

need only return those records that must be attached to the client's required forms under ERISA and the Internal Revenue Code. The enrolled actuary, however, must provide the client with reasonable access to review and copy any additional records of the client retained by the enrolled actuary under State law that are necessary for the client to comply with his or her obligations under ERISA and the Internal Revenue Code.

(2) For purposes of this section, records of the client include all documents or written or electronic materials provided to the enrolled actuary, or obtained by the enrolled actuary in the course of the enrolled actuary's representation of the client, that preexisted the retention of the enrolled actuary by the client. The term "records of the client" also includes materials that were prepared by the client or a third party (not including an employee or agent of the enrolled actuary) at any time and provided to the enrolled actuary with respect to the subject matter of the representation. The term "records of the client" also includes any return, claim for refund, schedule, affidavit, appraisal or any other document prepared by the enrolled actuary, or his or her employee or agent, that was presented to the client with respect to a prior representation if such document is necessary for the taxpayer to comply with his or her current obligations under ERISA and the Internal Revenue Code. The term "records of the client" does not include any return, claim for refund, schedule, affidavit, appraisal or any other document prepared by the enrolled actuary or the enrolled actuary's firm, employees or agents if the enrolled actuary is withholding such document pending the client's performance of its contractual obligation to pay fees with respect to such document.

\* \* \* \* \*

(l) The rules of this section apply to all actuarial services and related acts performed on or after May 2, 2011.

■ **Par. 10.** Section 901.31 is amended by revising paragraphs (a) and (c) to read as follows:

**§ 901.31 Grounds for suspension or termination of enrollment.**

(a) *Failure to satisfy requirements for enrollment.* The enrollment of an actuary may be terminated if it is found that the actuary did not satisfy the eligibility requirements set forth in § 901.11 or § 901.12.

\* \* \* \* \*

(c) *Disreputable conduct.* The enrollment of an actuary may be suspended or terminated if it is found that the actuary has, at any time after he/she applied for enrollment, engaged in any conduct set forth in § 901.12(f) or other conduct evidencing fraud, dishonesty, or breach of trust. Such other conduct includes, but is not limited to, the following:

\* \* \* \* \*

■ **Par. 11.** Section 901.32 is amended by revising the last sentence to read as follows:

**§ 901.32 Receipt of information concerning enrolled actuaries.**

\* \* \* If any other person has information of any such violation, he/she may make a report thereof to the Executive Director.

■ **Par. 12.** Section 901.47 is amended by revising the last sentence to read as follows:

**§ 901.47 Transcript.**

\* \* \* Copies of exhibits introduced at the hearing or at the taking of depositions will be supplied to parties upon the payment of a reasonable fee (31 U.S.C. 9701).

■ **Par. 13.** Section 901.72 is added to read as follows:

**§ 901.72 Additional rules.**

The Joint Board may, in notice or other guidance of general applicability, provide additional rules regarding the enrollment of actuaries.

Approved: March 2, 2011.

**Carolyn Zimmerman,**  
Chairman, Joint Board for the Enrollment of Actuaries.

[FR Doc. 2011-7573 Filed 3-29-11; 11:15 am]

BILLING CODE 4810-25-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 510, 520, 522, 524, and 558

[Docket No. FDA-2011-N-0160]

#### **Animal Drugs, Feeds, and Related Products; Withdrawal of Approval of New Animal Drug Applications; Chorionic Gonadotropin; Cuprimyxin; Diethylcarbamazine; Levamisole; Nitrofurazone; Phenylbutazone; Pyrantel; Tylosin; Tylosin and Sulfamethazine**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations by removing those portions that reflect approval of 13 new animal drug applications (NADAs). In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of these NADAs.

**DATES:** This rule is effective April 11, 2011.

**FOR FURTHER INFORMATION CONTACT:** John Bartkowiak, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9079, e-mail: [john.bartkowiak@fda.hhs.gov](mailto:john.bartkowiak@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The sponsors of the 13 approved NADAs listed in table 1 have requested that FDA withdraw approval because the products are no longer manufactured or marketed.

TABLE 1—VOLUNTARY REQUESTS FOR WITHDRAWAL OF APPROVAL OF 13 NADAs

Sponsor	NADA No. product (established name of drug)	21 CFR section affected (sponsor's drug labeler code)
Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054-1298.	NADA 093-029, UNITOP Cream (cuprimyxin) .....	524.520 (063238).
Quali-Tech Products, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318.	NADA 097-981, TYLAN 40 Sulfa-G Premix (tylosin phosphate/sulfamethazine).	558.630 (016968).
Abraxis Pharmaceutical Products, Division of Abraxis Bioscience, 6133 River Rd., suite 500, Rosemont, IL 60018.	NADA 100-840, Chorionic Gonadotropin for Injection (chorionic gonadotropin).	522.1081 (063323).
Furst-McNess Co., Freeport, IL 61032 .....	NADA 100-991, McNess Custom Premix L200 (tylosin phosphate).	558.625 (010439).
Fort Dodge Animal Health, Division of Wyeth Holdings, a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017.	NADA 101-079 TRAMISOL-10% Pig Wormer (levamisole)	Not codified (000856).
Waterloo Mills Co., 2050 Mitchell Ave., Waterloo, IA 50704	NADA 101-905, Mill Co-Medicator TY-10 (tylosin phosphate).	558.625 (017139).
Waterloo Mills Co., 2050 Mitchell Ave., Waterloo, IA 50704	NADA 101-906, Mill Co-Medicator TS-40 Premix (tylosin phosphate/sulfamethazine).	558.630 (017139).
Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.	NADA 102-824, Phenylbutazone Tablets (phenylbutazone)	520.1720a (055246).
Wendt Laboratories, Inc., 100 Nancy Dr., Belle Plaine, MN 56011.	NADA 108-487, DEC Tabs (diethylcarbamazine citrate) ....	520.622a (015579).
Wendt Laboratories, Inc., 100 Nancy Dr., Belle Plaine, MN 56011.	NADA 108-863, DEC Chewable Tabs (diethylcarbamazine citrate).	520.622c (015579).
Furst-McNess Co., Freeport, IL 61032 .....	NADA 140-820, TYLAN 40 Sulfa-G Premix (tylosin phosphate/sulfamethazine).	558.630 (010439).
Furst-McNess Co., Freeport, IL 61032 .....	NADA 140-825, BANMINTH Intermediate Premix (pyrantel tartrate).	558.485 (010439).
Hess & Clark, Inc., 944 Nandino Blvd., Lexington, KY 40511.	NADA 140-910, NFZ Wound Powder (nitrofurazone) .....	524.1580c (050749).

In a notice published elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 93-029, 97-981, 100-840, 100-991, 101-079, 101-905, 101-906, 102-824, 108-487, 108-863, 140-820, 140-825, and 140-910, and all supplements and amendments thereto, is withdrawn, effective April 11, 2011. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these withdrawals of approval and a current format.

Following these changes of sponsorship, Abraxis Pharmaceutical Products, Furst-McNess Co., Roche Vitamins, Inc., Waterloo Mills Co., and Wendt Laboratories, Inc., are no longer the sponsors of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

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

##### 21 CFR Part 510

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

##### 21 CFR Parts 520, 522, and 524

Animal drugs.

##### 21 CFR Part 558

Animal drugs, Animal feeds.

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, 520, 522, 524, and 558 are amended as follows:

#### PART 510—NEW ANIMAL DRUGS

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

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

##### § 510.600 [Amended]

- 2. In § 510.600, in the table in paragraph (c)(1), remove the entries for "Abraxis Pharmaceutical Products", "Furst-McNess Co.", "Roche Vitamins, Inc.", "Waterloo Mills Co.", and "Wendt Laboratories, Inc."; and in the table in paragraph (c)(2), remove the entries for "010439", "015579", "017139", "063238", and "063323".

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

- 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

- 4. In § 520.622a, remove and reserve paragraph (a)(1); in paragraph (a)(5), remove "000081" and in its place add "No. 000061"; and revise paragraph (b)(2) to read as follows:

##### § 520.622a Diethylcarbamazine citrate tablets.

\* \* \* \* \*

(b) \* \* \*

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

- 5. In § 520.622c, remove and reserve paragraph (b)(1); remove reserved paragraph (b)(7); and revise paragraph (c)(3) to read as follows:

##### § 520.622c Diethylcarbamazine citrate chewable tablets.

\* \* \* \* \*

(c) \* \* \*

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

##### § 520.1720a [Amended]

- 6. In § 520.1720a, remove and reserve paragraph (b)(4).

## PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

### § 522.1081 [Amended]

■ 8. In paragraph (b)(2) of § 522.1081, remove “Nos. 058639 and 063323” and in its place add “No. 058639”.

## PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 9. The authority citation for 21 CFR part 524 continues to read as follows:

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

### § 524.520 [Removed]

■ 10. Remove § 524.520.

### § 524.1580c [Amended]

■ 11. In paragraph (b) of § 524.1580c, remove “Nos. 000010, 000069, and 050749” and in its place add “Nos. 000010 and 000069”.

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

■ 12. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

### § 558.485 [Amended]

■ 13. In § 558.485, in paragraph (b)(3), remove “010439”.

### § 558.625 [Amended]

■ 14. In § 558.625, remove and reserve paragraphs (b)(42) and (b)(45).

### § 558.630 [Amended]

■ 15. In § 558.630, remove and reserve paragraph (b)(4); and in paragraph (b)(5), remove “010439,” and “016968,”.

Dated: March 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-7560 Filed 3-30-11; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1310

[Docket No. DEA-320F]

RIN 1117-AB24

### Control of Ergocristine, a Chemical Precursor Used in the Illicit Manufacture of Lysergic Acid Diethylamide, as a List I Chemical

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

**SUMMARY:** This rulemaking finalizes a February 24, 2010, Notice of Proposed Rulemaking in which DEA proposed to control the chemical precursor ergocristine as a List I chemical under the Controlled Substances Act (CSA). Clandestine laboratories are using this chemical as a substitute for the List I chemicals ergotamine and ergonovine to illicitly manufacture the schedule I controlled substance lysergic acid diethylamide (LSD).

This rule is being finalized as proposed. Therefore, handlers of ergocristine shall be subject to the chemical regulatory provisions of the CSA and its implementing regulations. This rulemaking does not establish a threshold for domestic and international transactions of ergocristine. As such, all transactions involving ergocristine, regardless of size, shall be regulated. This rulemaking also specifies that chemical mixtures containing ergocristine will not be exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of ergocristine shall be regulated and subject to control under the CSA.

**DATES:** This rulemaking becomes effective May 2, 2011. Persons seeking registration must apply on or before May 2, 2011 to continue their business pending final action by DEA on their application.

**FOR FURTHER INFORMATION CONTACT:** Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152; telephone: (202) 307-7183.

#### SUPPLEMENTARY INFORMATION:

#### Background

Lysergic acid diethylamide (LSD) is a synthetic schedule I hallucinogen. It is the most potent hallucinogen known

and only microgram amounts are required to produce overt hallucinations. It induces a heightened awareness of sensory input that is accompanied by an enhanced sense of clarity, but reduced ability to control what is experienced.

#### Illicit Production of LSD

LSD has been manufactured illegally since the 1960s. A limited number of chemists, probably less than a dozen, are believed to be manufacturing nearly all of the LSD available in the United States. Clandestine laboratory operators must adhere to precise and complex production procedures, and production of LSD is relatively difficult.

LSD has historically been produced from lysergic acid, which is made from ergotamine or ergonovine, substances derived from an ergot fungus on rye, or from lysergic acid amide, a chemical found in morning glory seeds.

#### Movement to Ergocristine as LSD Precursor and Largest LSD Laboratory Ever Seized by DEA

Because of the existing CSA regulatory controls on the LSD precursors lysergic acid, lysergic acid amide, ergotamine, and ergonovine, clandestine laboratory operators have sought uncontrolled sources of precursor material for the production of LSD. This has led to the illicit utilization of the precursor chemical ergocristine as a direct substitute for ergotamine and ergonovine for the illicit production of LSD. In fact, the largest clandestine LSD laboratory ever seized by DEA utilized ergocristine as the LSD precursor. Recipes documenting procedures for utilizing ergocristine in LSD synthesis are easily found on the Internet.

#### Availability of the Precursor Chemical

DEA has determined that ergocristine is readily available from commercial chemical suppliers. DEA has identified at least three suppliers of ergocristine, of which one distributor is located domestically; the other two are based in Germany and the Czech Republic.

This rule implements both domestic and import/export controls on ergocristine (and its salts). As noted in the February 24, 2010, Notice of Proposed Rulemaking (75 FR 8287), such controls are deemed necessary for law enforcement to identify domestic and international transactions in ergocristine, due to growing concerns regarding its use for the illicit manufacture of LSD.