union movement, and other matters of concern to the Administration, and provides policy advice to the Board and operating officials. The Director is assisted by a Deputy Director, an Assistant Director and Directors of the Divisions of Statistics and Regulatory Policy and Research.

(9) *Director, Office of Consumer Affairs.* The Director of the Office of Consumer Affairs directs the Administration's programs for consumer law compliance, consumer education and complaint handling. The Director provides policy advice to the Board on issues affecting consumers. The Director is assisted by a Deputy Director, and Directors of the Divisions of Enforcement and Consumer Policy.

* * * * *

(c) *Regional Offices.* (1) There are six Regional Offices of the Administration. The office address and the geographical area covered by each is as follows:

| Region No. | Area within region | Office address |
|---|---|---|
| * | * | * |
| II | | 310 North Second Street, Harrisburg, Pennsylvania 17101. |
| * | * | * |
| VI | | 77 Geary Street (2nd Floor), San Francisco, California 94108. |

(2) A Regional Director is in charge of each regional operation. The Regional Director performs such duties as directing the chartering, insurance, examination, and supervision programs, managing regional resources, directing the Administration's programs within the region, maintaining good public relations, operating an Information Service Center, and is responsible for initial determinations on requests for information properly made to the regional office. The Regional Director is aided by a Deputy Regional Director, and Chiefs of the Branches of Supervision and Examination, Consumer Affairs, Liquidations, and Credit Union Structure. In addition, each region is divided into financial examiner districts and consumer examiner districts. The consumer examiners report directly to the Chief of Consumer Affairs; the financial examiners are subordinate to Supervisory Examiners, who in turn report directly to the Regional Director or Deputy Regional Director.

(d) * * *

(2) * * * The Board is assisted in managing the Facility by the President, who is appointed by and is responsible to the Board.

(3) *President.* The President is the chief executive officer of the Facility and works under the general supervision of the Board. The President provides overall executive direction and guidance and is responsible for the ongoing management of the Facility. The President manages the Facility staff and their activities; provides general supervision to the other officers of the Facility; and initiates and maintains working relations with the credit union community, other Federal and State government authorities, and the banking and investment communities. The President is assisted by an Executive Vice President, a Vice President for Credit and Finance, a Treasurer and a Secretary.

* * * * *

(Sec. 120, 73 Stat. 635 (12 U.S.C. 1766); sec. 209, 84 Stat. 1014 (12 U.S.C. 1789); sec. 307, 92 Stat. 3722 (12 U.S.C. 1795f))

[FR Doc. 81-26557 Filed 9-10-81; 8:45 am]

BILLING CODE 7535-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 444

[Docket No. 81N-0223]

## Antibiotic Drugs; Gentamicin Sulfate Cream; Potency Testing Methods

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) amends the antibiotic drug regulations to provide for a new sample preparation method to be used in potency testing for the certification of gentamicin sulfate cream. The manufacturer has supplied sufficient data and information to establish the safety and efficacy of this drug.

**DATES:** Effective September 11, 1981; comments, notice of participation, and request for hearing by October 13, 1981; data, information, and analyses to justify a hearing by November 10, 1981.

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

**FOR FURTHER INFORMATION CONTACT:** Joan Eckert, Bureau of Drugs (HFD-140), 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 providing for the certification of gentamicin sulfate cream assayed for potency using a new sample preparation method. This revised potency assay procedure incorporates an extraction method for sample preparation in lieu of the existing blending method. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when the drug is used as directed in the labeling and that the regulations should be amended in Part 444 (21 CFR Part 444) to provide for its certification.

The agency has determined pursuant to 21 CFR 25.24(b)(22) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## PART 444—OLIGOSACCHARIDE ANTIBIOTIC DRUGS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 507, 701(f), (g), 52 Stat. 1055-1056 as amended, 59 Stat. 463 as amended (21 U.S.C. 357, 371(f), (g))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 444 is amended in § 444.520b by revising paragraph (b) to read as follows:

### § 444.520b Gentamicin sulfate cream.

* * * * *

(b) *Tests and methods of assay; potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the cream into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of 0.1*M* potassium phosphate buffer, ph 8.0 (solution 3), and shake gently to avoid gel formation. Allow the layers to separate. Remove the buffer layer and repeat the extraction procedure with each of three more 20 to 25 milliliter quantities of solution, 3. Combine the buffer extractives and adjust to an appropriate volume to obtain a stock solution of convenient concentration. Further dilute with solution 3 to the reference concentration of 0.1 microgram of gentamicin per milliliter (estimated).

This regulation announces standards that FDA has accepted in a request for approval of an antibiotic drug. In accordance with the conditions for certification in section 507 of the act, FDA permits the manufacturer to market this drug on a "release" status pending the regulation's becoming effective. Because this regulation is not controversial and because when effective it provides notice of accepted standards and permits earlier certification of regulated products, notice and comment procedure and delayed effective date are found to be unnecessary and not in the public interest. The amendment, therefore, is effective upon the date of publication in the Federal Register. However, interested persons may, on or before October 13, 1981, submit written comments on this rule 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 regulation may file objections to it, request a hearing, and show reasonable grounds for the hearing. Any person who decides to seek a hearing must file (1) on or before October 13, 1981, a written notice of participation and request for hearing, and (2) on or before November 10, 1981, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 430.20. 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 analysis, 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 430.20.

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 between 9 a.m. and 4 p.m., Monday through Friday.

*Effective date.* This regulation shall be effective September 11, 1981.

(Secs. 507, 701(f), (g), 52 Stat. 1055–1056 as amended, 59 Stat. 463 as amended (21 U.S.C. 357, 371(f) (g)))

Dated: September 2, 1981.

**Mary A. McEniry,**

*Assistant Director for Regulatory Affairs, Bureau of Drugs.*

[FR Doc. 81-26367 Filed 9-10-81; 8:45 am]

BILLING CODE 4110-03-M

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## 21 CFR Parts 510 and 558

## Animal Drugs, Feeds, and Related Products; Ammonium Chloride, Feed Grade; Removal of Sponsor

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is removing Pennwalt Corp. from the list of sponsors of approved applications and from the regulation for ammonium chloride, feed grade. Pennwalt Corp. has requested the withdrawal of approval of the new animal drug application (NADA).

**EFFECTIVE DATE:** September 21, 1981.

**FOR FURTHER INFORMATION CONTACT:** David Scarr, Bureau of Veterinary Medicine (HFV-214), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4093.

**SUPPLEMENTARY INFORMATION:** In a notice published elsewhere in this issue of the Federal Register, approval of NADA 40–978 for Sal Ammoniac (ammonium chloride, feed grade) is withdrawn. This document amends the regulation for the use of ammonium chloride, feed grade, by removing Pennwalt Corp. as a sponsor of the product. In addition, because Pennwalt Corp. is not currently the sponsor of any other approved new animal drug it is being removed from the regulations as a sponsor of an approved application.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(2) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345–347 (21 U.S.C. 360b(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.84), Parts 510 and 558 are amended as follows:

### PART 510—NEW ANIMAL DRUGS

**§ 510.600 [Amended]**

1. In Part 510, § 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in paragraph (c)(1) by removing the entry for "Pennwalt Corp." and in paragraph (c)(2) by removing the entry for "000018".

### PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

2. In Part 558, § 558.45 is amended by revising paragraph (c) to read as follows:

**§ 558.45 Ammonium chloride, feed grade.**

* * * * *

(c) *Approvals.* Premix level of 99 percent granted to No. 011462 in § 510.600(c) of this chapter.

* * * * *

*Effective date.* This regulation is effective September 21, 1981.

(Sec. 512(e), 82 Stat. 345–347 (21 U.S.C. 360b(e)))

Dated: September 1, 1981.

**Gerald B. Guest,**

*Acting Director, Bureau of Veterinary Medicine.*

[FR Doc. 81-26461 Filed 9-10-81; 8:45 am]

BILLING CODE 4110-03-M

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## DEPARTMENT OF LABOR

## Occupational Safety and Health Administration

## 29 CFR Part 1910

## Occupational Noise Exposure; Hearing Conservation Amendment

*Correction*

In FR Doc. 81–24448 appearing at page 42622 in the issue for Friday, August 21, 1981, make the following correction:

On page 42635, in Appendix A to § 1910.95, in the second column, in the first paragraph, the equation

"$T = \frac{8}{2^{(L-90)/5}}$"

should have read

"$T = \frac{8}{2^{(L-90)/5}}$"

BILLING CODE 1505-01-M

## ADVISORY COUNCIL ON HISTORIC PRESERVATION

### 36 CFR Part 810

### Freedom of Information Act; Implementation

**AGENCY:** Advisory Council on Historic Preservation.

**ACTION:** Final regulations.

**SUMMARY:** These final regulations will implement Council responsibilities under the Freedom of Information Act (5 U.S.C. 552). Heretofore, the Council has opted to follow the Department of the Interior's Freedom of Information Act regulations. These final regulations will provide the Council with its own regulations to better meet its specific needs.

**EFFECTIVE DATE:** September 11, 1981.

**FOR FURTHER INFORMATION CONTACT:** John M. Fowler, General Counsel, Advisory Council on Historic Preservation, 1522 K Street NW., Washington, D.C. 20005; 202–254–3967.

**SUPPLEMENTARY INFORMATION:** The Council was established by the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), and consists of the Secretary of the Interior, the Secretary of Housing and Urban Development, the Administrator of the General Services Administration, the Secretary of the Treasury, the Secretary of Agriculture, the Secretary of Transportation, the Architect of the Capitol, the Chairman of the National Trust for Historic Preservation, the President of the National Conference of State Historic Preservation Officers, and four members from the general public appointed by the President, four historic preservation experts appointed by the President, and a governor and a mayor. The Act generally charges the Council with advising the President and the Congress on historic preservation matters. The Council's administrative support is provided by the Department of the Interior. Heretofore, the Council has opted to follow the Department's Freedom of Information Act regulations. These final regulations will provide the Council with its own regulations to better meet its specific needs.

No comments were received on the proposed rule and no changes or additions have been made in the final regulations. The final regulations were approved by the Council at its meeting on August 25, 1981.

Pursuant to 36 CFR 805, "National Environmental Policy Act Implementation Procedures," the Council has determined that an Environmental Impact Statement is not required.

Principal Author: Katherine Raub Ridley, Attorney Advisor.

**Robert R. Garvey, Jr.,**

*Executive Director.*

September 4, 1981.

36 CFR is amended by adding Part 810 to read as follows:

## PART 810—FREEDOM OF INFORMATION ACT REGULATIONS

Sec.

810.1 Purpose and scope.
810.2 Procedure for requesting information.
810.3 Action on requests.
810.4 Appeals.
810.5 Fees.
810.5 Exemptions.

**Authority:** Pub. L. 89–665, 80 Stat. 915 (16 U.S.C. 470) as amended by Pub. L. 91–243, Pub. L. 93–54, Pub. L. 94–422, Pub. L. 94–458, Pub. L. 96–199, Pub. L. 96–244, Pub. L. 96–515.

### § 810.1 Purpose and scope.

This subpart contains the regulations of the Advisory Council on Historic Preservation implementing the Freedom of Information Act (5 U.S.C. 552). Procedures for obtaining the records covered by the Act are established in these regulations. Persons seeking information or records of the Council are encouraged to consult first with the staff of the Council before filing a formal request under the Act pursuant to these regulations. The informal exchange of information is encouraged wherever possible.

### § 810.2 Procedure for requesting information.

(a) Requests for information or records not available through informal channels shall be directed to the Administrative Officer, Advisory Council on Historic Preservation, 1522 K Street NW., Washington, D.C. 20005. All such requests should be clearly marked "FREEDOM OF INFORMATION REQUEST" in order to ensure timely processing. Requests that are not so marked will be honored, but will be deemed not to have been received by the Council, for purposes of computing the response time, until the date on which they are identified by a member of the Council staff as being a request pursuant to the Freedom of Information Act.

(b) Requests should describe the records sought in sufficient detail to allow Council staff to locate them with a reasonable amount of effort. Thus, where possible, specific information, including dates, geographic location of cases, and parties involved, should be supplied.

(c) A request for all records falling within a reasonably specific category shall be regarded as conforming to the statutory requirement that records be reasonably described if the records can be identified by any process that is not unreasonably burdensome or disruptive of Council operations.

(d) If a request is denied on the ground that it does not reasonably describe the records sought, the denial shall specify the reasons why the request was denied and shall extend to the requester an opportunity to confer with Council staff in order to reformulate the request in sufficient detail to allow the records to be produced.

### § 810.3 Action on requests.

(a) Once a requested record has been identified, the Administrative Officer shall notify the requester of a date and location where the records may be examined or of the fact that copies are available. The notification shall also advise the requester of any applicable fees under § 810.5.

(b) A reply denying a request shall be in writing, signed by the Administrative Officer and shall include:

(1) Reference to the specific exemption under the Act which authorizes the denial of the record, a brief explanation of how the exemption applies to the record requested, and a brief statement of why a discretionary release is not appropriate; and,

(2) A statement that the denial may be appealed under § 810.4 within 30 days by writing to the Executive Director, Advisory Council on Historic Preservation, 1522 K Street NW., Washington, D.C. 20005.

(c) The requirements of § 810.3(b)(1)–(2) do not apply to requests denied on the ground that they are not described with reasonable specificity and consequently cannot be identified.

(d) Within 10 working days from receipt of a request, the Administrative Officer shall determine whether to grant or deny the request and shall promptly notify the requester of the decision. In certain unusual circumstances specified below, the time for determinations on requests may be extended up to a total of 10 additional working days. The

requester shall be notified in writing of any extension and of the reason for it, as well as of the data on which a determination will be made. Unusual circumstances include:

(1) The need to search for and collect records from field offices or other establishments that are separate from the Washington office of the Council;

(2) The need to search for, collect, and examine a voluminous amount of material which is sought in a request; or,

(3) The need for consultation with another agency having substantial interest in the subject matter of the request.

If no determination has been made by the end of the 10-day period or the end of the last extension, the requester may deem his request denied and may exercise a right of appeal in accordance with Section 810.4.

**§ 810.4 Appeals.**

(a) When a request has been denied, the requester may, within 30 days of receipt of the denial, appeal the denial to the Executive Director of the Council. Appeals to the Executive Director shall be in writing, shall be addressed to the Executive Director, Advisory Council on Historic Preservation, 1522 K Street NW., Washington, D.C. 20005, and shall be clearly marked "FREEDOM OF INFORMATION APPEAL." Requests that are not so marked will be honored, but will be deemed not to have been received by the Council, for purposes of computing the response time, until the date on which they are identified by a member of the Council staff as being an appeal pursuant to the Freedom of Information Act.

(b) The appeal will be acted on within 20 working days of receipt. A written decision shall be issued. Where the decision upholds an initial denial of information, the decision shall include a reference to the specific exemption in the Freedom of Information Act which authorizes withholding the information, a brief explanation of how the exemption applies to the record withheld, and a brief statement of why a discretionary release is not appropriate. The decision shall also inform the requester of the right to seek judicial review in the U.S. District Court where the requester resides or has his principal place of business, or in which the agency records are situated, or in the District of Columbia.

(c) If no decision has been issued within 20 working days, the requester is deemed to have exhausted his administrative remedies.

**§ 810.5 Fees.**

(a) Fees shall be charged according to the schedules contained in paragraph (b) of this section unless it is determined that the requested information will be of primary benefit to the general public rather than to the requester. In that case, fees may be waived. Fees shall not be charged where they would amount to less than $3.00.

(b) The following charges shall be assessed:

(1) Copies of documents—$0.10 per page.

(2) Clerical searches—$1.00 for each one quarter hour in excess of the first quarter hour spent by clerical personnel in searching for requested records.

(3) Professional searches—$2.00 for each one quarter hour in excess of the first quarter hour spent by professional or managerial personnel in determining which records are covered by a request or other tasks that cannot be performed by clerical personnel.

(c) Where it is anticipated that fees may amount to more than $25.00, the requester shall be advised of the anticipated amount of the fee and his consent obtained before the request is processed. The time limits for processing the request under § 810.3 shall not begin to run until the requester's written agreement to pay the fees has been received. In the discretion of the Administrative Officer, advance payment of fees may be required before requested records are made available.

(d) Payment should be made by check or money order payable to the Advisory Council on Historic Preservation.

**§ 810.6 Exemptions.**

(a) The Freedom of Information Act exempts from disclosure nine categories of records which are described in 5 U.S.C. 552(b).

(b) When a request encompasses records which would be of concern to or which have been created primarily by another Federal agency, the record will be made available by the Council only if the document was created primarily to meet the requirements of the Council's regulations implementing Section 106 of the National Historic Preservation Act or other provisions of law administered primarily by the Council. If the record consists primarily of materials submitted by State or local governments, private individuals, organizations, or corporations, to another Federal agency in fulfillment of requirements for receiving assistance, permits, licenses, or approvals from the agency, the Council may refer the request to that agency. The requester shall be notified in writing of the referral.

[FR Doc. 81-26562 Filed 9-10-81; 8:45 am]
BILLING CODE 4310-10-M

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[A-3-FRL 1674-3a]**

### Approval of Revision of Maryland State Implementation Plan

**AGENCY:** Environmental Protection Agency.

**ACTION:** Final rule.

**SUMMARY:** The purpose of this notice is to formally withdraw Sections .06G (1), (2) and (3) of Maryland Regulations 10.18.04 and 10.18.05 from the Maryland SIP. Although these regulations, pertaining to control of photochemically reactive organic materials (PROM) were originally appproved by EPA on March 13, 1979, 44 FR 14555, EPA has subsequently determined that such approval action was in error.

**EFFECTIVE DATE:** Effective September 11, 1981.

**ADDRESSES:** Copies of the revision and the accompanying support documents are available for inspection during normal business hours at the following offices:

U.S. Environmental Protection Agency, Region III, Air Programs Branch, Curtis Building, Tenth Floor, Sixth and Walnut Streets, Philadelphia, Pennsylvania 19106, ATTN: Patricia Sheridan;

Maryland Department of Health and Mental Hygiene, Environmental Health Administration, Air Quality Programs, 201 W. Preston Street, Baltimore, Maryland 21201, ATTN: George P. Ferreri;

Public Information Reference Unit, EPA Library, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460;

The Office of the Federal Register, 1100 L Street, N.W., Room 8401, Washington, D.C. 20408.

**FOR FURTHER INFORMATION CONTACT:** Mr. Harold A. Frankford (3AH12), U.S. Environmental Protection Agency, Region III, Sixth and Walnut Streets, Philadelphia, Pennsylvania 19106, Telephone (215) 597-8392.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On April 18, 1980, 45 FR 26369, and May 7, 1980, 45 FR 30089, EPA published