Drug, and Cosmetic Act; or human cells, tissues, or cellular or tissue-based products regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264) and 21 CFR part 1271.

On April 20, 2016, (81 FR 23303), FDA announced the availability of a revised draft guidance entitled ''Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information.'' This was a revised draft of a draft guidance published in February 2003. We revised the February 2003 draft guidance in 2016 for the following reasons:

- To include current pharmaceutical quality concepts.
- To provide more flexibility regarding filing procedures for a notification of modifications to an approved CP in less burdensome reporting categories than a prior approval supplement.
- To add an appendix to address commonly asked questions.

The Center for Veterinary Medicine, which was included in the February 2003 draft guidance, published recommendations for animal drugs in a separate guidance.

We received a number of comments on the revised draft guidance, which the Agency considered carefully as it prepared this final guidance. Additional information has been included in the final guidance on proposing an appropriate reporting category for implementation of changes under a CP once approved. Additional examples have been included for notification of modifications to an approved CP in less burdensome reporting categories than a prior approval supplement. Information has been included in the appendix on cross-referencing of a master file, including a Drug Master File, in a CP and submitting a CP to a master file. Also, the recommendations in the guidance for industry ICH Q12 have been carefully considered when revising this guidance to maximize consistency. We also have made clarifications and editorial changes to the final guidance document.

This final guidance provides recommendations to original applicants and holders of approved applications for human drugs and certain biological products on implementing CMC postapproval change(s) through the use of a CP. In many cases, submission and approval of a CP will facilitate the subsequent implementation and reporting of CMC changes, which could result in moving a drug or biological product into distribution or facilitating a proactive approach to reinforcing the supply of a product sooner than if a CP were not used.

The final guidance recommends a framework to promote continuous improvement in the manufacturing of quality drug and biological products by encouraging applicants to employ the following:

- Effective use of knowledge and understanding of the product and manufacturing process;
- Risk management activities over the life cycle of a product; and
- An effective pharmaceutical quality system

This final guidance incorporates the modern regulatory concepts stated in the guidance for industry entitled ''PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance,'' the Pharmaceutical Quality for the 21st Century—A Risk Based Approach, the Critical Path Initiative, and the quality by design principles described in the guidance for industry entitled ''Q8(R2) Pharmaceutical Development.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA.'' It does not establish any rights for any person and, with the exception of section V, 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.

As noted, insofar as section V of this guidance sets forth that certain modifications to an approved CP must be submitted in a changes being effected supplement or annual report rather than a prior approval supplement, it has binding effect, as indicated by the use of the words *must, shall,* or *required.* Such binding effect derives from section 506A of the FD&C Act, as implemented in 21 CFR 314.70 and 601.12.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR parts 210 and 211 relating to current good manufacturing practices have been approved under OMB control number 0910–0139. The collections of information relating to section 351(k) of the PHS Act have been approved under OMB control number 0910–0718.

III. Electronic Access

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

Dated: October 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22334 Filed 10–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2335]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the Statement of Work to assess communication between FDA and sponsors through product quality information requests during application review and to identify best practices and areas of improvement. The independent assessment is part of FDA performance commitments under the recent reauthorization of the Prescription Drug User Fee Act (PDUFA). The independent assessment of FDA and sponsors in communicating through product quality information requests is described in detail 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, the assessment will be conducted by an

independent contractor. FDA is providing for public comment on the statement of work before revising as needed and requesting contractor proposals.

DATES: Either electronic or written comments on the statement of work must be submitted by November 14, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 14, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2022–N–2335 for ''Prescription Drug User Fee Act VII Commitment to Assess Current Practices of the Food and Drug Administration and Sponsors in Communicating Through Product Quality Information Requests During Application Review.'' 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, 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.'' FDA 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: Emily Ewing, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1148, Silver Spring, MD 20993–0002, 240–402–0196, *Emily.Ewing@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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 reauthorization of PDUFA for the next 5-year period (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 sponsors during application review.

FDA and sponsors 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.

IRs from both CDER and CBER are expected to follow Four-Part Harmony in which reviewers are expected to communicate: (1) what was provided, (2) what is the issue or deficiency, (3) what is needed, and (4) why it is needed. This expectation can be found in CDER's Manual of Policies and Procedures (MAPP) 5016.8, ''Communication Guidelines for Quality-Related Information Requests and Deficiencies.'' As a result of FDA's implementation of Four-Part Harmony in CMC–IRs, sponsors should understand what information FDA needs to continue their review. The PDUFA VII goals letter includes commitments for FDA to update and conduct training on existing policies and procedures (MAPPs and Standard Operating Policy and Procedure (SOPPs)), to reflect Four-Part Harmony. CDER MAPP 5016.8, ''Communication Guidelines for Quality-Related Information Requests and Deficiencies'' will be revised and made public. CBER SOPP 8401.1, ''Issuance of and Review of Responses to Information Request Communications to Pending Applications'' will also be revised.

In addition to updating the documents and conducting training, FDA is committed to contracting with an independent third party to assess current practices of CDER, CBER, and sponsors in communicating through product quality IRs during application review and effectiveness of Four-Part Harmony. This assessment will identify best practices and areas of improvement in communications between FDA review staff and sponsors through product quality IRs and is the subject of this task order.

The Statement of Work can be accessed at: *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-assessment-fda-and-sponsor-communications-through-product-quality-information-requests.*

Dated: October 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22335 Filed 10–13–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0008]

Request for Nominations for Individuals and Consumer Organizations for Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may be self-nominated or may be nominated by a consumer organization. FDA seeks to include the views of individuals on its advisory committee regardless of their gender identification, religious affiliation, racial and ethnic identification, or disability status and, therefore, encourages nominations of appropriately qualified candidates from all groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA (see **ADDRESSES**) by November 28, 2022, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by November 28, 2022. Nominations will be accepted for current vacancies and for those that will or may occur through December 31, 2023.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process should be submitted electronically to *ACOMSSubmissions@fda.hhs.gov or* by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002.

Consumer representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm,* or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002. Additional information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT:

For questions relating to participation in the selection process: Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002, 301–796–8220, *kimberly.hamilton@fda.hhs.gov.*

For questions relating to specific advisory committees or panels, contact the appropriate contact person listed in table 1.

TABLE 1—ADVISORY COMMITTEE CONTACTS

Contact person	Committee/panel
Rakesh Raghuwanshi, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993–0002, 301–796–4769, *Rakesh.Raghuwanshi@fda.hhs.gov*.	FDA Science Board Advisory Committee.
Prabhakara Atreya, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1226, Silver Spring, MD 20993–0002, 240–402–8006, *Prabhakara.Altreya@fda.hhs.gov*.	Allergenic Products Advisory Committee.