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 when 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, 2016, public meeting (https://www.federalregister.gov/articles/2016/05/11/2016-11096/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 docket, 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). 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
recategorization (table 1, Ref. 4)
according to public health impact and
Center resources, in order to determine
the top priority procodes for which
recategorization 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
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.

• If you want to submit a comment with confidential information that you do not wish to make publicly available, submit your 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–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 docket, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.