Drug labeler code	Firm name and address
* * *	* * * *
012579	Roussel-UCLAF SA, Animal Health Division, 102 Route de Noisy, 93235 Romainville Cedex, France.
* * *	* * * *

Dated: August 20, 1996.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–22486 Filed 9–3–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Xylazine Injection

AGENCY: Food and Drug Administration, HHS.

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 Chanelle Pharmaceuticals Manufacturing Ltd. The ANADA provides for intravenous, intramuscular, or subcutaneous use of xylazine injection in dogs and cats to produce sedation accompanied by a shorter period of analgesia.

EFFECTIVE DATE: September 4, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center For Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland, filed ANADA 200–184, which provides for intravenous, intramuscular, and subcutaneous use of Chanazine® (20 milligrams/milliliter (mg/mL)) Injectable (xylazine hydrochloride equivalent to 20 mg xylazine per mL) in dogs and cats to produce sedation accompanied by a shorter period of analgesia. The drug is limited to use by or on the order of a licensed veterinarian.

Approval of ANADA 200–184 for Chanelle's Chanazine® (xylazine 20 mg/mL) Injectable is as a generic copy of Bayer's NADA 47–955 for Rompun® (xylazine 20 mg/mL) injectable. The ANADA is approved as of July 12, 1996, and the regulations are amended by revising 21 CFR 522.2662(b) 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.2662 is amended by revising the first two sentences in paragraph (b) to read as follows:

§ 522.2662 Xylazine hydrochloride injection.

* * * * *

(b) *Sponsor.* See 000856 in § 510.600(c) of this chapter for use in horses, wild deer, and elk. See 000859 and 061651 in § 510.600(c) of this chapter for use in horses, wild deer, elk, dogs, and cats. * * *

* * * * *

Dated: August 20, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–22487 Filed 9–3–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[OH–238–FOR, #72]

Ohio Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Ohio regulatory program (hereinafter referred to as the ''Ohio program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Ohio proposed revisions to rules pertaining to underground mining. The amendment is intended to revise the Ohio program to be consistent with the corresponding Federal regulations.

EFFECTIVE DATE: September 4, 1996.

FOR FURTHER INFORMATION CONTACT: George Rieger, Field Branch Chief, Appalachian Regional Coordinating Center, OSM, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937–2153.

SUPPLEMENTARY INFORMATION:

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

I. Background on the Ohio Program

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Background information on the Ohio program, including the Secretary's findings, the disposition of comments, and the conditions of

approval can be found in the August 10, 1982, Federal Register (42 FR 34668). Subsequent actions concerning conditions of approval and program amendments can be found at 30 CFR 935.11, 935.12, 935.15, and 935.16.

II. Submission of the Proposed Amendment

By letter dated May 23, 1996, (Administrative Record No. OH–2166–00) Ohio submitted a proposed amendment to its program pursuant to SMCRA at its own initiative. Ohio proposed to revise the Ohio Administrative Code (OAC) at sections 1501:13–4–12(G)(3)(d) and 4(f),(I)—Requirements for Special Categories of Mining; 1501:13–9–08(A),(B)—Protection of Underground Mining; and 1501:13–13–01—Concurrent Surface and Underground Mining.

OSM announced receipt of the proposed amendment in the June 24, 1996, Federal Register (61 FR 32382), and in the same document opened the public comment period and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on July 24, 1996.

III. Director's Findings

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

Revisions not specifically discussed below concern nonsubstantive wording changes, or revised cross-references and paragraph notations to reflect organizational changes resulting from this amendment.

A. Revisions to Ohio's Regulations That Are Substantively Identical to the Corresponding Provisions of the Federal Regulations

State regulation	Subject	Federal counterpart
OAC 1501:13–4–12(G)(3)(d)	Variances	30 CFR 785.18(b)(4)
OAC 1501:13–4–12(G)(4)(f)	Permit Issuance	30 CFR 785.18(c)(6)
OAC 1501:13–4–12(G)(4)(i)	Permit Issuance	30 CFR 785.18(c)(9)(iii)
OAC 1501:13–9–08(A)(1)	Protection of Underground Mining	30 CFR 816.79(b)

Because the above proposed revisions are identical in meaning to the corresponding Federal regulations, the Director finds that Ohio's proposed rules are no less effective than the Federal rules.

B. Revisions to Ohio's Regulations With No Corresponding Federal Regulations

Ohio proposed to delete OAC 1501:13–9–08(B) which required that surface mining operations be designed to protect disturbed surface areas, including spoil disposal sites, so as not to endanger any present or future coal mining operation. There is no corresponding Federal requirement to this provision. Therefore, the Director finds that the proposed deletion will not render the State program less effective than the Federal regulations.

Ohio proposed to delete OAC 1501:13–13–01 which specifies performance standards for concurrent surface and underground mining activities operating under a variance from contemporaneous reclamation requirements. These provisions have no corresponding Federal requirements. Ohio's provisions for variances in contemporaneous reclamation appear in OAC 1501:13–4–12(G). The Director finds that the proposed deletion will not render the State program less effective than the Federal regulations.

IV. Summary and Disposition of Comments

Public Comments

The Director solicited public comments and provided an opportunity for a public hearing on the proposed amendment. Two public comments were received. Because no one requested an opportunity to speak at a public hearing, no hearing was held.

One commenter stated that by rescinding OAC 1501:13–13–01, underground and surface coal reserves will be sterilized needlessly. The commenter suggests that this provision provides a degree of flexibility and that the 500 foot barrier was meant for underground and surface mines in the same seam. The Director notes that the changes proposed by Ohio simplify its rule structure by eliminating OAC 1501:13–13–01 which duplicates requirements found under 1501:13–4–12(G) (contemporaneous reclamation) and 1501:13–9–08 (concurrence). The revisions are not intended to create the loss of any flexibility nor cause any impact that would sterilize or impact the ability to mine certain reserves beyond those that currently exist in the Ohio program and do not render the program less effective than the Federal regulations.

The second commenter, the Ohio Historic Preservation Office (OHPO), expressed several concerns. OHPO feels that proposed rule changes pertaining to surface mining operations are not routinely sent to OHPO for review. OHPO is particularly concerned that there is no basis for selecting the 500 foot distance requirement specified in OAC 1501:13–9–08. If feels this could create situations where there are adverse effects to a property eligible for inclusion in the National Register of Historic Places (NRHP). OHPO is also concerned that the proposed changes could result in an acceleration of surface affectment actions with increased risks for adverse effects to properties that may be eligible for inclusion in the NRHP. The Director acknowledges that all requirements of coordination and consultation between agencies responsible for implementing the National Historic Preservation Act (NHPA) must be met. However, the changes proposed by Ohio do not impact compliance with NHPS and the OHPA comments are, therefore, outside the scope of this amendment. The Director notes that the referenced 500 foot distance concerns the amount of barrier that may be necessary to ensure the protection of underground coal miners and is consistent with Federal requirements. The barrier is a hydrologic and structural consideration and not considered as a direct limitation on surface impacts as OHPA suggests. The Director concludes that none of the changes proposed by Ohio create barriers to compliance with the NHPA.

Federal Agency Comments

Pursuant to 30 CFR 732.17(h)(11)(I), the Director solicited comments on the proposed amendment from various Federal agencies with an actual or potential interest in the Ohio program. None were received.

Environmental Protection Agency (EPA)

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

None of the revisions Ohio proposed to make in its amendment pertains to air or water quality standards. Nevertheless, OSM requested EPA's concurrence with the proposed amendment. EPA did not respond to OSM's request.

V. Director's Decision

Based on the above findings, the Director approves the proposed amendment as submitted by Ohio on May 23, 1996.

The Federal regulations at 30 CFR Part 935, codifying decisions concerning the Ohio program, are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

VI. Procedural Determinations

Executive Order 12866

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

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that, to the extend allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

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

Paperwork Reduction Act

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

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

Unfunded Mandates

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

List of Subjects in 30 CFR 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: August 19, 1996.

Tim L. Dieringer,

Acting Regional Director, Appalachian Regional Coordinating Center.

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

PART 935—OHIO

1. The authority citation for Part 935 continues to read as follows:

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

2. Section 935.15 is amended by adding paragraph (bbbb) to read as follows:

§ 935.15 Approval of regulatory program amendments.

* * * * *

(bbbb) The following rules, as submitted to OSM on May 23, 1996 are approved effective September 4, 1996.

OAC 1501:13–4–12(G)(3)(d)—Variance
OAC 1501:13–4–12(G)(4)(f),(i)—Permit Issuance
OAC 1501:13–9–08(A)(1)—Protection of Underground Mining
OAC 1501:13–9–08(B) (Deletion)—Protection of Underground Mining
OAC 1501:13–13–01 (Deletion)—Concurrent Surface and Underground Mining

[FR Doc. 96–22447 Filed 9–3–96; 8:45 am]

BILLING CODE 4310–05–M

30 CFR Part 944

[SPATS No. UT–034]

Utah Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing approval of a proposed amendment to the Utah regulatory program (hereinafter, the ''Utah program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of revisions to rules pertaining to petitions to initiate rulemaking, and backfilling and grading and highwall retention. The amendment revises the Utah program to be consistent with the corresponding Federal regulations.

EFFECTIVE DATE: September 4, 1996.

FOR FURTHER INFORMATION CONTACT: James F. Fulton, Telephone: (303) 672–5524.

SUPPLEMENTARY INFORMATION:

I. Background on the Utah Program

On January 21, 1981, the Secretary of the Interior conditionally approved the Utah program. General background information on the Utah program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Utah program can be found in the January 21, 1981, Federal Register (46 FR 5899). Subsequent actions concerning Utah's program and program amendments can be found at 30 CFR 944.15, 944.16, and 944.30.

II. Proposed Amendment

By letter dated November 30, 1995, and March 11, 1996, Utah submitted to OSM rules that it had promulgated for its program (administrative record Nos. UT–1079 and UT–1081) pursuant to SMCRA (30 U.S.C. 1201 *et seq.*). With three exceptions, these rules were substantively identical to rules that