placed on the public record of this proceeding, including the *https://www.regulations.gov* website. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on *www.regulations.gov.*

If you file your comment on paper, write ''Pre-sale Availability Rule; PRA Comment: FTC File No. P072108'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC website at *www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record.[8] Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *www.regulations.gov,* we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 2, 2020. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *https://www.ftc.gov/site-information/privacy-policy.*

Heather Hippsley,

Deputy General Counsel.

[FR Doc. 2019–28194 Filed 12–30–19; 8:45 am]

BILLING CODE 6750–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–MR–2019–01; Docket No. 2019–0002; Sequence No. 35]

Modernizing Services for Regulation Management

AGENCY: Office Regulation Management, Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice of public meetings and request for comment.

SUMMARY: GSA is seeking public comment on any matters related to the modernization of Electronic Rulemaking Management. Background information on specific topics will be provided in electronic format through the *regulations.gov* docketing system to help inform the public on known issues around which to focus their input. Comments will also be accepted electronically.

To further inform the public on issues affecting the future of Electronic Rulemaking Management, GSA is hosting two town-hall style public meetings. In addition to inviting members of the public to attend these meetings, GSA is seeking subject matter experts who would be interested in participating in one or more panels at these meetings. Further Information regarding the public meetings, the process for requesting to present, and the comment process may be found under the heading **SUPPLEMENTARY INFORMATION.**

DATES: The public meetings will be conducted on January 30 and March 25, 2020. Both meetings will be held from 2:00 p.m., to 4:00 p.m., Eastern Time (ET).

Subject matter experts interested in serving on a panel at one or more public meetings must submit their proposed topics and qualifications/experience, in the form of a resume, for the relevant subject area no later than the following dates:

For the meeting on January 30, 2020, proposals are due midnight January 10, 2020.

For the meeting on March 25, 2020, proposals are due midnight March 2, 2020.

Comments related to any aspect of modernization of Electronic Rulemaking Management must be submitted no later than April 30, 2020.

ADDRESSES: All public meetings will take place at GSA's Central Office at 1800 F Street NW, Washington, DC 20006.

Submit proposals to present by emailing *eRulemaking@gsa.gov.*

Pre-register to attend the January 30, 2020, public meeting at *https://regulationsmanagement.eventbrite.com.*

Pre-register to attend the March 25, 2020, public meeting at *https://regulationsmanagement2.eventbrite.com.*

Submit comments in response to Notice–MR–2019–01 using Docket No. 2019–0002; Sequence No. 35, on *regulations.gov* (*http://www.regulations.gov*).

FOR FURTHER INFORMATION CONTACT: For further information, please contact *eRulemaking@gsa.gov.*

SUPPLEMENTARY INFORMATION:

Background on Electronic Rulemaking Management

GSA's Office of Regulation Management, within OGP, is interested in conducting a dialogue with the public, including industry, special interest groups, academia, researchers, and individuals about challenges and opportunities related to the modernization of the Electronic Rulemaking Management process. The dialogue begins with this public notice and request for comment.

The Office of Regulation Management manages two programs that deliver shared regulatory IT services. The eRulemaking Program manages *Regulations.gov* and the Federal Docket

[8] *See* FTC Rule 4.9(c).

Management System (FDMS). The Regulatory Information Service Center (RISC) manages *RegInfo.gov* and the RISC/OIRA Consolidated Information System (ROCIS).

GSA's strategy for Rulemaking Modernization is three-fold:

1. Better integrate data and information technology among Federal regulatory information systems to support data analytics, both for rule makers and members of the public.

2. Apply innovative approaches to promote public access, accountability, and transparency.

3. Reduce duplication and increase efficiency across the Federal rulemaking landscape through improved processes and technologies.

Docket No. 2019–0002; Sequence No. 35 at *Regulations.gov* will contain background documents on various topics on the regulatory process within a docket.

You can discover more about the Office of Regulation Management and its regulatory work at: *https://www.gsa.gov/policy-regulations/regulations/how-you-can-improve-regulations.*

You can discover more about e-Rulemaking, including FDMS and *regulations.gov* at: *https://www.fdms.gov/fdms/public/aboutus* and *https://www.regulations.gov/aboutProgram.*

You can discover more about the Regulatory Information Service Center at: *https://www.gsa.gov/about-us/organization/office-of-governmentwide-policy/office-of-acquisition-policy/governmentwide-acq-policy/regulatory-information-service-center* and *https://www.reginfo.gov/public/.*

Written Comments

To assist GSA and OMB in planning for the modernization of the Electronic Rulemaking Management process, GSA and OMB are inviting interested parties to submit written comments.

Instructions: The referenced electronic docket in *www.regulations.gov* is a collection of documents related to this request for comment. Interested members of the public may comment on any individual document, whether or not addressed in one of the public meetings. The public may also comment on any matter relating to modernization of Electronic Rulemaking Management by commenting on the primary document for this notice, referenced in the docket as Notice–MR–2019–01.

From the home page of *regulations.gov,* search for ''Docket No. 2019–0002; Sequence No. 35.'' Identify the specific document within the docket that you would like to comment on, select the link ''Comment Now,'' and follow the instructions provided at the screen. For example, interested parties may wish to comment on the general information in the notice. Others may wish to comment on other more specific background documents that describe the Federal regulatory process and actions under consideration to improve and modernize the process.

For formal consideration, all comments must be submitted to *regulations.gov* at the referenced docket. Comments may be submitted up to April 30, 2020, on any topic related to Electronic Rulemaking Modernization.

GSA may publicly post all presentations submitted to the public meetings, all transcripts associated with the public meetings, and any comments received to the docket on *regulations.gov* without change. Read the *regulations.gov* notifications below regarding sharing of personally identifiable and/or business confidential information.

Individual documents posted on the docket will provide any details on the nature of input sought from the public on specific topics.

In general, GSA is seeking input on the business/mission needs of you or your organization as a participant or interested stakeholder in the rulemaking process. Specifics on proposed services or service improvements, including benefits and costs, would be helpful. Specific suggestions on service management, including performance measures and approaches for ongoing customer engagement would also be helpful.

Comments are also welcome on related technology services, including any specific recommendations for how technology can be applied to achieve specific business needs for regulatory management.

GSA also welcomes any references to existing research, processes, services, or technologies directly related to regulation management or related to functions that can be applied to regulation management.

Please note that comments on individual proposed rulemakings or other agency actions should be addressed to the specific agency and any dockets that they have created for that action.

The role of GSA is that of a shared service provider for supporting public participation and government efficiencies in the regulatory process.

Public Meetings

GSA will be conducting the following public meetings on the topics as indicated below. Attendance at these meetings is not required to provide comments. The public meetings are intended to supplement the background materials in the docket and provide additional insight into specific topics related to Electronic Regulation Management. Transcripts and any presentations from the meetings will be publicly posted to the docket within a reasonable period of time for others to view and provide comments.

Those in attendance at each meeting will have an opportunity to ask questions or make comments through the Town Hall forum, as time permits. However, the meeting forum is not a formal comment process.

The meetings and topics are as follows:

January 30, 2020, from 2:00 p.m. to 4:00 p.m., (ET). GSA is seeking presenters on topics that relate to:

- General challenges and opportunities for improving transparency and public participation in the development and review of regulations.
- The challenges relating to agency management of large volumes comments on proposed regulations.
- Public concern, risks, and solutions addressing instances where the identity of the entity submitting a comment has been falsified, known as the ''fake commenter issue.''
- What technologies or policies could assist with the management of mass comments or fake commenters?
- Perspectives of the commenting community on the value of mass comments from single entities or interest groups.
- Perspectives of the commenting community on how to minimize the levels of organizations submitting comments on behalf of ''fake commenters.''
- The value of mass comments relative to smaller numbers of potentially more substantive comments.

On March 25, 2020, from 2:00 p.m. to 4:00 p.m. (ET), GSA is seeking presenters on topics that relate to:

- General challenges and opportunities for analysis across multiple regulations. For example, a single regulated entity may be subject to multiple overlapping or inconsistent regulations.
- How desirable is it for the public to be able to have a line of sight across the entire life cycle of a rulemaking, from law, to regulation, to U.S. Code? What are the benefits?
- What other types of data analysis tools or reports would be useful for the public?

- What types of regulatory trends or information should be analyzed to benefit the regulatory process?
- What technologies or policies could assist with sharing of data or interoperability of regulatory management systems across the Federal government?
- What are the challenges and opportunities for third party service providers to use regulatory information alone or in combination with other data to deliver commercial services or analysis?
- What technologies or policies could assist with increasing public access to data for or through commercial applications?

In-Person Attendance

Interested parties are invited to attend the public meetings to be held at GSA Headquarters, located at 1800 F St. NW, Washington, DC 20006. While walk-ins will be allowed if there is seating capacity, the public is encouraged to pre-register prior to the scheduled date due to seating limitations. Pre-register for the January 30, 2020, meeting at *https://regulationsmanagement.eventbrite.com. Pre-register for the March 25, 2020, meeting at https://regulationsmanagement2.eventbrite.com.* Check for additional information regarding meeting logistics on *regulations.gov,* Docket No. 2019–0002; Sequence No. 35 as dates approach. Questions may be directed to *eRulemaking@gsa.gov.*

Registration check-in will begin at 1:00 p.m. (ET), and each meeting will start promptly at 2:00 p.m. (ET). Depending on levels of attendance for registered attendees, walk-in registration may or may not be available. Updates on whether registration has reached capacity will be posted on *regulations.gov,* Docket No. 2019–0002; Sequence No. 35. Walk-ins may be admitted if registered attendees do not show. Attendees must present government-issued photo identification.

Virtual Attendance

Interested parties may also attend virtually through GSA's virtual meeting platform, hosted by Adobe Connect. Further details on the virtual meeting will be made available via GSA Interact at *https://interact.gsa.gov/group/commercial-platform-initiative.*

Meeting Accommodations

The public meeting is physically accessible to people with disabilities. Sign language interpretation and auxiliary aids will be available at the meetings and online. Any specific requests for accommodations and auxiliary aids must be directed to *eRulemaking@gsa.gov* no later than 10 working days prior to the scheduled meetings.

Panel Presentations

GSA intends to conduct two town-hall/panel style discussions, with each event focused on the respective topics outlined above. Each meeting is expected to consist of two panels with three to five participants per panel. Each panel is expected to run 50 minutes, with 45 minutes of panel discussion and 10 minutes of audience questions.

Subject matter experts interested in serving on a panel at one or both public meetings must submit their proposals, to include a resume, an indication of the selected meeting or meetings, and a synopsis of their proposed topics and key points of no more than 250 words, no later than the following dates:

For the January 30, 2020, meeting, proposals are due midnight January 10, 2020.

For the March 25, 2020, meeting, proposals are due midnight March 2, 2020.

Submissions are to be emailed to *eRulemaking@gsa.gov.* GSA will select the panelists and will formally notify and coordinate with them in advance of the respective meeting. In selecting panelists, GSA will seek an array of perspectives, backgrounds, and experiences.

Dated: December 24, 2019.

Tobias Q. Schroeder,

Director, eRulemaking Program Management Office, Office of Regulation Management, Office of Government-wide Policy, General Services Administration.

[FR Doc. 2019–28242 Filed 12–30–19; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–3877]

Determination That GLUCOPHAGE (Metformin Hydrochloride) Oral Tablets, 500 Milligrams, 850 Milligrams, and 1 Gram, and GLUCOPHAGE XR (Metformin Hydrochloride) Oral Extended-Release Tablets, 500 Milligrams and 750 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that, GLUCOPHAGE (metformin hydrochloride) oral tablets, 500 milligrams (mg), 850 mg, and 1 gram (g), and GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Carlarease Hunter, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3702, *Carlarease.Hunter@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn