4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 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; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

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: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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.

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