claims for exemptions are still pending, will be revised.

e. Internal references will be corrected.

These regulations are being published as a direct final rule because the amendments do not impose any requirements on any member of the public. These amendments are the most efficient means for the Joint Board to implement its internal requirements for complying with the Privacy Act. Accordingly, pursuant to 5 U.S.C. 553(b)(3)(B), the Joint Board finds good cause that prior notice and other public procedures with respect to this rule are unnecessary, and good cause for making this direct final rule effective 90 days after publication in the Federal Register.

Pursuant to Executive Order 12866, it has been determined that this direct final rule is not a significant regulatory action, and therefore, does not require a regulatory impact analysis.

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act, 5 U.S.C. 601–612, do not apply.

List of Subjects in 20 CFR Part 903
Access to Records.

Adoption of Amendments to the Regulations

Accordingly, 20 CFR part 903 is amended as follows:

PART 903—ACCESS TO RECORDS

§ 903.8 Exemptions.

(a) Names of systems: JBEA–2, Enrolled Actuary Disciplinary Records; and JBEA–4, Enrolled Actuary Enrollment Records.

(b) Provisions from which exempted: These systems contain records described in section (k)(2) of the Privacy Act of 1974, 5 U.S.C. 552a(k)(2).

Exemptions are claimed for such records only where appropriate from the following provisions: sections (c)(3); (d); (e)(1); (e)(4)(G), (e)(4)(H), and (e)(4)(I); and (f) of 5 U.S.C. 552a.

(i) * * * * For these reasons, the Joint Board claims exemption from the requirements of subsection (c)(3) of the Act.

(ii) * * * * For these reasons, the Joint Board claims exemptions from the requirements of subsections (d)(1), (e)(4)(H), and (f)(2), (3), and (5) of the Act.

(iii) * * * * Therefore, the Joint Board claims exemptions from the requirements of subsections (d)(2), (3), and (4), (e)(4)(H), and (f)(4).

(iv) * * * * For these reasons, the Joint Board claims exemptions from the requirements of subsections (e)(4)(G) and (f)(1).

(v) * * * * For these reasons, the Joint Board claims exemptions from the requirements of subsection (e)(4)(I).

(vi) * * * * For these reasons, the Joint Board claims exemption from the requirements of subsection (e)(4)(I).

Dated: November 4, 2010.

Carolyn E. Zimmerman,
Chair, Joint Board for the Enrollment of Actuaries.

[FR Doc. 2010–32165 Filed 12–27–10; 8:45 am]
BILLING CODE 4830–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

[Docket No. FDA–2010–N–0002]

New Animal Drugs; Deslorelin

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 Thorn Bioscience LLC. The NADA provides for the use of deslorelin acetate injectable suspension in mares for inducing ovulation.

DATES: This rule is effective December 28, 2010.

FOR FURTHER INFORMATION CONTACT: Amy L. Omer, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8336, e-mail: amy.omer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Thorn Bioscience LLC, 1044 East Chestnut St., Louisville, KY 40204, filed NADA 141–319 that provides for use of SUCRMATE Equine (deslorelin acetate), an injectable suspension, in mares for inducing ovulation. The NADA is approved as of November 5, 2010, and the regulations are amended in 21 CFR 522.533 to reflect the approval.

In addition, Thorn Bioscience LLC has not been previously listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this firm.

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.

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. 801–809.

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:


2. In § 510.600, in the table in paragraph (c)(1) alphabetically add an entry for “Thorn Bioscience LLC”; and in the table in paragraph (c)(2) numerically add an entry for “051330” 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

<table>
<thead>
<tr>
<th>Firm name and address</th>
<th>Drug labeler code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thorn Bioscience LLC, 1044 East Chestnut St., Louisville, KY 40204</td>
<td>051330</td>
</tr>
</tbody>
</table>

(2) * * *

Drug labeler code Firm name and address

<table>
<thead>
<tr>
<th>Drug labeler code</th>
<th>Firm name and address</th>
</tr>
</thead>
<tbody>
<tr>
<td>051330</td>
<td>Thorn Bioscience LLC, 1044 East Chestnut St., Louisville, KY 40204</td>
</tr>
</tbody>
</table>

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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


4. Revise § 522.533 to read as follows:

§ 522.533 Deslorelin.

(a) Specifications—(1) Each implant contains 2.1 milligrams (mg) deslorelin acetate.

(2) Each milliliter (mL) of suspension contains 1.8 mg deslorelin acetate. (b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter as follows: (1) No. 043246 for use of product described in paragraph (a)(1) as in paragraph (c)(1) of this section. (2) No. 051330 for use of product described in paragraph (a)(2) as in paragraph (c)(2) of this section.

(c) Conditions of use—(1) Horses and ponies—(i) Amount. One implant per mare or mare subsequently in the neck. (ii) Indications for use. For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 mL in diameter. (iii) 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. (2) Horses—(i) Amount. Administer 1.8 mg (1 mL) by intramuscular injection in the neck. (ii) Indications for use. For inducing ovulation within 48 hours in cyclic estrous mares with an ovarian follicle between 30 and 40 mL in diameter. (iii) Limitations. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

5. Revising the paragraph (d)(1)(iii).

6. Revising the third sentence of paragraph (c)(5) Example 3(i).

7. Revising the third sentence of paragraph (c)(5) Example 2(iv).

8. Revising the third sentence of paragraph (c)(5) Example 2(iv).

9. Revising the paragraph (d)(1)(ii).

10. Revising the paragraph (d)(1)(ii).

PART 1—INCOME TAXES

1. Revising the paragraph (b)(1)(ii)(A).

2. Revising the first sentence of paragraph (b)(1)(ii)(A).

3. Revising the first sentence of paragraph (c)(5) Example 3(i).

4. Revising the third sentence of paragraph (c)(5) Example 2(iv).

5. Revising the paragraph (d)(1)(ii).

6. Revising the first sentence of paragraph (f)(2)(iii).

The revisions read as follows:

§ 1.411(b)(5)–1 Reduction in rate of benefit accrual under a defined benefit plan.

(a) * * *

(b) * * *

(i) * * *(iii).

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For further information contact: Neil S. Sandhu, Lauson C. Green, or Linda S. F. Marshall at (202) 622–6090 (not a toll-free number).

Supplementary information:

Background

The final regulations (TD 9505) contain errors that may prove to be misleading and are in need of clarification.

List of subject in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

1. Revising the paragraph (b)(1)(ii)(A).

2. Revising the first sentence of paragraph (b)(1)(ii)(A).

3. Revising the first sentence of paragraph (c)(5) Example 3(i).

4. Revising the third sentence of paragraph (c)(5) Example 2(iv).

5. Revising the paragraph (d)(1)(ii).

6. Revising the first sentence of paragraph (f)(2)(iii).

The revisions read as follows:

§ 1.411(b)(5)–1 Reduction in rate of benefit accrual under a defined benefit plan.

(a) * * *

(b) * * *

(i) * * *(iii).

(2) * * *

(3) * * *

(4) * * *

(5) * * *

(6) * * *

For further information contact: Neil S. Sandhu, Lauson C. Green, or Linda S. F. Marshall at (202) 622–6090 (not a toll-free number).