

resulting overpayments. One commenter recommended that we clarify that an annulment ab initio will not affect the eligibility for child's benefits to stepchildren prior to annulments. One of these commenters asked us to notify families affected by this final rule.

*Response:* As we stated above, we are not adopting our proposed rules about ab initio or prospective marriage annulments at this time.

## Regulatory Procedures

### Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that this final rule meets the criteria for a significant regulatory action under Executive Order 12866. Thus, OMB reviewed it.

### Regulatory Flexibility Act

We certify that this final rule will not have a significant economic impact on a substantial number of small entities because it affects only individual persons. Therefore, the Regulatory Flexibility Act, as amended, does not require us to develop a regulatory flexibility analysis.

### Paperwork Reduction Act

This final rule does not impose reporting or recordkeeping requirements subject to OMB clearance.

(Catalog of Federal Domestic Assistance Program Nos. 96.001 Social Security-Disability Insurance; 96.002 Social Security-Retirement Insurance; 96.004 Social Security-Survivors Insurance)

### List of Subjects in 20 CFR Part 404

Administrative practice and procedure; Blind; Disability benefits; Old-Age, Survivors and Disability Insurance; Reporting and recordkeeping requirements; Social Security.

Dated: June 7, 2010.

**Michael J. Astrue,**  
*Commissioner of Social Security.*

■ For the reasons stated in the preamble, we are amending 20 CFR part 404 subpart D as set forth below:

## PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950— )

### Subpart D—[Amended]

■ 1. The authority citation for subpart D of part 404 continues to read as follows:

**Authority:** Secs. 202, 203(a) and (b), 205(a), 216, 223, 225, 228(a)–(e), and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 403(a) and (b), 405(a), 416, 423, 425, 428(a)–(e), and 902(a)(5)).

■ 2. Amend § 404.352 by adding paragraph (b)(7) to read as follows:

### § 404.352 When does my entitlement to child's benefits begin and end?

\* \* \* \* \*

(b) \* \* \*

(7) With the month in which the divorce between your parent (including an adoptive parent) and the insured stepparent becomes final if you are entitled to benefits as a stepchild and the marriage between your parent (including an adoptive parent) and the insured stepparent ends in divorce.

\* \* \* \* \*

■ 3. Amend § 404.363 by revising the section heading and introductory text to read as follows:

### § 404.363 When is a stepchild dependent?

If you are the insured's stepchild, as defined in § 404.357, we consider you dependent on him or her if you were receiving at least one-half of your support from him or her at one of these times—

\* \* \* \* \*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

[Docket No. FDA-2010-N-0002]

### New Animal Drugs; Change of Sponsor; Withdrawal of Approval of New Animal Drug Applications; Deslorelin Acetate; Dichlorophene and Toluene Capsules; Pyrantel Pamoate Suspension

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Peptech Animal Health Pty, Ltd. to Dechra, Ltd. and for an abbreviated new animal drug application (ANADA) from Church & Dwight Co., Inc., to Pegasus Laboratories, Inc. In addition, FDA is removing those portions of the regulations that reflect approval of two other NADAs transferred from Church & Dwight Co., Inc., to Pegasus Laboratories, Inc., for which voluntary withdrawal of approval was requested after the change of sponsorship. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of these two NADAs.

**DATES:** This rule is effective:

1. August 27, 2010 for 21 CFR 510.600(c), 520.2043, and 522.533.

2. September 7, 2010 for 21 CFR 520.580.

### FOR FURTHER INFORMATION CONTACT:

David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8307, e-mail: david.newkirk@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** Church & Dwight Co., Inc., 469 North Harrison St., Princeton, NJ 08543-5297, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 101-497 and NADA 101-498 for oral capsules containing dichlorophene and toluene, and ANADA 200-028 for an oral suspension of pyrantel pamoate to Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514. Accordingly, the agency is amending the regulations in 21 CFR 520.2043 to reflect the transfer of ownership.

Peptech Animal Health Pty, Ltd., 19-25 Khartoum Rd., Macquarie Park, New South Wales 2113, Australia, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141-044 for subcutaneous implants containing deslorelin acetate to Dechra, Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom. Accordingly, the agency is amending the regulations in 21 CFR 522.533 to reflect the transfer of ownership and a current format.

Following these changes of sponsorship, Pegasus Laboratories, Inc., has requested that FDA withdraw approval of the two NADAs for dichlorophene and toluene capsules because they are no longer manufactured or marketed. In a notice published elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADA 101-497 and 101-498, and all supplements and amendments thereto, is withdrawn, effective September 7, 2010. As provided in the regulatory text of this document, the agency is amending the regulations in 21 CFR 520.580 to reflect these withdrawals of approval.

Also, following these changes of sponsorship, Church & Dwight Co., Inc., and Peptech Animal Health Pty, Ltd., are no longer 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 and 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 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:** 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 “Church & Dwight Co., Inc.” and “Peptech Animal Health Pty, Ltd.”; and in the table in paragraph (c)(2), remove the entries for “010237” and “064288”.

## 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.

### § 520.580 [Amended].

■ 4. In paragraph (b)(1) of § 520.580, remove “010237.”

### § 520.2043 [Amended]

■ 5. In paragraph (b)(2) of § 520.2043, remove “010237” and in its place add “055246”.

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

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

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

■ 7. In § 522.533, revise the section heading and paragraph (b), add paragraph (c), and remove paragraph (d) to read as follows:

### § 522.533 Deslorelin.

\* \* \* \* \*

(b) *Sponsor.* See No. 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses and ponies—*(1) *Amount.* One implant per mare subcutaneously in the neck.

(2) *Indications for use.* For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 millimeters in diameter.

(3) *Limitations.* Do not use in horses or ponies intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: August 23, 2010.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

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**BILLING CODE 4160–01–S**

## DEPARTMENT OF STATE

### 22 CFR Parts 124, 125, 126, and 129

[Public Notice: 7134]

RIN 1400–AC62

### Amendment to the International Traffic in Arms Regulations: Removing Requirement for Prior Approval for Certain Proposals to Foreign Persons Relating to Significant Military Equipment

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Department of State is amending the International Traffic in Arms Regulations (ITAR) to remove the requirements for prior approval or prior notification for certain proposals to foreign persons relating to significant military equipment.

**DATES:** *Effective Date:* This rule is effective August 27, 2010.

**FOR FURTHER INFORMATION CONTACT:** Director Charles Shotwell, Office of Defense Trade Controls Policy, Department of State, Telephone (202) 663–2792 or Fax (202) 261–8199; E-mail [DDTCResponseTeam@state.gov](mailto:DDTCResponseTeam@state.gov). ATTN: Regulatory Change, Section 126.8.

**SUPPLEMENTARY INFORMATION:** In accordance with the President’s Export Control Reform effort, on March 29, 2010, the Department published a Notice of Proposed Rulemaking (NPRM) to eliminate the requirements for prior approval or prior notification for certain proposals to foreign persons relating to significant military equipment at § 126.8 of the ITAR. Effective September 1, 1977, the Department of State amended § 123.16 to require Department of State approval before a proposal or presentation is made that is designed to constitute the basis for a decision to purchase significant combat equipment,

involving the export of an item on the U.S. Munitions List, valued at \$7,000,000 or more for use by the armed forces of a foreign country (42 FR 41631, dated August 18, 1977). Also, § 124.06, entitled, “Approval of proposals for technical assistance and manufacturing license agreements,” was amended to require similar prior approval with respect to proposals and presentations for technical assistance and manufacturing license agreements involving the production or assembly of significant combat equipment.

“Proposals to foreign persons relating to significant military equipment” became § 126.8 in a final rule effective January 1, 1985 (49 FR 47682, dated December 6, 1984). Section 126.8 did not require prior approval of the Department of State when the proposed sale was to the armed forces of a member of the North Atlantic Treaty Organization (NATO), Australia, Japan, or New Zealand, except with respect to manufacturing license agreements or technical assistance agreements.

A prior notification requirement, instead of prior approval, was added to § 126.8 in a final rule effective March 31, 1985 (50 FR 12787, dated April 1, 1985). Prior notification to the Department of State was required 30 days in advance of a proposal or presentation to any foreign person where such proposals or presentations concerned equipment previously approved for export.

The current § 126.8 requires prior approval or prior notification for certain proposals and presentations to make a determination whether to purchase significant military equipment valued at \$14,000,000 or more (other than a member of NATO, Australia, New Zealand, Japan, or South Korea), or whether to enter into a manufacturing license agreement or technical assistance agreement for the production or assembly of significant military equipment, regardless of dollar value.

These types of proposals and presentations usually involve large dollar amounts. Before the defense industry undertakes the effort involved in formulating its proposals and presentations, if there is any doubt that the corresponding license application or proposed agreement would be authorized by the Department of State, the industry may request an advisory opinion (*see* § 126.9). The written advisory opinion, though not binding on the Department, helps inform the defense industry whether the Department would likely grant a license application or proposed agreement. Currently, the time between submitting a license application or proposed