

agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. Information collections in this IFR have been previously approved under OMB No. 1205-0466. No change in that collection is proposed by this IFR.

#### *L. Good Cause Exception*

The Department finds good cause to adopt this IFR, effective immediately, and without prior notice and comment. See 5 U.S.C. 553(b)(3) and 553(d)(3). The reasons for extending the transition period, discussed above, lead the Department to believe that action must be taken quickly to ensure that the Department and employers are able to meet their statutory obligations and to prevent confusion, ensure program integrity, and maximize the availability of job opportunities for the U.S. workforce during a time of economic crisis. Absent this extension, on approximately October 18, 2009, employers will be forced to comply with all elements of the 2008 Final Rule. In order to avoid the confusion and disruption that this will cause, it is essential that extension of the transition period be effective before that date. This circumstance precludes the receipt and consideration of comments before this rule becomes effective. In addition, as discussed above, the Department has considered the comments received after the promulgation of the April 16 Rule extending the transition period to January 1, 2010. There was no significant opposition to the extension and the current rule presents no new issues.

#### **List of Subjects in 20 CFR Part 655**

Administrative practice and procedure, Foreign workers, Employment, Employment and training, Enforcement, Forest and forest products, Fraud, Health professions, Immigration, Labor, Passports and visas, Penalties, Reporting and recordkeeping requirements, Unemployment, Wages, Working conditions.

■ For the reasons stated in the preamble, the Department amends 20 CFR part 655 as follows:

#### **PART 655—TEMPORARY EMPLOYMENT OF FOREIGN WORKERS IN THE UNITED STATES**

■ 1. The authority citation for part 655 continues to read as follows:

**Authority:** Section 655.0 issued under 8 U.S.C. 1101(a)(15)(E)(iii), 1101(a)(15)(H)(i) and (ii), 1182(m), (n) and (t), 1184(c), (g), and (j), 1188, and 1288(c) and (d); sec. 3(c)(1),

Pub. L. 101-238, 103 Stat. 2099, 2102 (8 U.S.C. 1182 note); sec. 221(a), Pub. L. 101-649, 104 Stat. 4978, 5027 (8 U.S.C. 1184 note); sec. 303(a)(8), Pub. L. 102-232, 105 Stat. 1733, 1748 (8 U.S.C. 1101 note); sec. 323(c), Pub. L. 103-206, 107 Stat. 2428; sec. 412(e), Pub. L. 105-277, 112 Stat. 2681 (8 U.S.C. 1182 note); sec. 2(d), Pub. L. 106-95, 113 Stat. 1312, 1316 (8 U.S.C. 1182 note); Pub. L. 109-423, 120 Stat. 2900; and 8 CFR 214.2(h)(4)(i). Section 655.00 issued under 8 U.S.C. 1101(a)(15)(H)(ii), 1184(c), and 1188; and 8 CFR 214.2(h). Subparts A and C issued under 8 CFR 214.2(h). Subpart B issued under 8 U.S.C. 1101(a)(15)(H)(ii)(a), 1184(c), and 1188; and 8 CFR 214.2(h). Subparts D and E authority repealed. Subparts F and G issued under 8 U.S.C. 1288(c) and (d); and sec. 323(c), Pub. L. 103-206, 107 Stat. 2428. Subparts H and I issued under 8 U.S.C. 1101(a)(15)(H)(i)(b) and (b)(1), 1182(n) and (t), and 1184(g) and (j); sec. 303(a)(8), Public Law 102-232, 105 Stat. 1733, 1748 (8 U.S.C. 1101 note); sec. 412(e), Pub. L. 105-277, 112 Stat. 2681; and 8 CFR 214.2(h). Subparts J and K authority repealed. Subparts L and M issued under 8 U.S.C. 1101(a)(15)(H)(i)(c) and 1182(m); sec. 2(d), Pub. L. 106-95, 113 Stat. 1312, 1316 (8 U.S.C. 1182 note); Pub. L. 109-423, 120 Stat. 2900; and 8 CFR 214.2(h).

■ 2. Amend § 655.100 by revising paragraph (b)(1) and the introductory text of paragraph (b)(2) to read as follows:

#### **§ 655.100 Overview of subpart B and definition of terms.**

\* \* \* \* \*

(b) \* \* \*

(1) *Compliance with these regulations.* Employers with a date of need for H-2A workers for temporary or seasonal agricultural services on or after June 1, 2010 must comply with all of the obligations and assurances required in this subpart.

(2) *Transition from former regulations.* Employers with a date of need for H-2A workers for temporary or seasonal agricultural services prior to June 1, 2010 will file applications in the following manner:

\* \* \* \* \*

Signed in Washington, DC, this 10th day of November 2009.

**Jane Oates,**

*Assistant Secretary, Employment and Training Administration.*

[FR Doc. E9-27496 Filed 11-16-09; 8:45 am]

**BILLING CODE 4510-FP-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 529**

[Docket No. FDA-2009-N-0665]

#### **Certain Other Dosage Form New Animal Drugs; Progesterone Intravaginal Inserts**

**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 original new animal drug application (NADA) filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The NADA provides for use of a progesterone intravaginal insert for induction of estrus in ewes during seasonal anestrus.

**DATES:** This rule is effective November 17, 2009.

#### **FOR FURTHER INFORMATION CONTACT:**

Suzanne J. Sechen, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8105, e-mail: [suzanne.sechen@fda.hhs.gov](mailto:suzanne.sechen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, has filed NADA 141-302 for over-the-counter use of EAZI-BREED CIDR (progesterone) Sheep Inserts for induction of estrus in ewes during seasonal anestrus. The NADA is approved as of October 1, 2009, and the regulations are amended in 21 CFR 529.1940 to reflect the approval.

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.

Under section 573(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ccc-2), this supplemental approval qualifies for 7 years of exclusive marketing rights beginning on the date of approval because the new animal drug has been declared a designated new animal drug by FDA under section 573(a) of the act.

The agency has determined under 21 CFR 25.33 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 529

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 529 is amended as follows:

#### PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 2. Section 529.1940 is revised to read as follows:

##### § 529.1940 Progesterone intravaginal inserts.

(a) *Specifications.* Each insert contains:

(1) 1.38 grams (g) progesterone in molded silicone over a nylon spine.

(2) 0.3 g progesterone in molded silicone over a flexible nylon spine.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter for use of the product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; and the product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See § 556.540(a) of this chapter.

(d) *Special considerations*—(1) *Cows and ewes.* Product labeling shall bear the following warnings: “Avoid contact with skin by wearing protective gloves when handling inserts. Store removed inserts in a sealable container until they can be disposed of in accordance with applicable local, state, and Federal regulations.”

(2) *Cows.* This product is approved with the concurrent use of dinoprost solution on day 6 of the 7-day administration period when used for indications listed in paragraph (e)(1)(ii)(A) of this section. See § 522.690(c) of this chapter.

(e) *Conditions of use*—(1) *Cows*—(i) *Amount.* Administer one intravaginal

insert per animal for 7 days. When used for indications listed in paragraph (e)(1)(ii)(A) of this section, administer 25 milligrams (mg) dinoprost (5 milliliters (mL) of 5 mg/mL solution as in § 522.690(a) of this chapter) as a single intramuscular injection one day prior to insert removal.

(ii) *Indications for use*—(A) For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, for advancement of first postpartum estrus in suckled beef cows, and for advancement of first pubertal estrus in replacement beef heifers.

(B) For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus.

(iii) *Limitations.* Do not use in animals with abnormal, immature, or infected genital tracts; or in beef cows that are fewer than 20 days postpartum; or in beef or dairy heifers of insufficient size or age for breeding. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should be disposed after a single use. Administration of vaginal inserts for periods greater than 7 days may result in reduced fertility. Dinoprost solution provided by No. 000009 in § 510.600(c) of this chapter.

(2) *Ewes*—(i) *Amount.* Administer one intravaginal insert per animal for 5 days.

(ii) *Indications for use.* For induction of estrus in ewes (sheep) during seasonal anestrus.

(iii) *Limitations.* Do not use in animals with abnormal, immature, or infected genital tracts; or in ewes that have never lambed. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should be disposed after a single use. A pre-slaughter withdrawal period is not required when this product is used according to directions.

Dated: November 3, 2009.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. E9–27497 Filed 11–16–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 9471]

RIN 1545–BH68

#### Employee Stock Purchase Plans Under Internal Revenue Code Section 423

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations.

**SUMMARY:** This document contains the final regulations relating to options granted under an employee stock purchase plan as defined in section 423 of the Internal Revenue Code (Code). These final regulations affect certain taxpayers who participate in the transfer of stock pursuant to the exercise of options granted under an employee stock purchase plan. These final regulations provide guidance to assist taxpayers in complying with section 423 in addition to clarifying certain rules regarding options granted under an employee stock purchase plan. This document also contains final regulations under sections 421, 422 and 424 of the Code.

**DATES:** *Effective Date:* These regulations are effective on November 17, 2009.

*Applicability Date:* These regulations apply as of January 1, 2010.

**FOR FURTHER INFORMATION CONTACT:** Thomas Scholz or Ilya Enkishev at (202) 622–6030 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

This document contains final amendments to the Income Tax Regulations (26 CFR part 1) under sections 421, 422, 423 and 424 of the Code.

Section 423 was added to the Code by section 221(a) of the Revenue Act of 1964, Public Law 88–272 (78 Stat. 63 (1964)). Changes to the applicable law concerning section 423 were made by sections 1402(b)(1)(C) and 1402(b)(2) of the Tax Reform Act of 1976, Public Law 94–455 (90 Stat. 1731 and 1732–1733 (1976)); section 1001(b)(5) of the Deficit Reduction Act of 1984, Public Law 98–369 (98 Stat. 1011 (1984)); section 1114 of the Tax Reform Act of 1986, Public Law 99–514 (100 Stat. 2451 (1986)); and sections 11801(c)(9)(D)(i), (ii) and 11801(c)(9)(E) of the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508 (104 Stat. 1388–525 (1990)).

Regulations under section 423 were published in the **Federal Register** on June 23, 1966 (TD 6887). These