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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–1092 for ''Over-the-Counter Monograph User Fees: Reopening of Comment Period; Stakeholder Meeting.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amy Bertha, Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1647, email: *OTCMonographUserFeeProgram@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is reopening until October 6, 2016, the comment period for the document that announced a public meeting in the **Federal Register** of May 11, 2016 (81 FR 29275). In the document, FDA invited public comment as the Agency considers a user-fee program for nonprescription (over-the-counter or OTC) monograph drugs. A user-fee program would provide funding to supplement congressional non-user-fee appropriations, and would support timely and efficient FDA review of the efficacy and safety of ingredients included in or proposed for inclusion in a monograph. A public meeting on this topic was held on June 10, 2016, and interested persons were given until July 11, 2016, to submit comments. To ensure that all interested persons have sufficient opportunity to share their views on a potential OTC monograph user-fee program, FDA is reopening the comment period until October 6, 2016.

FDA will hold a Webinar for stakeholders on September 6, 2016. This Webinar is intended to be a followup to the June 10, 2016, public meeting and provide stakeholders with a status update on the process of FDA and industry discussions that began in July 2016. Meeting minutes from these discussions can be found at: *http://www.fda.gov/omuf.* Additional background information on OTC monograph drugs (such as how OTC drugs can be marketed, the differences between marketing through approved applications and marketing under the monographs), factors FDA considers important in developing a user-fee program, and the questions FDA asked the public to consider and provide input, can be found in the **Federal Register** document from the June 10, 2106, public meeting (*https://www.federalregister.gov/articles/2016/05/11/2016-11098/over-the-counter-monograph-user-fees-public-meeting-request-for-comments*). The meeting transcript, meeting recording, and presentations from the June 10, 2016, public meeting, which can serve as further background information, can be found at: *http://www.fda.gov/Drugs/NewsEvents/ucm499390.htm.*

II. Stakeholder Meeting Participation

FDA is seeking participation at the Webinar by stakeholders, including scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and representatives of the OTC monograph industry. Participating in the Webinar is free. The Webinar format will include presentations by FDA staff and an opportunity for stakeholders to ask questions. If you wish to attend the Webinar, FDA asks that you please register through Eventbrite by Tuesday, August 30, 2016 (*https://www.eventbrite.com/e/over-the-counter-monograph-user-fees-stakeholder-meeting-tickets-26751882601*). FDA will email the registered attendees a URL to join the Webinar at least 1 day before the meeting.

Dated August 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18717 Filed 8–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1805]

Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the completion of the target of the goal established to address the Center for Devices and Radiological Health's (CDRH) 2014–2015 Strategic Priority ''Strike the Right Balance Between Premarket and Postmarket Data Collection.'' To achieve this Strategic Priority, CDRH established a goal to assure the appropriate balance between premarket and postmarket data

collection to facilitate and expedite the development and review of medical devices, in particular high-risk devices of public health importance. We established a target date of December 31, 2015, by which to review 100 percent of product codes subject to a premarket approval application (PMA) that are legally marketed and were approved prior to 2010 to determine, for each such product code, whether or not, based on our current understanding of the technology, to reduce premarket data collection by relying more on postmarket controls, and whether to shift some premarket data collection to the postmarket setting or to pursue down-classification.

DATES: Submit either electronic or written comments by October 7, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2015–N–1805 for ''Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nancy Braier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5454, Silver Spring, MD 20993–0002, 301–796–5676.

SUPPLEMENTARY INFORMATION:

I. Background

One of three Strategic Priorities for 2014–2015 in CDRH is to ''Strike the Right Balance Between Premarket and Postmarket Data Collection'' (Ref. 1).[1] CDRH's vision is for patients in the United States to have first-in-the-world access to high-quality, safe, and effective medical devices of public health importance. A key determinant of early U.S. patient access to high-quality, safe, and effective devices is the extent of premarket data that device developers provide to FDA. Once a device developer decides to seek U.S. marketing approval or clearance, the extent of data that are collected premarket has an impact upon the length of time needed to complete a premarket submission—the more data to be collected premarket, the longer it may take to acquire the data and make the submission. Consequently, such data collection issues affect when U.S. patients have access to a medical device. On the other hand, it is also important that there are sufficient data to demonstrate a reasonable assurance of safety and effectiveness before a device that is subject to a premarket approval application (PMA) is approved for marketing in the United States. For this reason, it is important that CDRH strike the right balance between premarket and postmarket data collection. If CDRH can shift, when appropriate, some premarket data collection to the postmarket setting, CDRH could improve patient access to high-quality, safe, and effective medical devices of public health importance. However, patient safety could be undermined if, after determining that certain data could appropriately be shifted from the premarket to the postmarket setting, CDRH shifted that data collection to the postmarket setting without adequate assurances that necessary and timely postmarket data collection will occur. For this reason, CDRH strives to balance the premarket data and postmarket collection, in accordance with section 513(a)(3)(C) (21 U.S.C. 360c(a)(3)(C)) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which directs CDRH to consider whether the extent of data that otherwise would be required for

[1] CDRH's 2014–2015 Strategic Priorities include ''Strengthen the Clinical Trial Enterprise'' and ''Provide Excellent Customer Service'' in addition to ''Strike the Right Balance Between Premarket and Postmarket Data Collection'' (Ref. 1).

approval of a PMA with respect to effectiveness can be reduced through reliance on postmarket controls.

In order to achieve the proper balance between premarket and postmarket data collection, CDRH resolved in its Strategic Priorities for 2014–2015 to take several actions. CDRH committed to developing and seeking public comment on a framework for when it would be appropriate to shift premarket data collection to the postmarket setting. Pursuant to this commitment, CDRH and the Center for Biologics Evaluation and Research (CBER) issued the guidance, ''Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval,'' on April 13, 2015 (80 FR 19672), which provided FDA's policy of balancing premarket and postmarket data collection during the Agency's review of PMAs (Ref. 2). This guidance outlines how FDA would consider the role of postmarket information in determining the appropriate type and amount of data that should be collected in the premarket setting to support premarket approval, while still meeting the statutory standard of a reasonable assurance of safety and effectiveness. Furthermore, under existing authorities, CDRH and CBER issued a guidance document on April 13, 2015 (80 FR 19669), entitled ''Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions'' (Ref. 3). This guidance describes FDA's voluntary expedited access PMA program for certain medical devices to facilitate patient access to these devices by expediting the development, assessment, and review of certain devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions. To expedite access for devices addressing unmet needs, this pathway to market shifts appropriate components of premarket data collection to the postmarket setting, while maintaining the statutory standard of a reasonable assurance of safety and effectiveness. In addition, CDRH has developed a mechanism to assure prospectively the appropriate balance of premarket and postmarket data collection for new devices subject to a PMA. Specifically, when CDRH issues a final decision for an original PMA or panel-track supplement to a PMA, CDRH conducts a prospective assessment to determine if the device type is a candidate for shifting some premarket data collection to the postmarket, reducing premarket data collection through reliance on postmarket controls or reclassification.

Another action in pursuit of the goal to strike the right balance between premarket and postmarket data collection was to commit to conducting a retrospective review of all PMA product codes (procodes) with active PMAs approved prior to 2010 to determine whether data typically collected premarket could be shifted to the postmarket setting, and whether premarket data collection could be reduced through reliance on postmarket controls or devices could be reclassified (down-classified) in light of our current understanding of the technology (Ref. 1). In general, some premarket data collections for class III devices that are currently marketed may be reduced through reliance on postmarket controls or shifted to the postmarket setting if warranted, based on CDRH's review experience as well as the postmarket performance and the current body of evidence regarding the benefit-risk profile of these devices. CDRH currently receives PMA submissions on the majority of these class III devices, and a change in premarket data collection is expected to expedite the approval of future PMA submissions. CDRH has periodically taken such actions consistent with the medical device statutory framework but has typically done so on an ad hoc basis. On the other hand, when FDA determines that it is necessary to provide reasonable assurance that a device is safe and effective, CDRH may require more data based on our current understanding of that type of technology or based on an issue raised by the data submitted by a sponsor for their device. CDRH will also up-classify a device, if warranted, based on the current state of the science. For example, on January 5, 2016, CDRH issued a final order up-classifying surgical mesh when intended for use for pelvic organ prolapse (81 FR 354), and on June 2, 2014, CDRH issued a final order up-classifying sunlamps and sunlamp products (tanning beds/booths) (79 FR 31205). However, up-classification is not warranted for the devices subject to this retrospective review, because they are already in the highest risk classification.

During this retrospective review, devices were analyzed according to procodes. CDRH targeted the date of December 31, 2014, by which to review 50 percent of the procodes for devices that are subject to a PMA and are legally marketed to determine whether or not to change premarket data collection by shifting the data collection to the postmarket setting, reducing premarket data collection through reliance on postmarket controls, or pursuing reclassification (Ref. 1). This target extended to have 75 percent completed by June 30, 2015, and 100 percent completed by December 31, 2015.

On April 29, 2015, CDRH announced its progress on this priority and solicited comments on the procodes that were identified as candidates for reclassification, a reduction in premarket data collection through reliance on postmarket controls, or a shift in premarket data collection to postmarket for those procodes reviewed through December 31, 2014 (80 FR 23798). FDA received 11 sets of comments, which generally supported FDA's retrospective review effort and provided input on specific procodes that were identified as candidates for reclassification or were determined to remain class III with no changes in data collection. FDA will consider these comments when making final determinations on the reclassification of these procodes.

During 2015, FDA reviewed the remaining procodes that were identified for the retrospective review. While completing the retrospective review, FDA found that the LMX procode was included in the retrospective review in error, because the jaundice meter device type is covered by a different procode, not within the scope of the retrospective review. The jaundice meter device type is classified under 21 CFR 862.1113 and assigned the procode MQM, and accordingly, this device type requires a 510(k) premarket notification. Therefore, the procode LMX has been excluded from the analysis.

The purpose of this **Federal Register** notice is to solicit comments on the remaining procodes that have been identified as candidates for reclassification, a reduction in premarket data collection through reliance on postmarket controls, or a shift in premarket data collection to postmarket for those procodes reviewed through December 31, 2015. Efforts to reclassify and to communicate changes to data collections with stakeholders will be prioritized based on both the public health impact and Center resources.

II. Achievement of Goal Targets

Retrospective analysis of the class III medical device procodes was intended to determine if current classifications and data collections remain appropriate for determining a reasonable assurance of safety and effectiveness. As our understanding of the technology associated with individual medical devices has increased and we have a better understanding of the risks

associated with the technology of each device, our understanding of the type and amount of data that are needed to demonstrate a reasonable assurance of safety and effectiveness also evolves. We use this evolution in our understanding to require the least burdensome amount of data necessary to evaluate device effectiveness, following the least burdensome provisions of the FD&C Act (section 513(a)(3)(D)(ii)). Under section 513 of the FD&C Act, a device is a class III device and requires premarket approval if general controls and special controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and if the device is to be used for supporting or sustaining human life or of substantial importance in preventing impairment of human health or if the device presents a potential unreasonable risk of illness or injury. In order to reclassify a class III device into class II, the device must meet the statutory criteria for class II: A device that cannot be classified as a class I device, because general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance. As new information becomes available over time, the accumulated information available for a device may be sufficient to establish special controls to provide a reasonable assurance of safety and effectiveness; therefore, the classification of the device may be changed either up or down.

In February 2014, CDRH began its retrospective review with procodes associated with active PMAs approved prior to 2010. PMA procodes created since 2010 were not included in this retrospective review because these recently created procodes do not yet have sufficient new information for a change in FDA's current understanding of the device's postmarket performance profile. As of December 31, 2015, CDRH reviewed all procodes included in this retrospective review, meeting its 100 percent review target.

The results of this analysis include recommendations for procodes that are candidates for reclassification, a reduction in premarket data collection through reliance on postmarket controls, or a shift in premarket data collection to postmarket collection. These results are published online, along with the results of the first cohort of procodes at *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/default.htm* (Ref. 4). The results of this second cohort of procodes reviewed for this analysis are additive to those previously reported. CDRH is continuing to consider the comments received on the first cohort of procodes reported in April 2015, and efforts to reclassify and to communicate changes to data collections with stakeholders are being prioritized based on both the public health impact and Center resources. The following paragraph describes the organization of the results into tables, which are available for public review online (Ref. 4).

As discussed in further detail below, for the purposes of this retrospective review, we evaluated each procode on a balance of factors to determine the current benefit-risk profile and if our review indicates special controls could be established to provide a reasonable assurance of safety and effectiveness. If so, the corresponding procode was listed in the category ''Candidates for Reclassification to Class II'' (table 1). If it was determined that special controls would not be sufficient to provide reasonable assurance of the safety and effectiveness of the device, then the procode was evaluated to determine if some premarket data collection for PMA submission could be shifted to postmarket collection, or if premarket data collection could be reduced through reliance on postmarket controls. If it was determined that a change of data collection could continue to provide reasonable assurance of the safety and effectiveness of the device, then the procode was listed in the category ''Candidates for reduction of data collection through reliance on postmarket controls or shift of data collection from premarket to postmarket'' (table 2). This category includes procodes for which premarket data collection could be shifted to postmarket data collection, premarket data collection could be decreased through reliance on postmarket controls, or postmarket data could no longer be needed. Finally, table 3 includes procodes for which a reduction in data collection through reliance on postmarket controls or shift in data collection from premarket to postmarket and/or reclassification occurred in 2015 during FDA's retrospective review of PMAs.

In this retrospective review, postmarket performance data, technology and performance considerations, and other relevant considerations were evaluated for each procode. These factors were used to evaluate the current benefit-risk profile to determine if the devices are good candidates for a reduction in premarket data collection through reliance on postmarket controls, a shift of premarket data collection to postmarket, or reclassification. Postmarket performance data (including recent PMA Annual Reports, literature reviews, total product lifecycle reports, medical device reporting analysis, market penetration, and recall analysis) were investigated for any performance concerns or problems that outpace any increases in device use or acceptance. In evaluating the technology and performance considerations for the procodes, performance concerns or problems that were uncovered in the review of postmarket data were considered unfavorable factors for a change in data collection or reclassification. Favorable factors to indicate that a device is a good candidate for a change in data collection or reclassification included: Whether risks are now well understood and are determined to be moderate to low; technology uncertainties have been alleviated; performance standards or non-clinical tests have been developed that could be surrogates for some clinical testing; the need for a controlled study could be eliminated due to defined objective performance criteria; the device has been shown to have good short-term performance; or concerns are limited to long-term performance or rare adverse events.

Finally, several relevant considerations were evaluated for each procode. Unfavorable factors for devices to be considered candidates for a change in data collection or reclassification included: Whether there have been significant changes implemented to address safety or effectiveness since the devices have been on the market; whether the review of annual reports and manufacturing changes has been important to maintain safety of the devices; whether there were a limited number of approvals or limited clinical use of the devices, due to inadequate data needed to conduct this scientific assessment.

After completion of this retrospective review, FDA will prioritize the procodes identified as candidates for reclassification (table 1, Ref. 4) according to public health impact and Center resources, in order to determine the top priority procodes for which reclassification would have the greatest impact. The procodes identified as top priority candidates for reclassification will proceed through the reclassification procedures according to 21 CFR part 860. FDA will also prioritize the procodes identified as candidates for a change in data collection (table 2, Ref. 4) according to public health impact and Center resources, in order to determine which reductions of or shifts to data collection would have the greatest

impact. FDA encourages firms to submit a presubmission to get feedback on their data collection plan or contact the appropriate review branch for additional information if they are in the process of developing a device in one of these categories.

III. Paperwork Reduction Act of 1995

This document refers to previously approved collections of information found in FDA regulations. These collections of information 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 part 814 have been approved under OMB control number 0910–0231.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA, ''CDRH 2014–2015 Strategic Priorities,'' 2014, *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM384576.pdf.*
2. ''Guidance for Industry and FDA Staff: Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval,'' April 2015, *http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm393994.pdf.*
3. ''Guidance for Industry and FDA Staff: Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions,'' April 2015, *http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm393978.pdf.*
4. ''Second and final cohort of Results of the 2014–2015 Strategic Priority: Strike the Right Balance between Premarket and Postmarket Data Collection, '' available at *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/default.htm.*

Dated: August 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18672 Filed 8–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2319]

Ulcerative Colitis: Clinical Trial Endpoints; 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 ''Ulcerative Colitis: Clinical Trial Endpoints.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of ulcerative colitis (UC) in adult and pediatric patients. Specifically, this guidance addresses FDA's current thinking regarding efficacy endpoints for UC clinical trials.

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 7, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://www.regulations.gov.*
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Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–2319 for ''Ulcerative Colitis: Clinical Trial Endpoints; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*