 U.S.C. 1222 (b)-(d) as detailed in the call for proposals. No portion of any research grant shall be applied to the acquisition by purchase or lease of any land or interests therein or the rental, purchase, construction, preservation or repair of any building.

§ 652.11 Transfers of research and allotment grant funds.

Under 30 U.S.C. 1223(b), mineral institutes are authorized to conduct cooperative programs with other mineral institutes and with such other agencies and individuals as may

contribute to the solution of the mining and mineral resource problems involved. Mineral institutes may utilize their funds to pay for projects at other institutions under the following limitations:

(a) The mineral institute director (for allotment grants) or the generic mineral technology center director (for research grants) for the institution awarded the funds by the Bureau, or the designated representative of the above, shall administer, conduct and supervise all funded programs.

(b) All proposals to fund noninstitute activities shall be specifically set forth in the grant proposal applications required under § 652.8 and § 652.10 and must be explicitly approved by the Bureau of Mines.

(c) All subgrants and subcontracts, service agreements, and interdivisional work authorizations shall be subject to the same terms and conditions as the grant.

(d) Copies of all agreements for funding of programs conducted by noninstitute organizations, universities, or individuals shall be made available to the Bureau of Mines upon request.

§ 652.12 Governing provisions for grants.

Performance under all grants shall be in accord with the terms and conditions set forth in OMB Circulars A-110 (General Administration), A-21 (Cost Principles), A-88 (Indirect Cost Rates and Audit), and all other applicable laws and regulations. Copies of the OMB circulars are available for public inspection at the Bureau of Mines, Division of Budget, Room 1007, 2401 E Street NW., Washington, DC 20241. All uses, products, processes, patents, and other developments under this program, with such exceptions as the Secretary may make in the public interest, are to be made promptly available to the public. Patentable inventions shall be governed by the provisions of Public Law 96-517.

§ 652.13 Reports.

The following reports are required from program participants:

(a) *Annual Institute Status Report* (30 U.S.C. 1223(a)(3)). On or before September 1 of each year, the mineral institute director for each institute shall submit to the Office a written report on work accomplished; the status of projects underway; a listing of scholarship and fellowship holders supported under this program, their departmental affiliation, citizenship, amount of award, and thesis title, if selected; and a statement of disbursements of funds received under this program. This report shall cover all

activities under both the allotment grant and research grant program.

(b) *Periodic Technical Reports.* Each mineral institute and generic center director shall make brief periodic written reports as specified in the grant document to the Office describing progress made on each active project. Generic center directors shall also send their periodic reports to members of the applicable Research Councils.

(c) *Periodic Financial Reports.* Each mineral institute and generic center shall submit completed Standard Form-269 reports concurrent with the periodic technical progress reports.

(d) *Annual Property Report.* Each mineral institute and generic center shall submit by November 15 a completed Bureau of Mines Form 6-359 on nonexpendable property.

(e) *Final Reports.* The annual institute status report will serve as the final report for allotment grants. A final report is required for each approved generic center research project. Principal investigators are encouraged to publish in the technical literature any information developed in the course of carrying out a research project. A published journal article may be substituted for a final report, provided the Grantee delivers five copies of the reprint to the Office. If the findings of a research project are not published, five copies of a final report shall be furnished. An unpublished final report should be prepared in accordance with ANSI Z39.18-1974, "American National Standard Guidelines for Format and Production of Scientific and Technical Reports."

(1) *Credits.* Every final research report or publication in the technical literature shall contain one of the following statements or the equivalent:

This research has been supported by the Department of the Interior's Mineral Institute Program administered by the Bureau of Mines under allotment grant number _____.

This research has been supported by the Department of the Interior's Mineral Institute Program administered by the Bureau of Mines through the Generic Mineral Technology Center for _____ under research grant number _____.

§ 652.14 Information collection.

The information collection requirements contained in this section have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* and assigned clearance number 1032-0116. The information is being collected to evaluate the effectiveness of the programs and responses are required to obtain a benefit in accordance with 30 U.S.C. 1221-1230. Public reporting burden for

this information, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information is as follows:

Performance Report.....16 hours
Report of Funded Scholarship and Fellowships..... 2 hours
Summary Report of Inventions and Subgrants.....1 hour
Grantee Inventory of Property Purchased from Grant Funds.....2 hours
Budget Information Report.....8 hours.

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Office of Statistical Standards, Bureau of Mines, Washington, DC 20241; and to the Office of Management and Budget, Paperwork Reduction Project (OMB No. 1032-0116), Washington, DC 20503.

§ 652.15 Advisory committee.

An Advisory Committee on Mining and Mineral Resources Research, appointed by the Secretary under 30 U.S.C. 1229, shall consult with and make recommendations to the Secretary on the operation of and the making of grants under this program and it shall determine the eligibility of a college or university to participate as a Mining and Mineral Resources Research Institute under the Act and make such recommendation to the Secretary.

§ 652.16 Site visits.

In relation to the substantive scientific and administrative operations of grantees, the Bureau of Mines or the Advisory Committee may perform inspections of activities authorized and financed pursuant to these regulations. Such inspections may cover acceptability of progress, consistency with approved plans, and institute eligibility.

§ 652.17 Grant modifications.

(a) The mineral institute and generic center directors are responsible for promptly notifying the Office of events which may require modification of grant agreements, such as:

- (1) Rebudgetings,
- (2) No-cost time extensions, or
- (3) Changes in scope.

(b) Permission of the Office is also required for the following actions under a grant:

- (1) Equipment purchase of \$1000 or more,
- (2) Property transfer, or
- (3) Foreign travel.

§ 2.18 Grant reduction and termination.

If a mineral institute or generic mineral technology center does not

follow the provisions and terms of a grant or does not fully implement a grant program, the Director may reduce the size of or may suspend or terminate a grant.

Dated: July 10, 1989.

Doyle G. Frederick,

Principal Deputy Assistant Secretary of the Interior.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPTS-50569A; FRL-3646-7]

Mixture of: 1,3-Benzenediamine, 2-Methyl-4,6-Bis(Methylthio)- and 1,3-Benzenediamine, 4-Methyl-2,6-Bis(Methylthio)-; Significant New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for the chemical substance: Mixture of: 1,3-benzenediamine, 2-methyl-4,6-bis(methylthio)- (CAS NO. 104983-85-9) and 1,3-benzenediamine, 4-methyl-2,6-bis(methylthio)- (CAS NO. 102093-68-5), which was the subject of premanufacture notice P-86-1322 and a TSCA section 5(e) consent order issued by EPA. EPA believes that this substance may be hazardous to human health and that the uses described in this rule may result in significant human exposure. As a result of this rule, certain persons who intend to manufacture, import, or process this substance for a significant new use must notify EPA at least 90 days before commencing that activity. The required notice will provide EPA with the opportunity to evaluate the intended uses and, if necessary, prohibit or limit those activities before they occur.

DATES: In accordance with 40 CFR 23.5 (50 FR 7271), this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern "daylight" time on October 2, 1989. This rule shall become effective December 1, 1989.

FOR FURTHER INFORMATION CONTACT:

Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room E-545, 401 M Street SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: This rule describes significant new uses and recordkeeping requirements for certain persons who intend to manufacture, import, or process the chemical substance: Mixture of: 1,3-benzenediamine, 2-methyl-4,6-bis(methylthio)- (CAS NO. 104983-85-9) and 1,3-benzenediamine, 4-methyl-2,6-bis(methylthio)- (CAS NO. 102093-68-5), which was the subject of premanufacture notice (PMN) P-86-1322 and a TSCA section 5(e) consent order issued by EPA. EPA believes that this substance may be hazardous to human health and that the uses described in this rule may result in significant human exposure. A requirement to notify EPA at least 90 days before commencing significant new uses will provide EPA with the opportunity to evaluate the intended uses and, if necessary, prohibit or limit those activities before they occur. This rule was proposed in the Federal Register of December 28, 1988 (53 FR 52443).

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use.

Persons subject to this SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of section 5(b) and (d)(1), the exemptions authorized by section 5(h) (1), (2), (3), and (5), and the regulations at 40 CFR part 720. Once EPA receives a SNUR notice, EPA may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities on which it has received a SNUR notice. If EPA does not take action, section 5(g) of TSCA requires EPA to explain in the Federal Register its reasons for not taking action.

Persons who intend to export a substance identified in a final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR part 707. Persons who intend to import a chemical substance are subject to the TSCA section 13