

Dated: December 2, 2010.

**Bernadette Dunham,**  
*Director, Center for Veterinary Medicine.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 522**

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

**Implantation or Injectable Dosage Form New Animal Drugs; Flunixin**

**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 a supplemental abbreviated new animal drug application (ANADA) filed by Agri Laboratories, Ltd. The supplemental ANADA provides for use of flunixin meglumine solution by intravenous injection in lactating dairy cows for control of pyrexia associated with acute bovine mastitis.

**DATES:** This rule is effective December 8, 2010.

**FOR FURTHER INFORMATION CONTACT:** John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: [john.harshman@fda.hhs.gov](mailto:john.harshman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed a supplement to ANADA 200-061 that provides for veterinary prescription use of FLU-NIX (flunixin meglumine) Injectable Solution. The supplemental ANADA provides for use of flunixin meglumine solution by intravenous injection in lactating dairy cows for control of pyrexia associated with acute bovine mastitis. The supplemental application is approved as of September 27, 2010, and the regulations are amended in 21 CFR 522.970 to reflect the approval.

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. 801-808.

**List of Subjects in 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 part 522 is amended as follows:

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

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

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

■ 2. In § 522.970, revise paragraphs (b), (e)(1)(iii), and (e)(2) to read as follows:

**§ 522.970 Flunixin.**

\* \* \* \* \*

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) See Nos. 000061, 055529, and 061623 for use as in paragraph (e) of this section.

(2) See No. 000856 for use as in paragraph (e)(1) of this section.

(3) See Nos. 057561 and 059130 for use as in paragraphs (e)(1) and (2) of this section.

\* \* \* \* \*

(e) \* \* \*

(1) \* \* \*

(iii) *Limitations.* Do not use in horses intended for human consumption.

(2) *Cattle—(i) Amounts and indications for use—(A) Administer 1.1 to 2.2 mg/kilogram (kg) (0.5 to 1.0 mg/lb) of body weight per day intravenously, as a single dose or divided into two doses administered at 12-hour intervals, for up to 3 days for control of pyrexia associated with bovine respiratory disease and endotoxemia or for control of inflammation in endotoxemia.*

(B) Administer 2.2 mg/kg (1.0 mg/lb) of body weight once intravenously for control of pyrexia associated with acute bovine mastitis.

(ii) *Limitations.* Cattle must not be slaughtered for human consumption within 4 days of last treatment. Milk that has been taken during treatment

and for 36 hours after the last treatment must not be used for food. Do not use in dry dairy cows. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal.

\* \* \* \* \*

Dated: December 1, 2010.

**Elizabeth Rettie,**  
*Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 2010-30769 Filed 12-7-10; 8:45 am]

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**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**24 CFR Parts 5, 84, and 85**

[Docket No. FR-5350-F-02]

RIN 2501-AD50

**Conforming Changes to Applicant Submission Requirements; Implementing Federal Financial Report and Central Contractor Registration Requirements**

**AGENCY:** Office of the Secretary, HUD.

**ACTION:** Final rule.

**SUMMARY:** This final rule follows publication of a July 15, 2010, interim rule that revised HUD regulations to reference the new governmentwide Federal Financial Report (FFR) approved by the Office of Management and Budget (OMB). The FFR consolidates requirements from the OMB-issued Standard Forms SF-269, SF-269A, SF-272, and SF-272A into a single governmentwide form. In incorporating reference to the new FFR in its regulations, HUD amended its regulations to remove references to old and outdated forms that are no longer in use. The July 15, 2010, interim rule also codified the requirement that applicants for HUD assistance possess an active Central Contractor Registration (CCR). HUD is adopting the interim rule without change.

**DATES:** *Effective Date:* January 7, 2011.

**FOR FURTHER INFORMATION CONTACT:** Barbara Dorf, Director, Office of Departmental Grants Management and Oversight, Office of Administration, Chief Human Capital Officer, Department of Housing and Urban Development, 451 7th Street, SW., Room 3156, Washington, DC 20410-0500, telephone number 202-708-0667. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at 800-877-8339.

**SUPPLEMENTARY INFORMATION:****I. Background**

On July 15, 2010 (75 FR 41087), HUD published an interim rule that revised HUD regulations to reference the new governmentwide FFR, approved by OMB. The FFR provides a uniform, governmentwide format and establishes standard reporting period end dates and due dates for the submission of cash management and financial information. The FFR also reduces the burden on grantees that are reporting using electronic systems and simplifies reporting procedures for grantees to facilitate uniformity in agencies' grantmaking process. HUD's July 15, 2010, interim rule amended 24 CFR parts 84 and 85, by removing references to old and outdated forms and substituting, where appropriate, the FFR. The interim rule also amended §§ 84.52 and 85.41 to conform to reporting requirements to those provided for by the FFR.

HUD's July 15, 2010, interim rule also revised 24 CFR part 5 to require that applicants, including private nonprofit organizations, educational organizations, and State and regional agencies, that are subject to § 5.1001 register with CCR and have an active CCR registration in order for HUD to obligate funds and in order for the applicant to receive funds from HUD. CCR collects, validates, stores, and disseminates data in support of agency missions, including Federal agency contract and assistance awards, and the electronic payment process. Codifying this registration requirement facilitates applicant and awardee use of a single public Web site that consolidates data on awards made under various types of Federal Financial Assistance, pursuant to the Federal Funding Accountability and Transparency Act of 2006 (Transparency Act) (Pub. L. 109-282) (Transparency Act).

**II. This Final Rule**

This final rule follows publication of the July 15, 2010, interim rule. The public comment period on the interim rule closed on September 13, 2010. HUD did not receive public comment on the interim rule. HUD is adopting the interim rule without change.

**III. Findings and Certifications***Executive Order 12866, Regulatory Planning and Review*

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and it was not reviewed by OMB. This rule is not

significant because it conforms HUD regulations to refer to the FFR, removes outdated references to forms that are obsolete, and codifies a requirement that HUD has included for several years in its notices of funding availability.

*Paperwork Reduction Act*

The information collection requirements contained in this final rule have been submitted to OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number. The OMB control number for the FFR is 0348-0061.

*Environmental Impact*

This final rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction; or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

*Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This final rule conforms HUD regulations to requirements applicable to all grantees that are already in place, as a result of action previously taken by OMB, and small entities were provided the opportunity for comment in connection with OMB's publications. With respect to financial reporting, this rule streamlines the financial reporting requirement by replacing, with one form, the several that have been used prior to Fiscal Year 2010 and, as a result, reducing the burden on all entities, including small entities, by simplifying the task of filing required financial reports. Similarly, CCR registration has been required of applicants and grantees for HUD's competitive programs to ensure the proper identity of applicants. This rule codifies the CCR registration

requirement that HUD grantees are already meeting. Accordingly, the undersigned certifies that this rule will not have a significant impact on a substantial number of small entities.

*Executive Order 13132, Federalism*

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the relevant requirements of section 6 of the Executive Order. This final rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

*Unfunded Mandates Reform Act*

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (12 U.S.C. 1531-1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, and on the private sector. This final rule would not impose any Federal mandates on any State, local, or Tribal governments, or on the private sector, within the meaning of UMRA.

**List of Subjects***24 CFR Part 5*

Administrative practice and procedure, Aged, Claims, Crime, Government contracts, Grants programs—housing and community development, Individuals with disabilities, Intergovernmental relations, Loans programs—housing and community development, Low and moderate income housing, Mortgage insurance, Penalties, Pets, Public housing, Rent subsidies, Reporting and recordkeeping requirements, Social Security, Unemployment compensation, Wages.

*24 CFR Part 84*

Accounting, Colleges and universities, Grant programs, Hospitals, Non-profit organizations, Reporting and recordkeeping requirements.

*24 CFR Part 85*

Accounting, Grant programs, Indians, Intergovernmental relations, Reporting and recordkeeping requirements.

■ Accordingly, the interim rule amending 24 CFR parts 5, 84, and 85, which was published at 75 FR 41087 on July 15, 2010, is adopted as final without change.

Dated: December 1, 2010.

**Shaun Donovan,**  
Secretary.

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 9508]

RIN 1545-BJ85

#### Source of Income From Qualified Fails Charges

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

**ACTION:** Temporary regulations.

**SUMMARY:** This document contains temporary regulations which set forth the source of income attributable to qualified fails charges. The temporary regulations provide guidance about the treatment of fails charges for purposes of sections 871 and 881, which generally require gross-basis taxation of foreign persons not otherwise subject to U.S. net-basis taxation and the withholding of such tax under sections 1441 and 1442. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

**DATES:** *Effective Date.* These regulations are effective on December 8, 2010.

*Applicability Date.* These regulations apply to qualified fails charges paid or accrued on or after December 8, 2010.

**FOR FURTHER INFORMATION CONTACT:** Sheila Ramaswamy or Anthony J. Marra, Office of Associate Chief Counsel (International) (202) 622-3870 (not a toll free call).

#### SUPPLEMENTARY INFORMATION:

##### Background

In response to persistent delivery failures in delivery-versus-payment transactions involving U.S. Treasury securities (Treasury securities), a trading practice governing failed deliveries of Treasury securities was published in 2008 by the Treasury Market Practices Group (TMPG) and the Securities Industry and Financial Markets Association (SIFMA). This trading practice, which was recommended by the Federal Reserve Bank of New York in addition to TMPG and SIFMA, has subsequently been voluntarily adopted by almost every participant in the

Treasury securities market. Transactions that involve delivery-versus-payment include a sale, a purchase, a sale and repurchase transaction (commonly known as a “repo”), a securities lending transaction, and an option.

The trading practice addresses the problem that in certain situations, including a low interest rate environment, a party to a delivery-versus-payment transaction may lack the economic incentive to deliver Treasury securities in a timely manner. Under the trading practice, the parties to a contract that provides for delivery-versus-payment of Treasury securities agree that if one party fails to deliver Treasury securities at the time specified in the contract, the failing party will pay an amount (a “fails charge”) to the party entitled to receive the Treasury securities. The fails charge is calculated using a formula that takes into account current interest rates and trade proceeds, and accrues each day that the failure to deliver continues. The trading practice is generally expected to impose a fails charge whenever the interest rate on a repo that can be settled with any of a variety of securities (referred to in the market as the “general collateral rate”) falls below a certain level.

As noted in this preamble, the delivery-versus-payment market encompasses a variety of transactions, each of which can generate a fails charge. Some transactions, such as a repo, where delivery is required both at inception and at settlement, can produce more than one fails charge. In back-to-back transactions, it can also be difficult to determine whether a party that incurs a fails charge is acting as an intermediary or a principal. As a result, there is considerable uncertainty about the treatment of fails charges for purposes of sections 871 and 881, which generally impose gross-basis taxation at a rate of 30 percent on certain U.S. source income of foreign persons that is not effectively connected with the conduct of a trade or business in the United States and the withholding of such tax under sections 1441 and 1442.

Notice 2009-61, (2009 IRB 181), issued in July 2009, addressed the issue temporarily by providing that the Internal Revenue Service (IRS) will not challenge the position taken by a taxpayer or a withholding agent that a fails charge that is paid on or before December 31, 2010 is not subject to U.S. gross-basis taxation. Notice 2009-61 further announced that the Treasury Department and the IRS were considering issuing prospective guidance on the circumstances, if any, that would cause a fails charge to be subject to U.S. gross-basis taxation.

These temporary regulations provide further guidance on the treatment of fails charges. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**. See § 601.601(d)(2).

#### Explanation of Provisions

In order to provide certainty and consistency in the treatment of fails charges for purposes of sections 871, 881, 1441 and 1442, these temporary regulations establish source rules for qualified fails charges that arise in the delivery-versus-payment market for Treasury securities. The temporary regulations provide that the source of income from a qualified fails charge is generally determined by reference to the residence of the taxpayer that is the recipient of the qualified fails charge income, with two exceptions. Qualified fails charge income earned by a qualified business unit (QBU) of a taxpayer is sourced to the country in which the QBU is engaged in a trade or business, and qualified fails charge income that arises from a transaction that is effectively connected to a United States trade or business is sourced in the United States and treated as effectively connected to the conduct of a United States trade or business.

The temporary regulations provide a source rule only for income from a qualified fails charge. In order to be a qualified fails charge, the fails charge must satisfy two requirements. First, it must be paid pursuant to a trading practice or similar guidance approved by a U.S. government agency or the Treasury Market Practices Group (which is sponsored by the Federal Reserve Bank of New York), or published in separate guidance by the IRS. Second, the transaction that generates the fails charge must be with respect to a bill, note, or other evidence of indebtedness issued by the United States Treasury Department. These temporary regulations do not address the source of any other type of damages payment, including a fails charge that is not a qualified fails charge.

Although there is not currently a fails charge trading practice relating to securities other than Treasury securities, one may be considered in the future for agency securities (including mortgage-backed securities). If a fails charge trading practice pertaining to agency securities is endorsed by the Treasury Market Practices Group or an agency of the United States government and widely adopted, the Treasury Department and the IRS will consider