

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule entitled “Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements” that appeared in the **Federal Register** of June 10, 2014 (79 FR 33072). The document amended FDA’s postmarketing safety reporting regulations for human drug and biological products to require that persons subject to mandatory reporting requirements submit safety reports in an electronic format that FDA can process, review, and archive. The document was published with an incorrect RIN number. This document corrects the error.

DATES: *Effective date:* September 8, 2014.

FOR FURTHER INFORMATION CONTACT: Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4466, Silver Spring, MD 20993-0002, 301-796-1874; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 2014, in FR Doc. 2014-13480, the following correction is made:

1. On page 33073, in the third column, the RIN number heading is corrected to read “RIN 0910-AF96”.

Dated: September 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-21266 Filed 9-5-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310, 314, 329, and 600

[Docket No. FDA-2008-N-0334]

RIN 0910-AF96

Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements; Corrections

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; corrections.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document entitled “Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements; Correction” that appeared in the **Federal Register** of August 14, 2014 (79 FR 47655). The document published without the required RIN number and in the Notice category. This document corrects those errors.

DATES: *Effective Date:* September 8, 2014.

FOR FURTHER INFORMATION CONTACT: Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4466, Silver Spring, MD 20993-0002, 301-796-1874; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 2014, in FR Doc. 2014-19255, the following correction is made:

1. On page 47655, in the first column, add the heading “RIN 0910-AF96” between the Docket No. and the title of the document.

Dated: September 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 558

[Docket No. FDA-2014-N-0002]

New Animal Drugs; Buprenorphine; Carprofen; Danofloxacin; Follicle Stimulating Hormone; Ractopamine; Salinomycin; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July 2014. FDA is

also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to add a cross reference to a tolerance.

DATES: This rule is effective September 8, 2014.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July 2014, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents 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. Persons with access to the Internet may obtain these documents at the Center for Veterinary Medicine (CVM) FOIA Electronic Reading Room: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>. Marketing exclusivity and patent information may be accessed in FDA’s publication, Approved Animal Drug Products Online (Green Book) at: <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.

Also, the animal drug regulations are being amended in 21 CFR 522.955 to add a cross reference to a tolerance for an inactive vehicle in an injectable dosage form product. This amendment is being made to improve the accuracy of the regulations.

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.