entitled ''Expiration Dating of Unit-Dose Repackaged Solid Oral Dosage Form Drug Products.'' FDA's current good manufacturing practice (CGMP) regulations for finished pharmaceuticals require that each drug product bear an expiration date determined by appropriate stability testing and that the date must be related to any storage conditions stated on the labeling, as determined by stability studies (21 CFR 211.137(a) and (b)). Samples used for stability testing must be in the same container-closure system as that in which the drug product is marketed (21 CFR 211.166(a)(4)). For unit-dose repackaged products, U.S. Pharmacopeial Convention (USP) General Chapter <1178> recommends that the expiration date ''not exceed (1) 6 months from the date of repackaging; or (2) the manufacturer's expiration date; or (3) 25% of the time between the date of repackaging and the expiration date shown on the manufacturer's bulk article container of the drug being repackaged, whichever is earlier.''

For solid oral dosage forms repackaged in unit-dose containers, the revised draft guidance states that FDA does not intend to take action regarding the requirements of §§ 211.137 and 211.166 (*i.e.,* expiration dating determined by stability studies) under certain conditions. This revised draft guidance describes these conditions.

This draft guidance revises an earlier draft guidance for industry, ''Expiration Dating of Unit-Dose Repackaged Drugs: Compliance Policy Guide.'' Changes include the following:

- Shortens the expiration date to be used under certain conditions for solid oral dosage forms repackaged in unit-dose containers from 12 months to 6 months or 25 percent of the time remaining until the expiration date on the container of the original manufacturer's product, whichever time period is shorter.
- Provides for an expiration date exceeding 6 months if supportive data from appropriate studies are available and other conditions are met.
- Excludes from the scope of the guidance products repackaged by State-licensed pharmacies, Federal facilities, and outsourcing facilities as defined under section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353b).
- Excludes from the scope of the guidance all dosage forms other than solid oral dosage forms.
- Provides for the use of containers meeting USP <671> Class B standards if certain conditions are met.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on expiration dating of unit-dose repackaged solid oral dosage form drug products. 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.

The current Compliance Policy Guide 480.200, ''Expiration Dating of Unit-Dose Repackaged Drugs,'' issued February 1, 1984, revised March 1995, will be withdrawn when the revised draft guidance is finalized.

II. The Paperwork Reduction Act of 1995

This revised draft guidance refers to previously approved collections of information that 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 parts 210 and 211 have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: August 3, 2017.

Anna K. Abram,

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

[FR Doc. 2017–16719 Filed 8–8–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4076]

Benefit-Risk Assessments in Drug Regulatory Decision-Making; 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 a public meeting to convene a discussion of topics related to the structured assessment of benefits and risks in drug regulatory decision-making. This meeting will focus on regulatory and industry experiences with approaches to structured benefit-risk assessments, approaches to incorporating patient perspectives into structured benefit-risk assessment, and exploration of methods to advance structured benefit-risk assessment. The format of the meeting will include a series of presentations on the above topics related to structured assessment of benefits and risks, followed by a discussion on those topics with invited panelists and audience members. This meeting satisfies an FDA commitment that is part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V).

DATES: The public meeting will be held on September 18, 2017, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by September 11, 2017 (see the **SUPPLEMENTARY INFORMATION** section for instructions). Public comments will be accepted through November 18, 2017. See the **ADDRESSES** section for information about submitting comments to the public docket.

ADDRESSES: The public meeting will be held on September 18, 2017, at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center (the Great Room), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For more information on parking and security procedures, please refer to *https://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 November 18, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 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–4076 for ''Benefit-Risk Assessments in Drug Regulatory Decision-Making; 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.

FDA will post the agenda approximately 5 days before the meeting at: *https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm378861.htm.*

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 301–796–5003, FAX: 301–847–8443, *graham.thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144). Title I of FDASIA reauthorizes PDUFA V and provides FDA with the user fee resources necessary to maintain an efficient review process for human drug and biological products. The reauthorization of PDUFA V includes performance goals and procedures for the Agency that represents FDA's commitments during fiscal years 2013–2017. These commitments are fully described in the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' (PDUFA Goals Letter), available on FDA's Web site at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.*

Section X of the PDUFA Goals Letter, entitled ''Enhancing Benefit-Risk Assessment in Regulatory Decision-Making,'' includes development of a plan to further develop and implement a structured approach to benefit-risk assessment in the human drug review process. As part of this enhancement, FDA committed to holding two public workshops on benefit-risk considerations from the regulator's perspective that will begin by the first quarter of fiscal year 2014. The public workshop held in 2014 fulfilled the first of the two workshop commitments. The workshop announced by this notice will fulfill the second of the two workshop commitments.

As part of its commitment, FDA has published the ''Structured Approach to Benefit-Risk Assessment in Drug Regulatory Decision-Making: Draft PDUFA V Implementation Plan,'' available on FDA's Web site at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf.* In this Plan, FDA identified as an area of further development the exploration of structured approaches to evaluate and communicate the assessment of benefits and risks. FDA's human drug regulatory decisions are informed by an extensive body of evidence on the safety and efficacy of a drug product, as well as other factors affecting the benefit-risk assessment, including the nature and severity of the condition the drug is intended to treat or prevent, the benefits and risks of other available therapies for the condition, and any risk management tools that might be necessary to ensure that the benefits outweigh the risks. A structured benefit-risk framework serves as a foundational element to FDA's benefit-risk assessments.

II. Purpose and Scope of the Meeting

This public meeting will focus on: (1) Regulatory and industry experiences with approaches to structured benefit-risk assessments, and the results of implementing structured frameworks at regulatory agencies both for premarket application review and postmarket safety review, (2) approaches to incorporating patient perspectives into structured benefit-risk assessment, and (3) exploration of methods to advance structured benefit-risk assessment. This meeting will be an opportunity to share any challenges and lessons learned in applying a more structured approach to regulatory decision-making. The public meeting will also explore more systematic and structured approaches to evaluate and communicate methods of assessing benefits and risks; and their implications on human drug regulatory decisions. Specifically, the workshop will examine FDA, other regulatory

agencies, industry, and external perspectives and experiences with structured benefit-risk assessment. This public meeting will have discussion sessions focusing on the entire drug development life cycle, including premarket drug review and postmarket safety surveillance. The format of the meeting consists of a series of presentations on topics related to structured assessment of benefits and risks, followed by a discussion on those topics with invited panelists and audience members.

III. Meeting Attendance and Participation

Registration: If you wish to attend this meeting, visit *https://fdabenefitrisk.eventbrite.com.* Please register by September 11, 2017. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Seating will be limited, so early registration is recommended.

Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability.

If you need special accommodations because of a disability, please contact Graham Thompson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm378861.htm.*

Dated: August 3, 2017.

Anna K. Abram,

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

[FR Doc. 2017–16720 Filed 8–8–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2802]

Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports.'' This draft guidance provides recommendations to holders of biologics license applications (BLAs) for specified products regarding the types of changes to be documented in annual reports. Specifically, the draft guidance describes chemistry, manufacturing, and controls (CMC) postapproval manufacturing changes that the Agency generally considers to have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product. Under FDA regulations, such minor changes in the product, production process, quality controls, equipment, facilities, or responsible personnel must be documented by applicants in an annual report.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 10, 2017.

ADDRESSES: You may submit 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–2017–D–2802 for ''CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports.'' 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.

- 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