because the effective date of the ban and the requested date coincide. Because FDA's estimate of the one-time, upper-bound cost for the conversion of canning lines in foreign countries was so broad ($33 million to $70 million), the cost information supplied by the Danish industry would not significantly alter the previous estimate.

V. Conclusions

FDA finds that a prior sanction exists for the use of lead solder in food cans. However, the available toxicological and exposure data on lead demonstrate that this use of lead solder may be injurious to the public health, particularly that of fetuses, infants, and children. Therefore, the agency is not codifying in its regulations the prior sanction for lead solder used in food cans and is instead amending its food additive regulations to prohibit this use of lead solder.

For clarification, FDA is modifying the language in proposed § 189.240(a) to read ''Lead solders are alloys of metals that include lead and are used in the construction of metal food cans.''

The ban on the initial introduction and initial delivery for introduction into interstate commerce of foods in lead-soldered cans will be effective 6 months after publication in the **Federal Register** of a final rule on this action. Existing stocks of lead-soldered canned foods will be allowed to be offered for sale within 1 year of the date of publication of the final rulemaking, so long as the level of lead in the food packaged in such cans is not such that the food may be rendered injurious to health.

FDA has now responded to a citizen petition (Docket No. 82P–0371/CP) requesting that the agency require warning labels on food cans that contain lead solder because the labeling issue will be moot with completion of this rulemaking.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before July 27, 1995, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from Mercedes Juan (Secretariat of Health, Mexico) to Jane E. Henney (FDA), dated June 3, 1993.

2. Letter from Myrna Sabino (Secretariat of Health, Brazil) to Jerry A. Burke (FDA), dated August 9, 1990.

3. Letter from Kazimierz Karlowski (National Institute of Hygiene, Poland) to Jerry A. Burke (FDA), dated December 21, 1990.

4. Letter from Alberto Rodas Maltez (Alimentos Kern, Guatemala) to Economics Staff (FDA), dated April 24, 1991.

5. Letter from Judith Sohar (National Institute of Food-Hygiene, Hungary) to Jerry A. Burke (FDA), dated September 26, 1990.

List of Subjects in 21 CFR Part 189

Food ingredients, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 189 is amended as follows:

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

1. The authority citation for 21 CFR part 189 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. New § 189.240 is added to subpart C to read as follows:

§ 189.240 Lead solders.

(a) Lead solders are alloys of metals that include lead and are used in the construction of metal food cans.

(b) Food packaged in any container that makes use of lead in can solder is deemed to be adulterated in violation of the Federal Food, Drug, and Cosmetic Act, based upon an order published in the **Federal Register** of June 27, 1995.

Dated: June 17, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–15593 Filed 6–26–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; 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 and intramuscular use of xylazine injection in horses and intramuscular use in *Cervidae* spp. to produce sedation accompanied by a shorter period of analgesia.

EFFECTIVE DATE: June 27, 1995.

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 200–139 which provides for intravenous and intramuscular use of Chanazine® (100 milligrams/milliliter (mg/mL)) Injectable (xylazine hydrochloride equivalent to 100 mg xylazine per mL) in horses and intramuscular use in *Cervidae* spp. (fallow deer, mule deer, Sika deer, white-tailed deer, and elk) 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 200–139 for Chanelle's Chanazine® (xylazine 100 mg/mL) Injectable is as a generic copy of Miles' NADA 047–956 for Rompun® (xylazine 100 mg/mL) Injectable. The ANADA is approved as of May 16, 1995, 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 addition, Chanelle Pharmaceuticals Manufacturing Ltd. has not previously been listed in the animal drug regulations as the sponsor of an approved application. At this time, 21 CFR 510.600(c) is amended to add entries for the firm.

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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Chanelle Pharmaceuticals Manufacturing Ltd.,'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''061651'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland.	061651
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
*	* * * * *
061651	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. 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).

4. Section 522.2662 is amended by revising the first sentence in paragraph (b) to read as follows:

§ 522.2662 Xylazine hydrochloride injection.

* * * * *

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

Dated: June 15, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–15594 Filed 6–26–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

[KY–206]

Kentucky Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving, with two exceptions, an amendment to the Kentucky regulatory program (hereinafter referred to as the ''Kentucky program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The revisions to the Kentucky Revised Statutes (KRS) pertain to remining, permits, definitions, appeal rights, water replacement, and permit revisions. The amendment is intended to revise the Kentucky program to be consistent with SMCRA.

EFFECTIVE DATE: June 27, 1995.

FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Director, Lexington Field Office, OSM, 2675 Regency Road, Lexington, Kentucky 40503. Telephone: (606) 233–2896.

SUPPLEMENTARY INFORMATION: .

I. Background on the Kentucky Program

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. Background information on the Kentucky program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the May 18, 1982, **Federal Register** (47 FR 21404). Subsequent actions concerning conditions of approval and program amendments can be found at 30 CFR 917.11, 917.13, 917.15, 917.16, and 917.17.

II. Submission of the Proposed Amendment

By letter dated April 29, 1994 (Administration Record No. KY–1279), Kentucky submitted a proposed amendment to its program pursuant to SMCRA. Kentucky proposed to revise the following sections of its statutes: KRS 42, 177, 211, 350, 351, and 352. The revisions pertain to remining, permits, definitions, appeal rights, water replacement, and permit revisions and are contained in Senate Bills 208, 214, 249, and House Bills 338 and 707.

OSM announced receipt of the proposed amendment in the May 20, 1994, **Federal Register** (59 FR 26472), 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 June 20, 1994.

By letter dated September 1, 1994 (Administrative Record No. KY–1319), Kentucky submitted additional explanatory information. Because the information merely clarified certain provisions of the proposed revisions,