



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 3

[Docket No. FDA-2004-N-0191]

Product Jurisdiction; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration is correcting a proposed rule to amend its regulations concerning the classification of products as biological products, devices, drugs, or combination products, and their assignment to Agency components for premarket review and regulation that appeared in the *Federal Register* of May 15, 2018. The document was published with an error in the discussion of the preliminary economic analysis impact. This document corrects that error.

DATES: Submit either electronic or written comments on the proposed rule by July 16, 2018.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20933, 301-796-8930, melissa.burns@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Tuesday, May 15, 2018, beginning on page 22428 for FR Doc. 2018-10321, table 1 on page 22433 is corrected to read:

Table 1.--Benefits, Costs, and Distributional Effects of the Proposed Rule^{1, 2}

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Costs	Annualized Monetized \$/year	\$17,000	\$12,000	\$27,000	2016	7%	10 years	
		\$15,000	\$10,000	\$23,000	2016	3%	10 years	

	Annualized Quantified					7%		
						3%		
	Qualitative							
Benefits	Annualized Monetized \$/year	\$28,000	\$25,000	\$89,000	2016	7%	10 years	
		\$28,000	\$25,000	\$89,000	2016	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Firms and FDA may realize savings from sponsors choosing to submit electronic RFDs.						
Transfers	Federal Annualized Monetized \$millions/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized Monetized \$millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: Small Business: Will not have a significant impact on a substantial number of small entities. Wages: Growth:							

¹ We use a 10-year time horizon for this rule with payments occurring at the end of each period.

² All dollar values are rounded to the nearest \$1,000.

Dated: June 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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