

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by G. C. Hanford Manufacturing Co. The ANADA provides for the use of penicillin G potassium in the drinking water of turkeys for the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*.

DATES: This rule is effective July 9, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lonnie.luther@fda.gov.

SUPPLEMENTARY INFORMATION: G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201, filed ANADA 200-372 that provides for use of Penicillin G Potassium, USP, in the drinking water of turkeys for the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*. G. C. Hanford Manufacturing Co.'s HAN-PEN (penicillin G potassium, USP) is approved as a generic copy of Fort Dodge Animal Health's Penicillin G Potassium, USP, approved under NADA 55-060. The ANADA is approved as of May 21, 2004, and the regulations are amended in 21 CFR 520.1696b to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

**PART 520—ORAL DOSAGE FORM
NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.1696b is amended by revising paragraph (b) to read as follows:

**§ 520.1696b Penicillin G potassium in
drinking water.**

* * * * *

(b) *Sponsors.* See Nos. 010515, 046573, 053501, 059130, 059320, and 061623 in § 510.600(c) of this chapter.

* * * * *

Dated: June 17, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04-15657 Filed 7-8-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF AGRICULTURE**Forest Service****36 CFR Part 228****RIN 0596-AC17****Clarification as to When a Notice of
Intent and/or Plan of Operations Is
Needed for Locatable Mineral
Operations on National Forest System
Lands**

AGENCY: Forest Service, USDA.

ACTION: Interim rule; request for comments.

SUMMARY: This interim rule sets forth technical amendments which clarify the regulations regarding the requirement for filing a notice of intent or a plan of operations for locatable mineral operations on National Forest System lands. The Forest Service invites written comments on this interim rule.

DATES: This interim rule is effective August 9, 2004. Comments on this interim rule must be received in writing by September 7, 2004.

ADDRESSES: Send written comments to Forest Service, USDA, Attn: Director, Minerals and Geology Management (MGM) Staff, (2810), Mail Stop 1126, Washington, DC 20250-1125; by electronic mail to 36cfr228a@fs.fed.us;

by fax to (703) 605-1575; or by the electronic process available at Federal eRulemaking portal at <http://www.regulations.gov>. If comments are sent by electronic mail or by fax, the public is requested not to send duplicate written comments via regular mail. Please confine written comments to issues pertinent to the interim rule; explain the reasons for any recommended changes; and, where possible, reference the specific wording being addressed. All comments, including names and addresses when provided, will be placed in the record and will be available for public inspection and copying. The public may inspect comments received on this interim rule in the Office of the Director, MGM Staff, 5th Floor, Rosslyn Plaza Central, 1601 North Kent Street, Arlington, Virginia, on business days between the hours of 8:30 a.m. and 4 p.m. Those wishing to inspect comments are encouraged to call ahead at (703) 605-4646 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Sam Hotchkiss, Minerals and Geology Management Staff, (703) 605-4852.

SUPPLEMENTARY INFORMATION:**Public Notification and Request for
Comments**

The Department will make every effort to ensure locatable mineral operators, locatable mineral related organizations and associations, and other interested parties are informed of the availability of the interim rule. In order to ensure the widest distribution, the interim rule shall be distributed by paper copy mailings, e-mail notices, posting on the Forest Service Minerals and Geology Management Staff internet Web site, as well as published notices in local newspapers. Copies of the interim rule will also be provided to the appropriate Congressional Committee members.

Background and Need for Interim Rule

Since 1974, the Forest Service has applied the regulations at 36 CFR part 228, subpart A, to minimize adverse environmental impacts from mineral operations by requiring mineral operators to file proposed plans of operations for mineral operations which the District Ranger determines will likely cause significant surface disturbance to National Forest System (NFS) lands. These regulated operations may include the construction of storage facilities, mills, and mill buildings; placement of trailers or other personal equipment; residential occupancy and use; storage of vehicles and equipment;

excavation of holes, trenches, and pits by non-mechanized procedures; diversion of water; use of sluice boxes and portable devices for separating gold from sediments; off highway vehicle use; road and bridge construction; handling and disposal of mine and other wastes; and signing and fencing to restrict public use of the National Forest area affected by mining. The Forest Service and the courts have consistently required locatable mineral operators to obtain approval of a plan of operations whenever such operations would likely cause a significant surface disturbance whether or not those operations would always involve mechanized earth moving equipment or the cutting of trees. However, last year a District Court departed from this consistent interpretation and ruled that 36 CFR 228.4 (a)(2)(iii) allows a mining operation to occur on NFS lands without prior notification to the Forest Service or Forest Service approval when the operation, irrespective of the impact of its surface disturbing activities, does not involve mechanized earthmoving equipment or the cutting of trees. This unprecedented ruling severely restricts the ability of the Forest Service to regulate miners engaged in surface disturbing operations which have serious environmental impacts although they do not involve mechanized earth moving equipment or the cutting of trees. Moreover, this new interpretation of 36 CFR 228.4 (a)(2)(iii), if left unclarified, will result in significant and unnecessary impacts to NFS lands and resources, including impacts to water quality, visual quality, natural features, species listed under the Endangered Species Act, and conflicts with other National Forest users.

The technical changes contained in this interim rule, for which prior notice and opportunity for public comment is not legally required, are designed to prevent confusion as to the proper interpretation of the regulations. Specifically, the technical amendments clarify the long-standing requirement that a notice of intent and/or plan of operations is mandatory whenever the District Ranger determines that there may be significant surface disturbance to NFS lands and resources, whether or not the operation involves the cutting of trees or use of mechanized earth moving equipment.

Clarification for Submitting a Notice of Intent and a Plan of Operations

The technical amendments to § 228.4(a) clarify the requirement that a notice of intent is mandatory in any situation in which a mining operation causes a surface disturbance, regardless

of whether that disturbance is caused by mechanized earth moving equipment or the removal of timber. The technical amendments to § 228.4(a) also seek to eliminate any possible confusion by more specifically addressing the issue of what level of operation requires a notice of intent and what level of operation requires a plan of operations by directing a mining operator to submit a notice of intent to operate when the proposed operation might cause a disturbance to surface resources. After a notice of intent is submitted, the District Ranger determines whether the proposed operations will likely cause a significant disturbance of surface resources. If the determination is that the proposal will likely cause a significant disturbance of surface resources, the operator is notified that a plan of operations is required.

Exemption From Notice and Comment

Prior notice and opportunity for public comment is not required to promulgate technical amendments to a regulation. Moreover, even if the changes to 36 CFR 228.4(a) adopted herein were not technical amendments to that provision, the Administrative Procedure Act (the "APA") allows agencies to promulgate rules without notice and comment when an agency, for good cause, finds that notice and public comment are "impracticable, unnecessary, or contrary to the public interest." (5 U.S.C. 553(b)(3)(B)). Furthermore, the APA exempts certain rulemakings from its notice and comment requirements, including rulemakings involving "public property" (5 U.S.C. 553(a)(2)).

In 1971, Secretary of Agriculture Hardin announced a voluntary partial waiver from the APA notice and comment rulemaking exemptions. (July 24, 1971; 36 FR 13804). Thus, USDA agencies proposing rules generally provide notice and an opportunity for public comment on proposed rules. However, the Hardin policy permits agencies to publish final rules without prior notice and opportunity for public comment when an agency finds for good cause that notice and comment procedures would be impracticable, unnecessary, or contrary to the public interest. The courts have recognized this good cause exception of the Hardin policy and have indicated that since the publication requirement was adopted voluntarily, the Secretary should be afforded "more latitude" in making a good cause determination. *See Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984).

To the extent that 5 U.S.C. 553 applies to this interim rule, good cause exists to

exempt this rulemaking from advance notice and comment. (5 U.S.C. 553(b)(B) and 553(d)(3)). There has been widespread dissemination of the district court decision among groups of small miners who have long objected to obtaining prior approval for their mining operations, and who frequently believe that mining operations invariably justify residential occupancy of NFS lands. This, coupled with the fact that the season for locatable mineral operations has already begun in many areas of the country due to favorable weather conditions, including unusually low snow pack levels in much of the west, has resulted in the initiation of many mining operations on NFS lands for which a notice of intent to operate or a plan of operations has always been required without the submission of a notice of intent to operate or the approval of a plan of operations. Consequently, many operations are already ongoing and a much larger number are imminent which will unnecessarily and unjustifiably adversely impact NFS lands and resources, including water quality, visual quality, natural features and species listed under the Endangered Species Act. The only means by which such significant adverse environmental effects can be avoided during this field season for locatable mineral operations is to promulgate the amended rule immediately. Under these circumstances, the Department has determined that prior notice and opportunity for public comment are not practicable and are contrary to the public interest.

Comments received on this interim rule will be considered in adoption of a final rule, notice of which will be published in the **Federal Register**. The final rule will include a response to comments received and identify any revisions made to the rule as a result of the comments.

Regulatory Impact

This interim rule has been reviewed under USDA procedures and Executive Order 12866 on Regulatory Planning and Review. It has been determined that this interim rule is not significant. It will not have an annual effect of \$100 million or more on the economy nor adversely affect productivity, competition, jobs, the environment, public health or safety, nor State or local governments. This interim rule would not interfere with an action taken or planned by another agency nor raise new legal or policy issues. Finally, this action will not alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and

obligations of recipients of such programs.

Moreover, this interim rule has been considered in light of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), and it has been determined that this action will not have a significant economic impact on a substantial number of small entities as defined by that act. Therefore, a regulatory flexibility analysis is not required.

Environmental Impacts

This interim rule more clearly establishes the criteria for determining when a notice of intent to operate or a plan of operations should be submitted by the operator. Section 31.1b of Forest Service Handbook 1909.15 (57 FR 43168; September 18, 1992) excludes from documentation in an environmental assessment or impact statement “rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instruction.” This interim rule clearly falls within this category of actions and no extraordinary circumstances exist which would require preparation of an environmental assessment or an environmental impact statement.

Energy Effects

This interim rule has been reviewed under Executive Order 13211 of May 18, 2001, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.” It has been determined that this interim rule does not constitute a significant energy action as defined in the Executive Order.

Controlling Paperwork Burdens on the Public

This interim rule does not contain any new record keeping or reporting requirements or other information collection requirements as defined in 5 CFR part 1320 that are not already required by law or not already approved for use. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320 do not apply.

Federalism

The agency has considered this interim rule under the requirements of Executive Order 13132, Federalism, and Executive Order 12875, Government Partnerships. The agency has made a preliminary assessment that the interim rule conforms with the federalism principles set out in these Executive orders; would not impose any compliance costs on the States; and would not have substantial direct effects on the States, on the relationship

between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Based on comments received on this interim rule, the agency will consider if any additional consultations will be needed with the State and local governments prior to adopting a final rule.

Consultation and Coordination With Indian Tribal Governments

This interim rule does not have tribal implications as defined by Executive Order 13175, Consultation and Coordination With Indian Tribal Governments, and, therefore, advance consultation with tribes is not required.

No Takings Implications

This interim rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12630. It has been determined that the interim rule does not pose the risk of a taking of private property.

Civil Justice Reform

This interim rule has been reviewed under Executive Order 12988 on civil justice reform. If this interim rule were adopted, (1) all State and local laws and regulations that are in conflict with this interim proposed rule or that impedes its full implementation would be preempted; (2) no retroactive effect would be given to this interim proposed rule; and (3) it would not require administrative proceedings before parties may file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), which the President signed into law on March 22, 1995, the agency has assessed the effects of this interim rule on State, local, and tribal governments and the private sector. This interim rule would not compel the expenditure of \$100 million or more by any State, local, or tribal government or anyone in the private sector. Therefore, a statement under section 202 of the act would not be required.

List of Subjects in 36 CFR Part 228

Environmental protection, Mines, National forests, Oil and gas exploration, Public lands—mineral resources, Public lands—rights-of-way, Reporting and recordkeeping requirements, Surety bonds, Wilderness areas.

■ Therefore, for the reasons set forth in the preamble, amend part 228 of title 36 of the Code of Federal Regulations as follows:

PART 228—MINERALS

Subpart A—Locatable Minerals

■ 1. The authority citation for part 228 continues to read as follows:

Authority: 30 Stat. 35 and 36, as amended (16 U.S.C. 478, 551); 41 Stat. 437, as amended sec. 5102(d), 101 Stat. 1330–256 (30 U.S.C. 226); 61 Stat. 681, as amended (30 U.S.C. 601); 61 Stat. 914, as amended (30 U.S.C. 352); 69 Stat. 368, as amended (30 U.S.C. 611); and 94 Stat. 2400.

■ 2. Revise § 228.4(a) to read as follows:

§ 228.4 Plan of operations—notice of intent—requirements.

(a) If the District Ranger determines that any operation is causing or will likely cause significant disturbance of surface resources, the operator shall submit a proposed plan of operations to the District Ranger.

(1) Unless the District Ranger determines that an operation is causing or will likely cause a significant disturbance of surface resources, the requirements to submit a plan of operations shall not apply:

(i) To operations which will be limited to the use of vehicles on existing public roads or roads used and maintained for National Forest purposes;

(ii) To individuals desiring to search for and occasionally remove small mineral samples or specimens;

(iii) To prospecting and sampling which will not involve removal of more than a reasonable amount of mineral deposit for analysis and study;

(iv) To marking and monumenting a mining claim; or

(v) To subsurface operations.

(2) Except as provided in this paragraph, a notice of intent to operate is required from any person proposing to conduct operations which might cause disturbance of surface resources. Such notice of intent shall be submitted to the District Ranger having jurisdiction over the area in which the operations will be conducted. Each notice of intent to operate shall provide information sufficient to identify the area involved, the nature of the proposed operations, the route of access to the area of operations, and the method of transport. If a notice of intent is filed, the District Ranger will, within 15 days of receipt thereof, notify the operator whether a plan of operations is required. A notice of intent need not be filed:

(i) Where a plan of operations is submitted for approval in lieu thereof;

(ii) For operations excepted in paragraph (a)(1) of this section from the requirement to file a plan of operations; or

(iii) For operations which will not involve the use of mechanized earthmoving equipment such as bulldozers or backhoes or the cutting of trees, unless those operations otherwise might cause a disturbance of surface resources.

* * * * *

Dated: June 30, 2004.

Mark Rey,

Under Secretary, Natural Resources and Environment.

[FR Doc. 04-15483 Filed 7-8-04; 8:45 am]

BILLING CODE 3410-11-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[HI 001-001a; FRL-7778-5]

Revisions to the Hawaii State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a revision to the Hawaii State Implementation Plan (SIP). Under authority of the Clean Air Act as amended in 1990 (CAA or the Act), we are approving an amendment to the Air Quality Surveillance Network.

DATES: This rule is effective on September 7, 2004 without further notice, unless EPA receives adverse comments by August 9, 2004. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Send comments to Andy Steckel, Rulemaking Office Chief (AIR-4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901 or e-mail to steckel.andrew@epa.gov, or submit comments at <http://www.regulations.gov>.

You can inspect copies of the submitted SIP revision, EPA's technical support document (TSD), and public comments at our Region IX office during normal business hours by appointment. You may also see copies of the submitted SIP revision by appointment at the following locations:

Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, Room B-102, 1301 Constitution Avenue, NW., (Mail Code 6102T), Washington, DC 20460.

Hawaii Department of Public Health, Environmental Protection and Health

Services Division, 1250 Punchbowl Street, Honolulu, Oahu, Hawaii 96801.

FOR FURTHER INFORMATION CONTACT: Julie A. Rose, EPA Region IX, (415) 947-4126, rose.julie@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, "we," "us" and "our" refer to EPA.

Table of Contents

- I. The State's Submittal
 - A. What revision did the State submit?
 - B. Are there other versions of this network?
 - C. What is the purpose of the submitted revision?
- II. EPA's Evaluation and Action.
 - A. How is EPA evaluating the revision?
 - B. Does the revision meet the evaluation criteria?
 - C. Public comment and final action.
- III. Statutory and Executive Order Reviews

I. The State's Submittal

A. What Revision Did the State Submit?

The Hawaii Department of Health (HDH) submitted a revision to their air quality surveillance network for particulate matter of 10 microns or less (PM-10).

B. Are There Other Versions of the Network?

The air quality surveillance network was submitted on August 21, 1980 and approved in the **Federal Register** on August 10, 1981.

C. What Is the Purpose of the Submitted Revision?

In accordance with 40 CFR parts 51 and 58, States are required to submit a plan that provides for the establishment of an air quality surveillance system. The system must consist of a network of monitoring stations designated as State and Local Air Monitoring Stations (SLAMS) and National Air Monitoring Stations (NAMS) which measure ambient concentrations of pollutants for which standards have been established. The HDH revised their air quality surveillance network for particulate to accommodate the PM-10 provisions. The ambient particulate samplers were converted to the EPA-approved ambient PM-10 samplers on July 1, 1989 for the SLAMS and on July 1, 1988 for the NAMS. The HDH also committed to keep the descriptions of these networks updated and available to the public.

II. EPA's Evaluation and Action

A. How Is EPA Evaluating the Revision?

This revision updates the State's air quality surveillance network to include PM-10. The network must meet the requirements of 40 CFR parts 51 and 58.

B. Does the Revision Meet the Evaluation Criteria?

This revision is consistent with the relevant policy and guidance regarding air quality surveillance networks.

C. Public Comment and Final Action

As authorized in section 110(k)(3) of the Act, EPA is fully approving the submitted plan revision because we believe they fulfill all relevant requirements. We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted plan revision. If we receive adverse comments by August 9, 2004, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on September 7, 2004. This will incorporate these rules into the federally enforceable SIP.

III. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This action merely approves State law as meeting Federal requirements and imposes no additional requirements beyond those imposed by State law. Accordingly, the Administrator certifies 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. 601 *et seq.*). Because this rule approves pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and