

compounder has the option of not filling a prescription with a compounded drug if a prescriber determination is not provided.

Issue Five: One commenter stated that requiring a notation on the prescription that a compounded drug was on the drug shortage list when compounded, and the date the list was checked, would be overly burdensome.

FDA Response to Issue Five: FDA does not believe this presents a significant burden, as a compounder that wants to rely on a drug shortage to establish that a compounded drug is not essentially a copy of a commercially available drug would need to check FDA's shortage website. Noting the date the list was checked is not onerous, and is necessary for FDA to verify compliance during inspections. FDA estimates this activity would take 2 minutes.

Issue Six: One commenter requested clarity on how long records should be maintained; what specific information

should be maintained; and when such records should be presented to FDA.

FDA Response to Issue Six: FDA has revised the guidance to include a recommended duration of 3 years for maintaining records. The guidance describes the records that can be retained to demonstrate compliance. FDA may request to review such records during establishment inspections.

FDA estimates the burden of this collection of information as follows:

We estimate that annually a total of approximately 6,888 compounders ("number of respondents" in table 1, line 1) will consult a prescriber to determine whether he or she has made a determination that the compounded drug has a change that produces a significant difference for a patient as compared to the comparable commercially available drug, and that the compounders will document this determination on approximately 172,200 prescription orders for compounded drugs ("total annual

disclosures" in table 1, line 1). We estimate that the consultation between the compounder and the prescriber and adding a notation to each prescription that does not already document this determination will take approximately 3 minutes per prescription order.

In addition, we estimate that a total of approximately 6,888 compounders ("number of respondents" in table 1, line 2) will document this information on approximately 344,400 prescription orders for compounded drugs ("total annual disclosures" in table 1, line 2). We estimate that checking FDA's drug shortage list and documenting this information will take approximately 2 minutes per prescription order.

We estimate that a total of approximately 3,444 compounders ("number of recordkeepers" in table 2) will keep approximately 165,312 records ("total annual records"). We estimate that maintaining the records will take approximately 2 minutes per record.

TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN ¹

Type of reporting	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Consultation between the compounder and prescriber and the notation on the prescription documenting the prescriber's determination of significant difference.	6,888	50	344,400	0.05 (3 minutes)	17,220
Checking FDA's drug shortage list and documenting on the prescription that the drug is in shortage.	6,888	50	344,400	0.03 (2 minutes)	10,332
Total	27,552

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Type of recordkeeping	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records of frequency and number of prescriptions filled for compounded drugs that are essentially a copy.	3,444	48	165,312	0.03 (2 minutes)	4,959

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 16, 2018.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0055]

Gastrointestinal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; 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) announces a forthcoming public advisory committee meeting of the Gastrointestinal Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing

a docket for public comment on this document.

DATES: The meeting will be held on March 8, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2018-N-0055. The docket will close on March 7, 2018. Submit either electronic or written comments on this public meeting by March 7, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 7, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of March 7, 2018. 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.

Comments received on or before February 22, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

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-2018-N-0055 for "Gastrointestinal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; 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." 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 the 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.

FOR FURTHER INFORMATION CONTACT: Jay R. Fajiculy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: GIDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss supplemental new drug application (sNDA) 203214 supplement 18, XELJANZ (tofacitinib) tablets, submitted by Pfizer Inc., proposed for the treatment of adult patients with moderately to severely active ulcerative colitis who have demonstrated an inadequate response, loss of response, or intolerance to corticosteroids, azathioprine, 6-mercaptopurine, or tumor necrosis factor inhibitor therapy.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the

appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 7, 2018. Oral presentations from the public will be scheduled between approximately 12:40 p.m. and 1:40 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 13, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 14, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at fdadoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jay R. Fajiculay (See, **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6969]

Product Title and Initial U.S. Approval in Highlights for Human Prescription Drug and Biological Products—Content and Format; 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 “Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products—Content and Format.” The labeling regulations for human drug and biological products require that the Highlights of Prescribing Information (Highlights) contain a product title and the year of initial U.S. approval. This draft guidance provides recommendations on the content and format of the product title and initial U.S. approval to bring greater consistency to the presentation of these required elements and to help ensure these elements provide clear and useful information to the health care provider.

DATES: Submit either electronic or written comments on the draft guidance by March 20, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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-6969 for “Product Title and Initial U.S. Approval in Highlights for Human Prescription Drug and Biological Products—Content and Format; Guidance for Industry; Availability.” 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 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