ewallet transactions. Mastercard requires that all Mastercard-branded debit cards loaded into ewallets be tokenized. And, in fact, nearly all such cards are tokenized by Mastercard—via decisions in which merchants have no say. Because Mastercard tokenizes these cards and then withholds detokenization, card-not-present ewallet transactions are not routable to competing networks—these networks are unable to process the transactions without the corresponding PANs. Mastercard thereby inhibits merchant routing choice by employing a technology that compels merchants to route transactions over Mastercard's network.

Additionally, Mastercard's agreements with ewallet providers require those providers to inform merchants that, by accepting card-not-present transactions through ewallets, merchants agree that transactions made with Mastercard-branded debit cards will be routed to Mastercard. Mastercard thereby inhibits merchant routing choice by contract.

III. Proposed Order

The proposed order seeks to remedy Mastercard's illegal conduct by requiring Mastercard to provide PANs so that merchants may route tokenized transactions using Mastercard-branded debit cards to the available network of their choosing. Under the proposed order, Mastercard must also refrain from interfering with the ability of other persons to serve as TSPs, and it must not take other actions to inhibit merchant routing choice in violation of Regulation II, 12 CFR 235.7(b).

Section I of the proposed order defines the key terms used in the order.

Section II of the proposed order addresses the core of Mastercard's conduct. Paragraph II.A. requires Mastercard, upon request by an authorized acquirer, authorized network, or other authorized person in receipt of a Mastercard token, to provide the PAN associated with the token for purposes of routing the transaction to any competing network enabled by the issuer. This provision is designed to restore and preserve merchant routing choice so that merchants may accept ewallet tokens without being forced to route all such transactions over Mastercard's network. The order specifically requires that Mastercard provide PANs for ecommerce, card-not-present debit transactions in the ordinary course, including in a manner consistent with the timeliness with which Mastercard provides PANs for card-present transactions and without requiring consideration for making the PANs available.

Paragraph II.B. prevents Mastercard from prohibiting or inhibiting any person's efforts to serve as a TSP or provision payment tokens for Mastercard-branded debit cards. This paragraph prevents Mastercard from taking other actions that would inhibit merchant routing choice in the context of tokenized transactions.

Paragraph II.C. prohibits Mastercard from, directly or indirectly by contract, requirement, condition, penalty, or otherwise, inhibiting the ability of any person that accepts or honors debit cards for payments to choose to route transactions over any network that may process such transactions, in violation of Regulation II, 12 CFR 235.7(b). This paragraph prevents Mastercard from taking other actions, even outside the context of tokenized transactions, that would inhibit merchant routing choice.

The proposed order also contains provisions designed to ensure Mastercard's compliance with the order. Section III requires Mastercard to provide notice to competing networks, acquirers, and issuers via an ad hoc Mastercard bulletin using language found in the proposed order's Appendix A. Section IV requires Mastercard to provide prior notice to the Commission before the commercial launch of any new debit product that requires merchants to route debit transactions to Mastercard's network. Sections V through VII contain provisions regarding compliance reports to be filed by Mastercard, notice of changes in Mastercard, and access to Mastercard documents and personnel.

As stated in Section VIII, the proposed order's purpose is to remedy Mastercard's alleged violation of the Durbin Amendment, EFTA Section 920(b)(1), 15 U.S.C. 1693o–2(b)(1), as set forth by the Commission in its complaint. Section IX provides that the order will terminate 10 years from the date it is issued. However, if the United States or Commission files a complaint in federal court alleging a violation of the proposed order (and the court does not dismiss the complaint or rule that there was no violation), then the order will terminate 10 years from the date such complaint is filed.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2023–00559 Filed 1–12–23; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Administrator of the Administration for Community Living the authorities vested in the Secretary of Health and Human Services under the Rehabilitation Act of 1973 as amended in the Workforce Innovation and Opportunity Act (Pub. L. 113–128), to Chair the Interagency Committee on Disability Research for the purposes of promoting the coordination and collaboration of federal disability and rehabilitation research and related activities as stipulated in the ICDR's statutory mission.

This authority may be redelegated to the Director of the National Institute on Disability, Independent Living and Rehabilitation Research. Exercise of this authority shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the Secretary. The Secretary retains the authority to submit reports to Congress and promulgate regulations.

This delegation is effective immediately. I hereby affirm and ratify any actions taken by subordinates that involved the exercise of the authorities delegated herein prior to the effective date of the delegation.

Dated: January 10, 2023.

Xavier Becerra,

Secretary.

[FR Doc. 2023–00574 Filed 1–12–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0201]

Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and

Format.'' This guidance is intended to assist applicants in developing the DOSAGE AND ADMINISTRATION section of labeling. The purpose of this guidance is to assist applicants in ensuring that the DOSAGE AND ADMINISTRATION section contains the dosage- and administration-related information needed for safe and effective use of a drug and that the information is clear, concise, and presented in a manner that is pertinent and understandable to health care practitioners. We are withdrawing the guidance for industry entitled ''Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' issued on March 29, 2010, and issuing this draft guidance.

DATES: Submit either electronic or written comments on the draft guidance by March 14, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0201 for ''Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Eric Brodsky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6485, Silver Spring, MD 20993–0002, 301–796–0855; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' FDA is also withdrawing its previous guidance for industry, issued on March 23, 2010 (75 FR 13766), which was entitled ''Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.''

The draft guidance, when finalized, is intended to assist applicants in developing the DOSAGE AND ADMINISTRATION section of labeling to ensure that this section contains the dosage- and administration-related information needed for safe and effective use of a drug and that the information is clear, concise, and presented in a manner that is pertinent and understandable to health care practitioners. Applicants should follow the recommendations in this guidance when developing this section for a new drug submitted to FDA under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or a biologics license application under section 351(a) of the Public Health Service Act, and when revising

existing information in the labeling for a currently approved drug in a supplement to such applications.

This draft guidance provides examples of required and recommended information in the DOSAGE AND ADMINISTRATION section. This guidance provides recommendations on including certain dosage- and administration-related information in the DOSAGE AND ADMINISTRATION section that is particularly critical to the safe and effective use of the drug (*e.g.,* lack of knowledge of the information or nonadherence to a recommendation could have serious consequences for patients).

This draft guidance addresses the dosage and route of administration for each indication in the DOSAGE AND ADMINISTRATION section and information about the dosage range, the starting or loading dose and dosage, titration schedule, the maximum recommended dosage, the maximum recommended duration, monitoring for effectiveness, and concomitant therapy information in the DOSAGE AND ADMINISTRATION section, as appropriate.

This draft guidance also addresses the following information in the DOSAGE AND ADMINISTRATION section:

- Other drugs used before, during, or after drug treatment or administration;
- Dosage modifications for adverse reactions or for drug interactions;
- Dosage in specific populations (*e.g.,* pediatric patients, geriatric patients, patients with renal impairment, patients with hepatic impairment);
- Information about switching to the subject drug from other products or substitution involving the subject drug;
- Recommendations regarding missed dose(s);
- Recommendations in event of vomiting after oral drug administration;
- Recommendations for drug discontinuation or dosage reduction when there are risks of withdrawal; and
- The recommended dosage for fixed-combination drug products and co-packaged products.

Furthermore, this draft guidance addresses when and how to include information in the DOSAGE AND ADMINISTRATION section on the preparation and/or administration of the drug (*e.g.,* parenteral products, a product stored in the refrigerator or freezer, pharmacy bulk packages, imaging bulk packages, solid oral dosage forms with qualified liquids or soft foods, oral dosage forms via enteral feeding tubes, liposome drug products); instructions to avoid harm related to drug handling and administration, radiation dosimetry; and information on drug incompatibilities if the drug is mixed with other drugs. This guidance also provides information on storage instructions for the reconstituted or diluted product.

Finally, this draft guidance describes information that should ordinarily not be included in the DOSAGE AND ADMINISTRATION section.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the ''Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314 and 21 CFR 601 have been approved under OMB control number 0910–0001 and 0910–0338. The collections of information in 21 CFR 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: January 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00619 Filed 1–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0945–0008]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before February 13, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Collection: Reinstatement with changes.

OMB No.: 0945–0008.

Abstract: This Information Collection Request is for a reinstatement with changes to previously approved collection 0945–0008 that is expired in December 2022, titled: Assurance of Compliance, Form HHS–690, subject to minor modifications. Such an assurance is required by the federal civil rights laws enforced by the Office for Civil Rights, as described herein. One method that the federal government uses to ensure civil rights compliance is to require covered entities to submit written assurances of compliance when applying for federal financial assistance. The assurances alert covered entities of their civil rights obligations and provide the Department with a valuable enforcement tool, as a recipient's written assurance and certification documents can provide an independent