

will reduce your SSI payment by \$90. We may consider that to be a substantial reduction.

Example 2: A Substantial Reduction Exists. You receive a title II benefit of \$550 and an SSI payment of \$73. Your PASS employment goal will result in work over the SGA level that eliminates your title II benefit but increases your SSI payment by \$90. We may consider that a substantial reduction because your work will eliminate your title II payment while only slightly increasing your SSI payment.

Example 3: A Substantial Reduction Does Not Exist. Your SSI monthly payment amount is \$603 and your PASS employment goal earnings will reduce your SSI payment by \$90. We may not consider that to be a substantial reduction.

(8) Contain a beginning date and an ending date to meet your employment goal;

(9) Give target dates for meeting milestones towards your employment goal;

(10) Show what expenses you will have and how they are reasonable and necessary to meet your employment goal;

(11) Show what money you have and will receive, how you will use or spend it to attain your employment goal, and how you will meet your living expenses; and

(12) Show how the money you set aside under the plan will be kept separate from your other funds.

(b) You must propose a reasonable ending date for your PASS. If necessary, we can help you establish an ending date, which may be different than the ending date you propose. Once the ending date is set and you begin your PASS, we may adjust or extend the ending date of your PASS based on progress towards your goal and earnings level reached.

(c) If your employment goal is self-employment, you must include a business plan that defines the business, provides a marketing strategy, details financial data, outlines the operational procedures, and describes the management plan.

(d) Your progress will be reviewed at least annually to determine if you are following the provisions of your plan.

Subpart L—[Amended]

■ 4. The authority citation for subpart L is revised to read as follows:

Authority: Secs. 702(a)(5), 1602, 1611, 1612, 1613, 1614(f), 1621, 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1381a, 1382, 1382a, 1382b, 1382c(f), 1382j, 1383, and 1383b); sec. 211, Pub. L. 93-66, 87 Stat. 154 (42 U.S.C. 1382 note).

■ 5. Section 416.1225 is revised to read as follows:

§ 416.1225 An approved plan to achieve self-support; general.

If you are blind or disabled, we will pay you SSI benefits and will not count resources that you use or set aside to use for expenses that we determine to be reasonable and necessary to fulfill an approved plan to achieve self-support.

■ 6. Section 416.1226 is revised to read as follows:

§ 416.1226 What is a plan to achieve self-support (PASS)?

(a) A PASS must—
 (1) Be designed especially for you;
 (2) Be in writing;
 (3) Be approved by us (a change of plan must also be approved by us);
 (4) Have a specific employment goal that is feasible for you, that is, a goal that you have a reasonable likelihood of achieving;

(5) Have a plan to reach your employment goal that is viable and financially sustainable, that is, the plan—

(i) Sets forth steps that are attainable in order to reach your goal, and
 (ii) Shows that you will have enough money to meet your living expenses while setting aside income or resources to reach your goal;

(6) Be limited to one employment goal; however, the employment goal may be modified and any changes related to the modification must be made to the plan;

(7) Show how the employment goal will generate sufficient earnings to substantially reduce your dependence on SSI or eliminate your need for title II disability benefits;

Example 1: A Substantial Reduction Exists. Your SSI monthly payment amount is \$101 and your PASS employment goal earnings will reduce your SSI payment by \$90. We may consider that to be a substantial reduction.

Example 2: A Substantial Reduction Exists. You receive a title II benefit of \$550 and an SSI payment of \$73. Your PASS employment goal will result in work over the SGA level that eliminates your title II benefit but increases your SSI payment by \$90. We may consider that a substantial reduction because your work will eliminate your title II payment while only slightly increasing your SSI payment.

Example 3: A Substantial Reduction Does Not Exist. Your SSI monthly payment amount is \$603 and your PASS employment goal earnings will reduce your SSI payment by \$90. We may not consider that to be a substantial reduction.

(8) Contain a beginning date and an ending date to meet your employment goal;

(9) Give target dates for meeting milestones towards your employment goal;

(10) Show what expenses you will have and how they are reasonable and necessary to meet your employment goal;

(11) Show what resources you have and will receive, how you will use them to attain your employment goal, and how you will meet your living expenses; and

(12) Show how the resources you set aside under the plan will be kept separate from your other resources.

(b) You must propose a reasonable ending date for your PASS. If necessary, we can help you establish an ending date, which may be different than the ending date you propose. Once the ending date is set and you begin your PASS, we may adjust or extend the ending date of your PASS based on progress towards your goal and earnings level reached.

(c) If your employment goal is self-employment, you must include a business plan that defines the business, provides a marketing strategy, details financial data, outlines the operational procedures, and describes the management plan.

(d) Your progress will be reviewed at least annually to determine if you are following the provisions of your plan.

[FR Doc. 06-4530 Filed 5-15-06; 8:45 am]

BILLING CODE 4191-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

New Animal Drugs; Change of Sponsor; Fomepizole

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) for fomepizole solution for injection from Orphan Medical, Inc., to Jazz Pharmaceuticals, Inc. The regulations are also being amended to reflect approval of a supplemental NADA to remove a vial of saline diluent from this product.

DATES: This rule is effective May 16, 2006.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Orphan Medical, Inc., 13911 Ridgedale Dr., suite 475, Minnetonka, MN 55305, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141-075 for ANTIZOL-VET (fomepizole) to Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304. A supplement was also filed to NADA 141-075 to remove a vial of saline diluent from this product. The supplemental NADA is approved as of April 18, 2006, and the regulations are amended in 21 CFR 522.1004 to reflect the change of sponsorship, the removal of a vial of saline diluent from the product, and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

Following these changes of sponsorship, Orphan Medical, Inc., is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for Orphan Medical, Inc.

The agency has determined under 21 CFR 25.33(d)(1) 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

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

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for

"Orphan Medical, Inc." and alphabetically add a new entry for "Jazz Pharmaceuticals, Inc."; and in the table in paragraph (c)(2) remove the entry for "062161" and numerically add a new entry for "068727" 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 | |
| * | * | * | * | * |
| Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304. | | | 068727 | |
| * | * | * | * | * |

| | | | | |
|-------------------|---|---|---|---|
| (2) * * * | | | | |
| Drug labeler code | | Firm name and address | | |
| * | * | * | * | * |
| 068727 | | Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304 | | |
| * | * | * | * | * |

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: 21 U.S.C. 360b.

■ 4. In § 522.1004, revise paragraphs (a), (b), (c)(1), and (c)(3) to read as follows:

§ 522.1004 Fomepizole.

(a) *Specifications.* Each vial contains 1.5 grams fomepizole (1.5 milliliter (mL) of 1.0 gram per mL solution).

(b) *Sponsor.* See No. 068727 in § 510.600(c) of this chapter.

(c) * * *

(1) *Amount.* 20 milligrams per kilogram (mg/kg) of body weight intravenously initially, followed by 15 mg/kg at 12 and 24 hours, and 5 mg/kg at 36 hours.

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

Dated: May 3, 2006.

Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 06-4534 Filed 5-15-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9243]

RIN 1545-BA65

Revision of Income Tax Regulations Under Sections 367, 884, and 6038B Dealing With Statutory Mergers or Consolidations Under Section 368(a)(1)(A) Involving One or More Foreign Corporations, and Guidance Necessary To Facilitate Business Electronic Filing Under Section 6038B; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to final regulations (TD 9243), that was published in the **Federal Register** on Thursday, January 26, 2006 (71 FR 4276). This final regulation amends the income tax regulations under various provisions of the Internal Revenue Code to account for statutory mergers and consolidations.

DATES: This correction is effective January 23, 2006.

FOR FURTHER INFORMATION CONTACT: Christopher Trump (202) 622-3860 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulation (TD 9243) that is the subject of this correction is under section 367 of the Internal Revenue Code.

Need for Correction

As published, TD 9243 contains an error that may prove to be misleading and is in need of clarification.

List of Subjects 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

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 1.367(b)-6 [Corrected]

■ **Par. 2.** Section 1.367(b)-6 is amended by removing the third sentence of