

**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](mailto: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 <sup>1 2</sup>

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
<b>Costs:</b>							
Annualized .....	\$17,000	\$12,000	\$27,000	2016	7	10	
Monetized \$/year .....	15,000	10,000	23,000	2016	3	10	
Annualized .....	.....	.....	.....	.....	7	.....	
Quantified .....	.....	.....	.....	.....	3	.....	
Qualitative .....	.....	.....	.....	.....	.....	.....	
<b>Benefits:</b>							
Annualized .....	28,000	25,000	89,000	2016	7	10	
Monetized \$/year .....	28,000	25,000	89,000	2016	3	10	
Annualized .....	.....	.....	.....	.....	7	.....	
Quantified .....	.....	.....	.....	.....	3	.....	
Qualitative .....	Firms and FDA may realize savings from sponsors choosing to submit electronic RFDs			.....	.....	.....	
<b>Transfers:</b>							
Federal .....	.....	.....	.....	.....	7	.....	
Annualized .....	.....	.....	.....	.....	.....	.....	
Monetized \$millions/year .....	.....	.....	.....	.....	3	.....	
From/To .....	From:			To:			
Other .....	.....	.....	.....	.....	7	.....	
Annualized .....	.....	.....	.....	.....	.....	.....	
Monetized \$millions/year .....	.....	.....	.....	.....	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:

<sup>1</sup> We use a 10-year time horizon for this rule with payments occurring at the end of each period.  
<sup>2</sup> All dollar values are rounded to the nearest \$1,000.

Dated: June 1, 2018.  
**Leslie Kux,**  
*Associate Commissioner for Policy.*  
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**POSTAL REGULATORY COMMISSION**  
**39 CFR Part 3050**  
**[Docket No. RM2018-5; Order No. 4630]**  
**Periodic Reporting**  
**AGENCY:** Postal Regulatory Commission.  
**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Commission is noticing a recent filing requesting that the Commission initiate an informal rulemaking proceeding to consider changes to an analytical method for use in periodic reporting (Proposal Two). This document informs the public of the filing, invites public comment, and takes other administrative steps.