

March 2010, the Federal Reserve proposed to amend Regulation DD and the official staff commentary. 75 FR 9126 (March 1, 2010). Based on comments it received, the Federal Reserve issued a final rule on June 4, 2010. 75 FR 31673 (June 4, 2010).

## II. Interim Final Rule

In compliance with TISA, NCUA issued an interim final rule with request for comment on July 29, 2010, that was substantially similar to the Federal Reserve's June 2010 final rule. The interim final rule also included technical corrections to the aggregate overdraft and returned item fees sample form for formatting purposes. The Board issued the rule as an interim final rule because there is a strong public interest in having consumer-oriented rules in place that are consistent with those recently promulgated by the Federal Reserve. Additionally, as discussed above, NCUA is statutorily required to issue rules substantially similar to those of the Federal Reserve within 90 days of the effective date of the Federal Reserve's rules.

## III. Summary of Comments

NCUA received three comments on the interim final rule. Two comments were from credit union trade associations and one comment was from a State credit union league. Each commenter suggested some degree of change to the final rule. As discussed below, the three areas where comments offered suggestions were use of the term "Total Overdraft Fees," use of model form B-12, and the mandatory compliance date for the amendments to § 707.11(a)(1)(i).

First, all three commenters requested the Board permit credit unions to use terms other than "Total Overdraft Fees" in a member's periodic statement. One commenter argued that the use of "Total Overdraft Fees" would actually result in more confusion as a credit union's account opening and promotional materials might use a different term than the one required by the rule on periodic statements. Another commenter suggested that the Board should allow credit unions to use the term "Total Overdraft Fees for paid items," which, the commenter argues, will further enhance the distinction between fees paid for items that are covered by the credit union and fees paid because an item is returned for insufficient funds. The third commenter requested that the Board allow credit unions to use a term that is substantially similar to "Total Overdraft Fees," which the commenter argues is in line with the Federal Reserve's regulations. The

Board disagrees with these comments and reiterates its position from the interim final rule that permitting the use of terminology other than "Total Overdraft Fees" could be confusing to members and potentially undermines their ability to compare costs, particularly if the member has accounts at different credit unions that each use different terminology. Further, the Board notes that requiring credit unions to use the term "Total Overdraft Fees" is identical to the requirement in the Federal Reserve's rule and this term in conjunction with the other provisions in the current rule provide sufficient distinction between overdraft fees and fees for insufficient funds.

Two commenters provided suggestions on the technical changes to model form B-12. One commenter asked for additional guidance on the requirement that credit unions disclose the information in model form B-12 in a tabular format. Another commenter requested that credit unions be required to continue using the original form to prevent them from needing to spend money on reformatting periodic disclosure forms. With regard to both comments, the Board notes that § 707.11(a)(3) of NCUA's regulations requires credit unions to use a format that is substantially similar to model form B-12. With respect to the first comment, the Board does not believe that a non-tabular disclosure is "substantially similar" to model form B-12 and, therefore, would be impermissible under the rule. With respect to the second comment, however, the Board does believe using model form B-12 without the interim final rule's technical corrections would be considered substantially similar. The technical corrections made in the interim final rule do not change the substance or purpose of the form, but rather ensure conformity with the model form used by the Federal Reserve. Credit unions can continue to use the non-amended form until their supplies are depleted.

Finally, one commenter requested the Board extend the mandatory compliance date for the use of the term "Total Overdraft Fees" to provide credit unions with sufficient time to implement this change. Since the mandatory compliance date has already passed and credit unions are currently required to use the term "Total Overdraft Fees," this comment is moot. Further, as noted in the preamble to the interim final rule, the Board did consider the burden on credit unions and chose a date that would allow compliance in conjunction with the Federal Reserve while

minimizing the inconvenience to credit unions.

## IV. Regulatory Procedures

Section III of the **SUPPLEMENTARY INFORMATION** to the July 2009 final rule sets forth the Board's analyses under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR part 1320 Appendix A.1), the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121), Executive Order 13132, and the Treasury and General Government Appropriations Act (Pub. L. 105-277, 112 Stat. 2681 1998). *See* 74 FR 36102-36106. Because the final amendments are clarifications and do not alter the substance of the analyses and determinations accompanying that final rule, the Board continues to rely on those analyses and determinations for purposes of this rulemaking.

By the National Credit Union Administration Board on January 13, 2010.

**Mary F. Rupp,**

*Secretary of the Board.*

## List of Subjects in 12 CFR Part 707

Advertising, Credit unions, Consumer protection, Reporting and recordkeeping requirements, Truth in savings.

Accordingly, the interim final rule amending 12 CFR Part 707, which was published at 75 FR 47173 on August 5, 2010, is adopted as a final rule without change.

[FR Doc. 2011-1091 Filed 1-19-11; 8:45 am]

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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; Oxytetracycline and 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 new animal drug application (NADA) filed by Norbrook Laboratories, Ltd. The NADA provides for veterinary prescription use of a combination drug injectable solution containing oxytetracycline and flunixin meglumine in cattle.

**DATES:** This rule is effective January 20, 2011.

**FOR FURTHER INFORMATION CONTACT:**

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail:

[cindy.burnsteel@fda.hhs.gov](mailto:cindy.burnsteel@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Norbrook Laboratories, Ltd., Station Works, Newry, BT35 6JP, Northern Ireland, filed NADA 141-312 that provides for veterinary prescription use of HEXASOL (oxytetracycline and flunixin meglumine) Injection for the treatment of bacterial pneumonia associated with *Pasteurella* spp. and for the control of associated pyrexia in beef and non-lactating dairy cattle. The application is approved as of November 29, 2010, and the regulations in part 522 (21 CFR part 522) are revised by adding 21 CFR 522.1664.

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 512(c)(2)(F)(ii) of the act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

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. Add § 522.1664 to read as follows:

**§ 522.1664 Oxytetracycline and flunixin.**

(a) *Specifications.* Each milliliter (mL) of solution contains 300 milligrams (mg) oxytetracycline base as amphoteric oxytetracycline and 20 mg flunixin base as flunixin meglumine.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.286 and 556.500 of this chapter.

(d) *Conditions of use cattle—(1) Amount.* Administer once as an intramuscular or subcutaneous injection of 1 mL per 22 pounds (lb) body weight (BW) (13.6 mg oxytetracycline and 0.9 mg flunixin per lb BW) where retreatment of calves and yearlings for bacterial pneumonia is impractical due to husbandry conditions, such as cattle on range, or where their repeated restraint is inadvisable.

(2) *Indications for use.* For the treatment of bacterial pneumonia associated with *Pasteurella* spp. and for the control of associated pyrexia in beef and nonlactating dairy cattle.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Discontinue treatment at least 21 days prior to slaughter of cattle. Do not use in female dairy cattle 20 months of age or older. Use in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Use of dosages other than those indicated may result in residue violations.

Dated: January 11, 2011.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

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**DEPARTMENT OF THE TREASURY**

**Alcohol and Tobacco Tax and Trade Bureau**

**27 CFR Parts 4, 9, and 70**

[Docket No. TTB-2007-0068; T.D. TTB-90; Re: Notice Nos. 78 and 80]

**RIN 1513-AB39**

**Revision of American Viticultural Area Regulations**

**AGENCY:** Alcohol and Tobacco Tax and Trade Bureau, Treasury.

**ACTION:** Final rule; Treasury decision.

**SUMMARY:** In this Treasury decision, the Alcohol and Tobacco Tax and Trade Bureau amends the regulations concerning the establishment of American viticultural areas (AVAs). The changes provide clearer regulatory standards for the establishment of AVAs and clarify the rules for preparing, submitting, and processing viticultural area petitions.

**DATES:** *Effective Date:* This final rule is effective on February 22, 2011.

**FOR FURTHER INFORMATION CONTACT:** Rita D. Butler, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 200-E, Washington, DC 20220; telephone: 202-453-2101.

**SUPPLEMENTARY INFORMATION:**

**Background**

*TTB Authority*

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels, and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the regulations promulgated under the FAA Act.

Part 4 of the TTB regulations (27 CFR part 4) provides for the establishment of definitive viticultural areas and for the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) prescribes the standards for submitting a petition to establish a new American viticultural area (AVA) or to modify an existing AVA, and it contains a list with descriptions of all approved AVAs. Part