III. The Response to the Requests

A. Request To Extend the Testing and Certification Date by an Additional 60 Days

We decline to extend the date by which a manufacturer of a child’s product subject to 16 CFR part 1610 must have such product tested by a third party conformity assessment body accredited to do so and must issue a certificate of compliance based on that testing. We have the authority to grant such a request only if there is insufficient laboratory capacity. The existence of 67 CPSC-accepted labs accredited to test to 16 CFR part 1610 as of November 16, 2010, belies the claim of insufficient laboratory capacity, even if the laboratories are not distributed geographically as the AAFA would prefer.

We also disagree with the AAFA’s assertion, as another basis for an extension, that some manufacturers are not fully aware that children’s product certifications must be based on testing conducted by CPSC-accepted third party laboratories, and that many companies are unaware that the stay of enforcement on the testing and certification requirements had been lifted for children’s apparel. The CPSIA became law in August 2008, and we published the notice of requirements pertaining to 16 CFR part 1610 in the Federal Register on August 18, 2010. The statute’s existence, as well as the publication of the notice of requirements for 16 CFR part 1610, provided notice of these manufacturers’ legal obligations. Additionally, the Commission encourages the apparel and textile trade associations to educate the industry on their obligations under the CPSIA and FFA.

Finally, we note that section 14(a)(3)(E) of the CPSA authorizes the Commission to extend the deadline for certification “by not more than 60 days.” Such a time period is measured from the date on which such certification would have been required. In this case, the certification requirement became effective for products manufactured after November 16, 2010; therefore, a 60-day extension, had it been granted, would have expired in mid-January 2011. Thus, the AAFA’s request for an extension is moot.

B. Request To Accept, for Children’s Product Certification Purposes, Tests Pursuant to 16 CFR Part 1610 Conducted by Accredited Third Party Laboratories Since August 18, 2009

We have considered AAFA’s request and, through this notice, are revising our position regarding “Limited Acceptance of Children’s Product Certifications Based on Third Party Conformity Assessment Body Testing Prior to the Commission’s Acceptance of Accreditation.” Due to the nature of the wearing apparel industry, there is a possible significant time lapse between fabric testing and the finished garment. This could mean that some products that were tested previously by laboratories that have since become CPSC-accepted, would need to be retested. Therefore, we agree that revising our position on “retrospective” testing is appropriate because it will reduce further the potential need for redundant testing. We will accept children’s product certifications based on third party conformity assessment body testing, prior to our acceptance of accreditation, under the following conditions:

- At the time of product testing, the product was tested by a third party conformity assessment body that was ISO/IEC 17025 accredited by an accreditation body that is a signatory to the ILAC–MRA;
- The third party conformity assessment body’s application for testing using the test methods in 16 CFR part 1610 is accepted by the CPSC on or before November 16, 2010;
- The product was tested under 16 CFR part 1610 on or after August 18, 2009;
- The accreditation scope in effect for the third party conformity assessment body at the time of testing expressly included testing to 16 CFR part 1610;
- The test results show compliance with the applicable current standards and/or regulations; and
- The third party conformity assessment body’s accreditation, including inclusion in its scope of 16 CFR part 1610, remains in effect through the effective date for mandatory third party testing and manufacturer certification for conformity with 16 CFR part 1610.

Dated: April 19, 2011.

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522


Implantation or Injectable Dosage Form New Animal Drugs; Enrofloxacin

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 new animal drug application (NADA) filed by Bayer HealthCare LLC. The supplemental NADA provides for the addition of a pathogen to the indications for use of enrofloxacin solution in cattle, as a single injection, for the treatment of respiratory disease.

DATES: This rule is effective April 22, 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.

SUPPLEMENTARY INFORMATION: Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed a supplement to NADA 141–068 for BAYTRIL 100 (enrofloxacin), an injectable solution. The supplemental NADA provides for the addition of Mycoplasma bovis to the pathogens in the indication for use of enrofloxacin solution in cattle, as a single injection, for the treatment of bovine respiratory disease (BRD). The supplemental NADA is approved as of March 10, 2011, and the regulation in 21 CFR 522.812 is amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and § 514.111(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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)[F][ii]), this supplemental 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:


2. In § 522.812, revise paragraph (e)(2)(ii) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(e) * * * *

(ii) Indications for use—(A) Single-dose therapy: For the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni, and Mycoplasma bovis in beef and non-lactating dairy cattle.

(B) Multiple-day therapy: For the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni in beef and non-lactating dairy cattle. * * * * *

Dated: April 15, 2011.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2011–9756 Filed 4–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9518]

RIN 1545–BJ52

Specified Tax Return Preparers Required To File Individual Income Tax Returns Using Magnetic Media; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document describes a correction to final regulations (TD 9518) that were published in the Federal Register on Wednesday, March 30, 2011 (76 FR 17521) providing guidance to specified tax return preparers who prepare and file individual income tax returns using magnetic media pursuant to section 6011(e)(3) of the Internal Revenue Code.

DATES: This correction is effective on April 22, 2011, and is applicable to individual income tax returns filed after December 31, 2010.

FOR FURTHER INFORMATION CONTACT: Keith L. Brau, (202) 622–4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of this correction are under section 6011 of the Internal Revenue Code.

Need for Correction

As published, final regulations (TD 9518) contain an error that may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of the final regulations (TD 9518) which were the subject of FR Doc. 2011–7571 is corrected as follows:

On page 17528, column 2, under CFR Part Heading “PART 301—PROCEDURE AND ADMINISTRATION”, the language “Par. 4. The authority citation for part 301 is amended by adding an entries in numerical order to read, in part, as follows:” is corrected to read “Par. 4. The authority citation for part 301 is amended by adding entries in numerical order to read, in part, as follows:”.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2011–9737 Filed 4–21–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 311

[Docket ID: DoD–2011–OS–0004]

Privacy Act of 1974; Implementation

AGENCY: Office of the Secretary, DoD.

ACTION: Direct final rule with request for comments.

SUMMARY: The Office of the Secretary of Defense is exempting those records contained in DMDC 12 DoD, entitled “Joint Personnel Adjudication System (JPAS)”, when investigatory material is compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that such material would reveal the identity of a confidential source.

This direct final rule makes nonsubstantive changes to the Office of the Secretary Privacy Program rules. These changes will allow the Department to add an exemption rule to the Office of the Secretary of Defense Privacy Program rules that will exempt applicable Department records and/or material from certain portions of the Privacy Act. This change will allow the Department to move part of the Department’s personnel security program records from the Defense Security Service Privacy Program to the Office of the Secretary of Defense Privacy Program. This direct final rule is consistent with the rule previously published at 32 CFR 321.13(h) and another rule is being published to remove and reserve 321.13(h). This will improve the efficiency and effectiveness of DoD’s program by preserving the exempt status of the applicable records and/or material when the purposes underlying the exemption(s) are valid and necessary.

This rule is being published as a direct final rule as the Department of Defense does not expect to receive any adverse comments, and so a proposed rule is unnecessary.