



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA-2017-N-6381]

RIN 0910-AH51

Postmarketing Safety Reports for Approved New Animal Drugs; Electronic Submission Requirements; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is correcting a final rule that published in the *Federal Register* of July 29, 2020. That final rule requires electronic submission of certain postmarketing safety reports for approved new animal drugs and provides a procedure for requesting a temporary waiver of the electronic submission requirement. Table 2 of the final rule published with errors and this document corrects those errors. We are placing a corrected copy of the final rule in the docket.

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

FOR FURTHER INFORMATION CONTACT: Linda Walter-Grimm, Center for Veterinary Medicine (HFV-240), Food and Drug Administration, 7519 Standish Pl., MPN4, Rm. 2666, Rockville, MD 20855, 240-402-5762, Linda.Walter-Grimm@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of July 29, 2020, (85 FR 45505), FDA published the final rule “Postmarketing Safety Reports for Approved New Animal Drugs; Electronic Submission Requirements” with errors in table 2.

In FR Doc. 2020-15441, appearing on page 45509 in the *Federal Register* of July 29, 2020, the following corrections are made:

Table 2.--Executive Order 13771 Summary Table (in 2016 Dollars over an Infinite Time Horizon)

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	\$69,720			\$75,346		
Present Value of Cost Savings	\$73,557			\$171,634		
Present Value of Net Costs	(\$3,837)			(\$96,287)		
Annualized Costs	\$4,880			\$2,260		
Annualized Cost Savings	\$5,149			\$5,149		
Annualized Net Costs	(\$269)			(\$2,889)		

Dated: August 14, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020-18263 Filed: 9/21/2020 8:45 am; Publication Date: 9/22/2020]