TABLE 1—DRUG PRODUCTS NOT WITHDRAWN FROM SALE FOR REASONS OF SAFETY OR EFFECTIVENESS—Continued

Application No.	Drug name	Active ingredient(s)	Dosage form/route	Strength(s)	Applicant
NDA 021071	AVANDIA	Rosiglitazone Maleate	EQ 2 mg Base; EQ 4 mg Base.	Tablet; Oral	Woodward Pharma Services LLC.
NDA 021160	PHOSLO GELCAPS	Calcium Acetate	667 mg	Capsule; Oral	Fresenius Medical Care.
NDA 021360	SUSTIVA	Efavirenz	600 mg	Tablet; Oral	Bristol Myers Squibb.
NDA 021493	ZYMAR	Gatifloxacin	0.3%	Solution/Drops; Ophthalmic.	Allergan.
NDA 021656	TRICOR	Fenofibrate	48 mg; 145 mg	Tablet; Oral	Abbvie.
NDA 021759	ELOXATIN	Oxaliplatin	50 mg/10 mL (5 mg/mL); 100 mg/20 mL (5 mg/mL).	Injectable; Intravenous	Sanofi Aventis US.
NDA 021779	VENTAVIS	Iloprost	10 Micrograms (mcg)/mL (10 mcg/mL); 20 mcg/mL (20 mcg/mL).	Solution; Inhalation	Actelion.
NDA 021849	ZEGERID	Omeprazole; Sodium Bicarbonate.	20 mg, 1.1 g; 40 mg, 1.1 g.	Capsule; Oral	Salix.
NDA 022428	MOXEZA	Moxifloxacin Hydrochloride.	EQ 0.5% Base	Solution/Drops; Ophthalmic.	Harrow Eye.
NDA 050006	VIBRAMYCIN	Doxycycline	EQ 25 mg Base/5 mL	For Suspension; Oral	Pfizer.
NDA 050541	TOBREX	Tobramycin	0.3%	Solution/Drops; Ophthalmic.	Novartis.
NDA 050808	SOLODYN	Minocycline Hydrochloride	55 mg; 65 mg; 80 mg; 105 mg; 115 mg.	Tablet, Extended Release; Oral.	Bausch.
NDA 207987	ABLYSINOL	Alcohol	99% (1 mL)	Solution; Intra-Arterial	BPI Labs, LLC.
NDA 208183	ULTRAVATE	Halobetasol Propionate	0.05%	Lotion; Topical	Lacer Pharmaceuticals.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 6, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08207 Filed 5–8–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1090]

Prescription Drug User Fee Act VII; Independent Assessment of Communication Through Product Quality Information Requests During Application Review; Final Report; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled ''Product Quality Information Request Communications Assessment: Final Report.'' This report fulfills a commitment under the recent reauthorization of the Prescription Drug User Fee Act (PDUFA) to assess communication between FDA and applicants through product quality information requests during application review and to identify best practices and areas of improvement. The assessment of FDA and applicants in communicating through product quality information requests was conducted by an independent contractor, as described in the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027.'' As part of FDA performance commitments described in this document, FDA is publishing the final assessment report and soliciting public comments.

DATES: Submit either electronic or written comments on the final report by July 31, 2025.

ADDRESSES: You may submit either electronic or written comments 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–2025–N–1090 for ''Independent Assessment of Communication Through Product Quality Information Requests During Application Review.'' 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.

FOR FURTHER INFORMATION CONTACT: Mahesh Ramanadham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3272, email: *Mahesh.Ramanadham@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

PDUFA provides FDA with a source of stable, consistent funding that has made it possible for the Agency to focus on promoting innovative therapies and help bring to market critical products for patients. When PDUFA was originally authorized in 1992, it had a 5-year term. The program has been subsequently reauthorized every 5 years. To prepare for the reauthorization of PDUFA for years 2023 to 2027, FDA conducted negotiations with the regulated industry and held regular consultations with public stakeholders, including patient advocates, consumer advocates, and healthcare professionals between September 2020 and February 2021.

Following these discussions, related public meetings, and Agency requests for public comment, FDA published the ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027'' document, available at *https://www.fda.gov/media/151712/download,* also known as the PDUFA VII ''goals letter,'' to supplement the statute. The goals letter includes the performance goals, procedures, and commitments that apply to aspects of the human drug review program that are important for facilitating timely access to safe, effective, and innovative new medicines for patients. Several of these commitments aim to continue to enhance communication between FDA and applicants during application review.

FDA and applicants interact in a variety of ways throughout application review. One such way is via a communication called an information request (IR), sent to an applicant as the discipline review occurs. FDA uses IRs to request further information or clarification that is needed or would be helpful to allow completion of the discipline review. IRs may be in the form of letters, emails, or faxes.

FDA uses product quality IRs to request further information or clarification needed for FDA's assessment of identity, strength, quality, purity, or potency of drug substances or drug products. Ensuring that patients can have confidence in the safety and effectiveness of their medications is a longstanding priority for FDA. The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have worked to address this priority in part by performing Chemistry, Manufacturing, and Controls (CMC) reviews for CDER-regulated and CBER-regulated products. CDER or CBER may issue a product quality, or CMC, IR as a result of CMC assessments conducted in support of the application.

CDER and CBER have established procedures for assessors to use Four-Part Harmony, a framework that describes four key elements that should be included in product quality IRs, specifically: (1) what was provided, (2) what is the issue or deficiency, (3) what is needed, and (4) why it is needed. These procedures can be found in CDER's Manual of Policies and Procedures (MAPP) 5016.8 Rev. 1, ''Using Four-Part Harmony in Quality-Related Assessment Communications'' and CBER's Standard Operating Procedures and Policies (SOPP) 8401.1, ''Issuance of and Review of Responses to Information Request Communications to Pending Applications.'' The PDUFA VII goals letter includes commitments for FDA to update and conduct training on existing policies and procedures (MAPPs and SOPPs), to reflect Four-Part Harmony. CDER MAPP 5016.8, ''Communication Guidelines for Quality-Related Information Requests and Deficiencies'' (*https://www.fda.gov/media/171613/download*) was revised in September 2023 and made public. CBER SOPP 8401.1, ''Issuance of and Review of Responses to Information Request Communications to Pending Applications'' (*https://www.fda.gov/media/85301/download*) was revised in October 2022.

In addition to updating the documents and conducting training, FDA committed to contracting with an independent third party to assess current practices of CDER, CBER, and applicants in communicating through product quality IRs during application review and effectiveness of Four-Part Harmony. This assessment has been completed, and in accordance with the PDUFA VII goals letter, FDA is seeking public comment on this ''Product Quality Information Request Communications Assessment: Final Report,'' available at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-assessment-fda-and-sponsor-communications-through-product-quality-information-requests.*

II. Request for Comments

FDA is soliciting comments on the ''Product Quality Information Request Communications Assessment: Final Report'' from interested parties. We request feedback on: (1) the assessment findings and recommendations, (2) whether certain recommendations are more desirable than others, and (3) other actions FDA and applicants should consider and why.

III. Electronic Access

Persons with access to the internet may obtain the report at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-assessment-fda-and-sponsor-communications-through-product-quality-information-requests.*

Dated: May 6, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08208 Filed 5–8–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0834]

Prescription Drug User Fee Act; Stakeholder Consultation Meetings on the Prescription Drug User Fee Act Reauthorization; Request for Notification of Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Prescription Drug User Fee Act (PDUFA). The statutory authority for PDUFA expires in September 2027. At that time, new legislation will be required for FDA to continue collecting user fees for the prescription drug program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next PDUFA program. The FD&C Act also requires that FDA hold discussions (at least every month) with patient and consumer advocacy groups during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by August 4, 2025. Stakeholder meetings will be held monthly. It is anticipated that they will commence in September 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Submit notification of intention to participate in monthly stakeholder meetings by email to *PDUFAReauthorization@fda.hhs.gov.* The meetings will be held in person at the FDA White Oak campus, 10903 New Hampshire Ave., Silver Spring, MD 20993 and virtually using the Microsoft Teams platform.

FOR FURTHER INFORMATION CONTACT: Andrew Kish, Center for Drug Evaluation and Research, Food and Drug Administration, 301–796–5215, *Andrew.Kish@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of PDUFA. PDUFA authorizes FDA to collect user fees from the regulated industry for the process for the review of human drugs. The authorization for the current program (PDUFA VII) expires in September 2027. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human drug review process.

Section 736B(f)(1) of the FD&C Act (21 U.S.C. 379h–2(f)(1)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer groups, healthcare professionals, and scientific and academic experts, in developing recommendations for the next PDUFA program. FDA will initiate the reauthorization process by holding a public meeting on July 14, 2025, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization. The FD&C Act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization. It is anticipated that these monthly stakeholder consultation meetings will commence in September 2025.

FDA is issuing this notice to request that stakeholder representatives from patient and consumer groups, healthcare professional associations, as well as scientific and academic experts, notify FDA of their intent to participate in the periodic stakeholder consultation meetings on PDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in the stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice will be included in all stakeholder consultation discussions while FDA negotiates with the regulated industry. If a stakeholder decides to participate in these monthly meetings at a later time, that stakeholder may join the remaining monthly stakeholder consultation meetings after notifying FDA of this intention (see **ADDRESSES**). These stakeholder discussions will satisfy the consultation requirement in section 736B(f)(3) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Stakeholder Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding PDUFA reauthorization, please provide notification by email to *PDUFAReauthorization@fda.hhs.gov* by August 4, 2025. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification.

Dated: May 6, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08209 Filed 5–8–25; 8:45 am]

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