other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act.

FDA created a Tobacco Call Center (with a toll-free number: 1–877–CTP–1373). Callers are able to report potential violations of the Tobacco Control Act, and FDA may conduct followup investigations based on information received. When callers report a violation, the caller will be asked to provide as much certain information as they can recall, including: The date the potential violation occurred; product type (*e.g.,* cigarette, smokeless, roll-your-own, cigar, e-cigarette, hookah, pipe tobacco); tobacco brand; potential violation type; type of potentially violative promotional materials; who potentially violated; and the name, address, phone number, and email address of the potential violator. The caller will also be asked to list the potential violator's Web site (if available), describe the potential violation, and provide any additional files or information pertinent to the potential violation.

FDA currently provides a form that may be used to solicit this information from the caller (Form FDA 3779, Potential Tobacco Product Violations Report), and seeks renewal of Form FDA 3779. This form is posted on FDA's Web site. The public and interested stakeholders are also able to report information regarding possible violations of the Tobacco Control Act through the following methods: Calling the Tobacco Call Center using the Center for Tobacco Products' (CTP) toll-free number; using a fillable Form FDA 3779 found on FDA's Web site; downloading a PDF version of the form to send via email or mail to FDA; requesting a copy of Form FDA 3779 by contacting CTP and sending by mail to FDA; and sending a letter to FDA's CTP.

In the **Federal Register** of November 7, 2016 (81 FR 78166), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity and FDA Form 3779	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting violations of the FD&C Act, as amended by the Tobacco Control Act via telephone, Internet form, mail, smartphone application, or email.	750	2	1,500	0.25 (15 minutes)	375

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that submitting the information (by telephone, Internet form, paper form by mail, or email) will take 0.25 hour (*i.e.,* 15 minutes) per response. Based on the type and rate of reporting that has been submitted through the Potential Tobacco Violation Reporting Form in the past, in addition to the increase that FDA has recently experienced in the rate of reporting due to the recent rule, ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act,'' FDA estimates the number of annual respondents to this collection of information will be 750, who will each submit 2 reports by telephone, Internet form, paper form, or email. Each report is expected to take 0.25 hour to complete and submit; therefore, total burden hours for this collection of information is estimated to be 375 hours (1,500 responses x 0.25 hour per response).

Dated: June 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–13018 Filed 6–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–3615]

Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following meeting: ''The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access.'' This public meeting is intended to provide the public an opportunity to submit comments concerning administration of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) to help ensure the intended balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs is maintained.

DATES: The meeting will be held on July 18, 2017, from 9 a.m. to 5 p.m. The deadline for submitting comments regarding this meeting is September 18, 2017.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 18, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 18, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2017–N–3615 for ''Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

• 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Philip Bonforte, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1668, Silver Spring, MD 20993, 240–402–6980, email: *GenericDrugPolicy@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

With the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (Hatch-Waxman Amendments), Congress intended to strike a balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs. See H.R. Rep. No. 98–857 (Part I), 98th Cong, 2d Sess. At 14–15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647–48; see also, *e.g., Teva Pharmaceutical Industries Ltd.* v. *Crawford,* 410 F.3d 51, 54 (D.C. Cir. 2005). To provide incentives intended to encourage the development of innovative new drugs and new uses of approved drugs, the Hatch-Waxman Amendments provided sponsors of innovator drugs with exclusivity and protections based on patent listings that protect certain aspects of innovator drugs from generic competition for certain periods of time. To ensure the availability of generic drugs, the Hatch-Waxman Amendments created an abbreviated new drug application (ANDA) process that allows sponsors of generic drugs to rely on the Agency's finding of safety and effectiveness for innovator drugs in seeking approval of their generic products after patent or marketing exclusivity protections held by the innovator expire or are otherwise removed.

FDA's generic drug program has dramatically expanded access to quality, affordable generic medicines. According to the IMS Institute for Healthcare Informatics, generic drugs saved the U.S healthcare system $1.68 trillion from 2005–2014.[1]

Over the past several years, the Agency has undertaken major initiatives to expand access to quality, affordable generic medicines. For example, pursuant to the Generic Drug User Fee Amendments of 2012 (GDUFA I), FDA modernized the ANDA review program, and adopted metric goals to promote timely and predictable ANDA review. As a result, in Fiscal Year 2016, combined ANDA approvals and tentative approvals reached record highs. Pursuant to the proposed GDUFA II,[2] FDA would further enhance the ANDA review program by clarifying regulatory expectations early in product development, helping applicants develop more complete submissions, and giving applicants more opportunities to address deficiencies within a review cycle, all with the goal of reducing the number of review cycles necessary to obtain ANDA approval.

The development and approval of an innovator drug, and the subsequent approval and marketing of a generic version, together make up the life cycle of that drug product as contemplated by the Hatch-Waxman Amendments.

At the front end of the life cycle, innovation in drug products—including improvements to approved innovator drug products—provides life-changing and oftentimes life-saving therapeutic benefits to patients. In enacting the Hatch-Waxman Amendments, Congress recognized the importance of providing incentives to develop new products, and

[1] IMS Health Institute for Healthcare Informatics (April 2015), available at *http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports*.

[2] GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022 (October 2016), available at *https://www.fda.gov/downloads/forindustry/userfees/genericdruguserfees/ucm525234.pdf*.

new conditions of use for approved products. To further incentivize innovation, Congress subsequently established additional incentives in the form of exclusivity periods for drug products studied in pediatric populations, rare diseases, and new antibiotic treatments. Congress also provided a period of 180-day exclusivity for certain first generic applications as an incentive for generic manufacturers to challenge patents on innovator drugs that might otherwise prevent approval or delay generic entry into the market. These exclusivities, which are generally designed to reward sponsors with finite periods of limited or no generic or follow-on competition, were intended to expand the availability of safe and effective medicines for which insufficient or no treatment previously existed or to encourage generic drug development that might not have been profitable otherwise.

In some cases, however, the legal framework surrounding these exclusivities may have been applied to delay generic competition to an extent that may not have been intended by the Hatch-Waxman Amendments, and in ways that may not serve the public health. Relatedly, certain elements of the approval process for both innovator and generic drugs have been used in ways that may (depending on the circumstances) inappropriately hinder generic competition. For example, innovators in some cases have made late changes in patent use codes that create new obstacles to previously acceptable labeling carve-outs. The entry of generic products to the marketplace is also affected by factors external to regulation under the FD&C Act—*e.g.,* the outcome of private party patent litigation, and commercial decisions not to market approved innovator or generic products. In other cases, restrictions on the distribution of innovator drug products, whether voluntarily adopted by the innovator or imposed as a requirement of FDA regulation, have prevented developers from accessing the product samples needed for testing to support ANDAs or other follow-on applications.

FDA will hold a public meeting on July 18, 2017, 9 a.m. to 5 p.m., to provide an opportunity for all interested stakeholders to submit comments concerning the appropriate balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs.

The format of the meeting involves presentations from the public only. The Agency will not be inviting specific presenters; rather, with this document, FDA is soliciting presentations from interested stakeholders. FDA also invites interested persons to submit written comments to the docket on the topics described in section II.

II. Topics for This Public Meeting

FDA is soliciting input from the public concerning how best to preserve the balance Congress intended to strike in the Hatch-Waxman Amendments between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs. Preserving this balance is critical to the public health, and innovators, generic drug manufacturers, and FDA (among others) all have a role to play in maintaining it. This public meeting is part of an effort to create a broader understanding of the interplay between the existing legal and regulatory framework, available incentives and marketplace practices, and consumer access to generic drugs.

The Agency welcomes any relevant information that stakeholders wish to share. We are particularly interested in stakeholder input on the following questions:

1. How has the balance struck in the Hatch-Waxman Amendments been affected by practices and trends related to the following:

a. Exclusivity periods,

b. Patents (including patent listing procedures),

c. Innovator drug product labeling,

d. Post-approval changes to innovator drug products, *e.g.,* reformulations, and

e. Other regulatory processes, including the citizen petition process?

2. The drugs described in more than half of all FDA-approved ANDAs are never marketed, marketed only after a substantial delay after approval, or marketed only intermittently. Such failures to market contribute to drug shortages, and hinder consumer access to approved products. What marketplace dynamics dis-incentivize the marketing of approved generic products? What should FDA do, within its statutory authority, to help more approved generics reach consumers?

3. For approximately 10 percent of all innovator drugs, patent and exclusivity protections have expired, but FDA has not received an ANDA. Are there market niches where the Hatch-Waxman Amendments incentives to develop an ANDA are insufficient? Similarly, are there niches where the incentives are insufficient to seek new drug approval of a marketed unapproved drug product that in turn could serve as a Reference Listed Drug? What should FDA do, consistent with its legal authority, to encourage submission development in any such market niches?

4. The statutory requirement that Risk Evaluation and Mitigation Strategies (REMS) that include elements to assure safe use (ETASU) be implemented through a ''single shared system'' relies on brand and generic companies agreeing on such a system before generic drugs may come to market. In some cases, challenges in reaching such an agreement between the parties may cause delays to generic competition. How should FDA apply its statutory authority to waive this requirement to implement a ''single shared system,'' or develop other administrative tools, to avoid these delays?

5. Restrictions on distribution, either required by innovators or as part of a REMS ETASU, can prevent generic companies from obtaining drug products for bioequivalence and other testing to support ANDA submissions. FDA published a draft guidance for industry, entitled ''How to Obtain a Letter from the Food and Drug Administration Stating That Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable Risk and Evaluation Mitigation Studies for Reference Listed Drugs,'' in December 2014. Despite this draft guidance, generic companies have reported continuing difficulties obtaining sufficient samples of drug products for testing. What additional actions should FDA take, within its legal authority, to promote access to these drug products for generic companies seeking to conduct studies required to support ANDA submissions?

6. What other elements of drug product development, regulation, and marketing have the potential to disrupt the Hatch-Waxman Amendments' balance between innovation and generic availability, and how should the Agency and other stakeholders address them?

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, email address, and fax number), and written material and requests to make oral presentations, to the contact person by July 3, 2017.

If you need special accommodations due to a disability, please contact Philip Bonforte (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *https://www.regulations.gov*. It may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: June 14, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–12641 Filed 6–21–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Information Collection Request Title: Rural Health Network Development Planning Performance Improvement and Measurement System Database, OMB No. 0915–0384—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than July 24, 2017.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Rural Health Network Development Planning Performance Improvement and Measurement System Database, OMB No. 0915–0384—Extension.

Abstract: The purpose of the Rural Health Network Development Planning (Network Planning) program is to assist in the development of an integrated health care network, specifically for entities that do not have a history of formal collaborative efforts. Health care networks can be an effective approach to help smaller rural health care providers and health care service organizations align resources, achieve economies of scale and efficiency, and address challenges more effectively as a group than as single providers. The Network Planning program promotes the planning and development of healthcare networks to: (1) Achieve efficiencies; (2) expand access to, coordinate, and improve the quality of essential health care services; and (3) strengthen the rural health care system as a whole.

Need and Proposed Use of the Information: Performance measures for the Network Planning program serve the purpose of quantifying awardee-level data that conveys the successes and challenges associated with the grant award. These measures and aggregate data substantiate and inform the objectives of the program. The approved measures encompass the following principal topic areas: network infrastructure, network collaboration, sustainability, and network assessment.

Likely Respondents: The respondents for these measures are Network Planning award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours, which are unchanged from the currently approved form, are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Health Network Development Planning Program Performance Improvement Measurement System	21	1	21	1	21
Total	21		21		21

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2017–13019 Filed 6–21–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following special workgroup activity.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards Meeting.

Date and Time: Monday, August 21, 2017: 9:00 a.m.–4:00 p.m.

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW., Room 800, Washington, DC 20201, (202) 690–7100.

Status: Open.

Purpose: The National Committee on Vital and Health Statistics (NCVHS) is the advisory body to the U.S. Department of Health and Human Services (HHS) Secretary on health data, statistics, privacy, and national health information policy. NCVHS' role includes advising HHS in the implementation of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Patient Protection and Affordable Care Act of 2010 (ACA). The Standards Subcommittee of NCVHS makes recommendations to the full Committee on health data standards, including