



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 300

[Docket No. FDA-2019-N-5553]

RIN 0910-AI36

Annual Summary Reporting Requirements Under the Right to Try Act; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is correcting a proposed rule that published in the *Federal Register* of July 24, 2020. That proposed rule proposes to establish requirements for the deadline and contents of submission in an annual summary. We are placing a corrected copy of the proposed rule in the docket.

FOR FURTHER INFORMATION CONTACT: Kathleen Davies, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3121, Silver Spring, MD 20993, 301-796-2205, kathleen.davies@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of July 24, 2020, (85 FR 44803), FDA published the proposed rule “Annual Summary Reporting Requirements Under the Right to Try Act” with several errors.

In the *Federal Register* of July 24, 2020, FR Doc. 2020-16016, the following corrections are made:

On page 44804, in the third column, in section “*D. Costs and Benefits*” the first paragraph, the fourth and fifth sentences are corrected as follows: “The total estimated present

value of this rule’s costs is \$39,991 at a seven percent discount rate and \$49,345 at a three percent discount rate (in 2018 dollars). The annualized cost of this rule over 10 years is \$5,694 at a seven percent discount rate and \$5,785 at a three percent discount rate.” On page 44808, in table 1, in column 2 (“Primary estimate”) rows 4 and 5 (“Costs” category) are corrected as follows: “\$5,694” and \$5,785”, respectively, and the “7” in column 4 (“High estimate”) is removed. On pages 44808 and 44809, in column 6 (“Discount Rate (10%)”) is corrected to read as follows:

Table 1.--Summary of Benefits and Costs in 2018 Dollars Over a 10-Year Time Horizon

Category	Primary Estimate	Low Estimate	High Estimate	Units			Notes
				Year Dollars	Discount Rate (%)	Period Covered	
Benefits	Annualized Monetized \$/year			2018	7	10	
				2018	3	10	
	Annualized Quantified				7		
					3		
Qualitative						Disclosure of serious adverse events and outcomes related to investigational new drug treatments	
Costs	Annualized Monetized \$/year	\$5,694		2018	7	10	
		\$5,785		2018	3	10	
	Annualized Quantified				7		
					3		
Qualitative							
Transfers	Federal Annualized Monetized \$/year				7		
					3		
	From/ To	From:		To:			
	Other Annualized Monetized \$/year				7		
Effects					3		
	From/To	From:		To:			
	State, Local or Tribal Government:						
	Small Business:						
	Wages:						
	Growth:						

Dated: August 20, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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