

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 (years)	
Costs:							
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	
Benefits:							
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			
Transfers:							
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:

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.
 [FR Doc. 2018-12201 Filed 6-6-18; 8:45 am]
BILLING CODE 4164-01-P

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.

DATES: *Comments are due:* July 16, 2018.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

On May 25, 2018, the Postal Service filed a petition pursuant to 39 CFR 3050.11 requesting that the Commission initiate a rulemaking proceeding to consider changes to analytical principles relating to periodic reports.¹ The Petition identifies the proposed analytical changes filed in this docket as Proposal Two.

II. Proposal Two

Background. Proposal Two relates to new sampling and weighting procedures for the city carrier portion of the In-Office Cost System (IOCS).² The current IOCS design uses a multi-stage probability sample to randomly select city carriers, then an interval of work time from the city carrier's tour, resulting in an observation ("reading") that represents a "snapshot" of work activity in a sampled interval.³ Under the current IOCS design, data collection for city carriers is widely dispersed in both time and location, so the Postal Service conducts most city carrier readings by telephone. The Postal Service states that the availability of detailed clock ring data from the Time and Attendance Collection System (TACS) and Delivery Operations Information System (DOIS) data now allows for a change to the current IOCS

sampling design for city carriers. *Id.* at 1-2.

Proposal. The Postal Service proposes to change the current IOCS sample design for city carriers to a cluster sampling approach that would include using TACS workhours to weight the sampling data. *Id.* at 3-4. In the morning, on-site clustered city carrier readings would be conducted by an IOCS data collector, rather than with telephone respondents in sampled delivery zones.⁴ In zones with six or more routes (sampling mode 1), a maximum of six carriers would be randomly selected to represent the zone and morning readings would be taken on-site by the IOCS data collector once every 30 minutes.⁵ In zones with fewer than six city carriers working the selected zone (sampling mode 2), morning readings would be taken on-site by the IOCS data collector on all carriers once every 15 minutes.⁶ In the afternoon (sampling mode 3), all city carrier readings would be conducted by telephone and clustered into one-hour intervals.⁷

Under the cluster sampling design, the Postal Service proposes to use TACS workhours to weight sampling data by zone, and to provide cost controls for city carriers by time-of-day (morning and afternoon) and day-of-week group (weekday/Saturday group and Sunday/Holiday group). *Id.* at 4-5. Additionally, the Postal Service states that it will use DOIS and TACS data for the sampled zone to weight the readings for each test relative to other tests within the same Cost Ascertainment Group (CAG) strata, and to post-stratify readings by route group and city carrier craft group. *Id.* at 4, 7. However, the Postal Service states that all afternoon readings are scaled to the total hours in the afternoon and not estimated by CAG separately because it asserts that "there are insufficient afternoon tallies" and "no significant difference [for in-office cost] is expected" because carriers would be on the street. *Id.* at 7.

The Postal Service asserts that the proposal adopts the approach suggested by the Commission in Order No. 4399 for developing route group weighting factors when there were "empty cells" within the combination of route group and carrier group. *Id.* at 12.

⁴ *Id.* at 2, 4. "Zone is defined by both ZIP Code and finance number." *Id.* at 4 n.5.

⁵ *Id.* at 5. All morning readings would begin when carriers start their workday and would continue until 11 a.m. *Id.* at 6.

⁶ The Postal Service plans to synchronize IOCS-Cluster readings with City Carrier Cost System (CCCS) tests when a data collector is already scheduled to be at a delivery unit.

⁷ All afternoon readings would be conducted between 11:00 and 19:00 hours. *Id.* at 6.

Proposal Two would also "[u]se TACS data to provide control totals for the portion of supervisor costs incurred by employees whose base craft is carrier, but who have clocked as supervisor." *Id.* at 4. Additionally, unlike the current IOCS methodology, under the Proposal Two methodology, no IOCS readings would be conducted on Sundays and Holidays.⁸ However, for purposes of evaluating and presenting the estimated impact on FY 2017 costs, the Postal Service "shows the effects of attributing all Sunday/Holiday costs" to Parcel Select. *Id.* at 9.

Rationale and impact. The Postal Service states that the primary objective of Proposal Two is to replace telephone readings with on-site readings, particularly while carriers are on the premises and handling mail. *Id.* at 10.

The Postal Service projects that the IOCS-Cluster system will obtain twice as much on-premises data as the current system, but "due to the improvement in sampling efficiency, will not require additional data collection resources." *Id.* at 8. Further, the Postal Service asserts that "[t]he new design improves data quality by obtaining far more data from on-site rather than telephone readings, while simultaneously improving data collection efficiency." *Id.* at 1.

The Postal Service lists several benefits of the proposal including the ability to scan barcodes, providing feedback at the time of the reading for less-common products and assisting with "back-end processing of tallies." *Id.* at 10. Additionally, the Postal Service states that on-site data collectors may do a better job than a telephone respondent of recognizing some of the mailpiece markings that are less common and more obscure. *Id.* Further, unlike city carrier telephone respondents, under Proposal Two, on-site IOCS data collectors would not have other duties that may affect and constrain participating in a reading under the current IOCS sampling system. *Id.*

The Postal Service states that the proposal will result in a significant increase in the percentage of direct tallies where the carrier is handling the mailpiece, and decreases in tallies for support and administrative activities, training, and mixed mail. *Id.* at 12. The Postal Service also anticipates a

⁸ *Id.* at 5. Instead, the Postal Service states that it will develop control total costs for Sunday/Holiday from TACS hours and distribute costs using scanning data from Product Tracking and Reporting (PTR). *Id.* at 5, 9. The Postal Service explains that it intends to file a separate proposal outlining the use of the PTR data for Sunday/Holiday costs. *Id.* at 5.

¹ Petition of the United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Two), May 25, 2018 (Petition).

² Petition at 1. The IOCS "is a continuous, ongoing probability sample of work time to estimate costs of various activities performed by clerks, mail handlers, city carriers, and supervisors." See Docket No. ACR2017, Library Reference USPS-FY17-37, file "USPS-FY17-37.Preface.pdf," at 2.

³ Petition, Proposal Two at 1. The Postal Service currently uses cost estimates from the IOCS to develop total accrued costs for both city carrier in-office and street time. *Id.*

significant increase in tallies in the parking area, potentially making it possible to distribute mixed mail tallies separately from in-facility. *Id.* at 13.

The Postal Service states that the pilot data indicate some significant shifts in product costs, including a decrease in costs for First-Class letters, and increases in costs for a number of products including parcel-shaped products, carrier route bundled

products, Periodicals, and International Mail. *Id.* at 14–15. The Postal Service asserts that the shifts in product costs are most likely due to the use of on-site data collectors rather than telephone respondents. *Id.* at 15. The proposal would also impact costs associated with supervising city carriers.⁹

⁹ *Id.* at 14. The pilot data showed a 9.1-percent increase in supervisor city carrier costs, which

The Postal Service's estimate of the effect on product unit costs is presented in Table 5 of Proposal Two, which is reproduced here. *Id.* at 16.

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resulted in a slight increase in piggyback factors on city carrier costs. *Id.*

CLASS, SUBCLASS, OR SPECIAL SERVICE	CRA Class	OFFICE AND STREET WITH PIGGYBACK'S No Cluster	OFFICE AND STREET WITH PIGGYBACK'S IOC\$ClusterV2	% CHANGE OFFICE AND STREET COSTS	FY17 VOL VAR UNIT COST, FY17 ACR	FY17 UNIT COST WITH IOC\$ClusterV2	% CHANGE	DIFF UNIT COST
COLUMN NUMBER		(8)	(9)	(13)	(14)	(15)	(16)	(17)
UNITS		\$ in thousands	\$ in thousands	%	\$	\$	%	\$
MARKET DOMINANT								
First-Class Mail								
Single-Piece Letters	3	817,238	671,148	-18%	\$ 0.287	\$ 0.270	-5.7%	\$(0.018)
Single-Piece Cards	4	35,606	32,138	-10%	\$ 0.316	\$ 0.306	-3.1%	\$(0.010)
Presort Letters	8	687,197	619,572	-10%	\$ 0.118	\$ 0.114	-3.2%	\$(0.004)
Presort Cards	9	29,185	34,300	18%	\$ 0.075	\$ 0.079	6.2%	\$ 0.005
Flats	0	138,910	140,550	1%	\$ 1.055	\$ 1.058	0.2%	\$ 0.002
Parcels	19	14,010	17,042	22%	\$ 2.502	\$ 2.590	3.5%	\$ 0.087
Total First-Class Mail	80	1,722,144	1,514,750	-12%	\$ 0.200	\$ 0.193	-3.6%	\$(0.007)
USPS Marketing Mail								
High Density and Sat Letters	21	135,284	151,716	12%	\$ 0.072	\$ 0.078	6.3%	\$ 0.005
High Density and Sat Flats/Parc.	22	339,937	375,967	11%	\$ 0.110	\$ 0.116	5.7%	\$ 0.006
Every Door Direct Mail-Retail	24	18,871	21,095	12%	\$ 0.086	\$ 0.072	9.7%	\$ 0.006
Carrier Route	23	410,167	456,803	11%	\$ 0.209	\$ 0.220	5.5%	\$ 0.012
Letters	25	882,440	892,506	1%	\$ 0.102	\$ 0.102	0.4%	\$ 0.000
Flats	26	411,899	364,309	-12%	\$ 0.518	\$ 0.496	-4.2%	\$(0.022)
Parcels	27	8,250	7,561	-8%	\$ 1.793	\$ 1.755	-2.1%	\$(0.037)
Total USPS Marketing Mail	81	2,206,847	2,269,958	3%	\$ 0.137	\$ 0.139	1.2%	\$ 0.002
Total Periodicals	82	278,824	325,916	17%	\$ 0.373	\$ 0.391	4.9%	\$ 0.018
Package Services								
Bound Printed Matter Flats	42	13,826	23,717	72%	\$ 0.500	\$ 0.568	13.7%	\$ 0.068
Bound Printed Matter Parcels	43	40,340	55,973	39%	\$ 0.971	\$ 1.075	10.7%	\$ 0.104
Media/Library Mail	44	13,216	15,459	17%	\$ 4.600	\$ 4.656	1.2%	\$ 0.056
Total Package Services	83	67,383	95,149	41%	\$ 1.244	\$ 1.327	6.7%	\$ 0.083
US Postal Service	85	30,123	25,887	-14%				
Free Mail	86	1,879	2,738	46%	\$ 0.910	\$ 0.950	4.4%	\$ 0.040
Total Domestic MD Mail	90	4,307,200	4,234,398	-2%				
Ancillary Services								
Certified Mail	51	78,708	86,421	10%	\$ 2.759	\$ 2.842	3.0%	\$ 0.083
COD	52	234	261	12%	\$ 6.642	\$ 6.764	1.9%	\$ 0.123
Insurance	54	1,456	1,769	21%	\$ 3.173	\$ 3.204	1.0%	\$ 0.031
Registered Mail	55	1,022	776	-24%	\$ 11.029	\$ 10.778	-2.3%	\$(0.251)
Other Ancillary Services	58	41,921	39,701	-5%				
Total Domestic MD Svcs	91	123,340	128,927	5%				
Total Domestic MD Mail/Svcs	92	4,430,540	4,363,325	-2%				
Total Domestic Cmp Mail/Svcs	192	813,998	1,132,533	39%	\$ 2.430	\$ 2.548	4.8%	\$ 0.117
INTERNATIONAL	185	79,785	86,334	8%				
Total Volume Variable	198	5,324,323	5,582,192	5%				

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III. Notice and Comment

The Commission establishes Docket No. RM2018-5 for consideration of matters raised by the Petition. More information on the Petition may be accessed via the Commission's website

at <http://www.prc.gov>. Interested persons may submit comments on the Petition and Proposal Two no later than July 16, 2018. Pursuant to 39 U.S.C. 505, Lyudmila Y. Bzhilyanskaya is designated as an officer of the Commission (Public Representative) to

represent the interests of the general public in this proceeding.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. RM2018-5 for consideration of the matters raised by the Petition of the

United States Postal Service for the Initiation of a Proceeding to Consider Proposed Changes in Analytical Principles (Proposal Two), filed May 25, 2018.

2. Comments by interested persons in this proceeding are due no later than July 16, 2018.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Lyudmila Y. Bzhilyanskaya to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,
Acting Secretary.

[FR Doc. 2018-12200 Filed 6-6-18; 8:45 am]

BILLING CODE 7710-FW-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 27

[WT Docket No. 18-120; FCC 18-59]

Transforming the 2.5 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission or FCC) seeks comment on proposed service rules on the 2.5 GHz band and on refinements to the adopted rules in this document.

DATES: Comments are due on or before July 9, 2018; reply comments are due on or before August 6, 2018.

ADDRESSES: You may submit comments, identified by WT Docket No. 18-120, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Federal Communications Commission's Website:* <https://www.fcc.gov/ecfs/filings>. Follow the instructions for submitting comments.

- *People With Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: FCC504@fcc.gov, phone: 202-418-0530 or TTY: 202-418-0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: John J. Schauble of the Wireless Telecommunications Bureau, Broadband Division, at 202-418-0797 or by email to John.Schauble@fcc.gov. For information regarding the PRA information collection requirements contained in this PRA, contact Cathy Williams, Office of Managing Director, at (202) 418-2918 or Cathy.Williams@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking, WT Docket No. 18-120, FCC 18-59*, adopted and released on May 10, 2018. The complete text of this document is available for public inspection and copying from 8 a.m. to 4:30 p.m. Eastern Time (ET) Monday through Thursday or from 8 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW, Room CY-A257, Washington, DC 20554. The complete text is available on the Commission's website at <http://wireless.fcc.gov>, or by using the search function on the ECF's web page at <http://www.fcc.gov/cgb/ecfs/>. Alternative formats are available to persons with disabilities by sending an email to fcc504@fcc.gov or by calling the Consumer & Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (tty).

Comment Filing Procedures

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: <https://www.fcc.gov/ecfs/filings>. Filers should follow the instructions provided on the website for submitting comments. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket number, WT Docket No. 18-120.

- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial

overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW, Room TW-A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Dr., Annapolis Junction, Annapolis, MD 20701.

- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554.

People With Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 888-835-5322 (tty).

Ex Parte Rules—Permit-But-Disclose

Pursuant to § 1.1200(a) of the Commission's rules, this *NPRM* shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents