amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 CFR part 803 (part 803). Part 803 mandates the use of Form FDA 3500A for reporting to FDA on medical devices. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), signed into law October 26, 2002, amended section 519 of the FD&C Act. The MDUFMA amendment (section 303) required FDA to revise the MedWatch forms to facilitate the reporting of information relating to reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused.

II. Proposed Modification to Existing Forms FDA 3500, 3500A, and 3500B

General changes—The proposed modifications to Forms FDA 3500 and 3500A reflect changes that will bring the form into conformance, since the previous authorization in 2015, with current regulations, rules, and guidances.

The proposed extension to Forms FDA 3500, 3500A, and 3500B will only have changes in the form instructions to provide clarity of reporting. The proposed changes are regulatory driven, improving the Centers' work, and improving report processing. The Agency welcomes comments about translation of Form FDA 3500B (consumer) into Spanish and other languages.

Formatting modifications are being proposed to several fields to enhance the quality, utility, and clarity of the information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Center/FDA Form/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research:					
Form 3500	14,727	1	14,727	0.66 (40 min)	9,720
Form 3500A (§§ 310.305, 314.80, 314.98, 600.80, 1271.350).	599	98	58,702	1.21	71,029
Form 3500A (§§ 310.305 outsourcing facilities)	50	2	100	1.21	121
Center for Devices and Radiological Health:					
Form 3500	5,233	1	5,233	0.66 (40 min)	3,454
Form 3500A (803)	2,277	296	673,992	1.21	815,530
Center for Food Safety and Applied Nutrition:					
Form 3500	1,793	1	1,793	0.66 (40 min)	1,183
Form 3500A	1,659	1	1,659	1.21	2,007
Center for Tobacco Products:					
Form 3500	39	1	39	0.66 (40 min)	26
All Centers:					
Form 3500B	13,750	1	13,750	0.46 (28 min)	6,325
Total					909,395

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

The burden estimates have not changed from the current approval.

Dated: March 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05337 Filed 3–15–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0976]

Arthritis 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 Arthritis 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 April 23, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 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–0976. The docket will close on April 20, 2018. Submit either electronic or written comments on this public meeting by April 20, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 20, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 20, 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 April 9, 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–0976 for ''Arthritis 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 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: Yinghua S. Wang, 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: *AAC@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 new drug application (NDA) 207924, for baricitinib tablets, submitted by Eli Lilly and Company, for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. The discussion will include the following: Efficacy, safety, including the risk of thromboembolic adverse events, dose selection, and overall risk benefit considerations.

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. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before April 9, 2018, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 March 30, 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 April 2, 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 *fdaoma@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 Yinghua Wang (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: March 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05386 Filed 3–15–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0757]

Pathways to Global Unity; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the Association of Food and Drug Officials (AFDO), is announcing the following public workshop entitled ''Pathways to Global Unity.'' This 2½-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industries.

DATES: The public workshop will be held on June 11–12, 2018, from 8 a.m. to 5:30 p.m., and on June 13, 2018, from 8 a.m. to 12 p.m.

ADDRESSES: The public workshop will be held at the Doubletree by Hilton Hotel Burlington Vermont, 870 Williston Rd., Burlington, VT 05403, 802–865–6626. For directions to the hotel and information on lodging, visit *http://burlington.afdo.org/hotel.html.* Attendees are responsible for their own accommodations.

FOR FURTHER INFORMATION CONTACT: Krystal Reed, Association of Food and Drug Officials, 155 West Market St., 3rd Floor, York, PA 17401, 717–757–2888, Fax: 717–650–3650, email: *kreed@afdo.org.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government agencies to small businesses.

II. Topics for Discussion at the Public Workshop

The public workshop helps fulfill the Department of Health and Human Services and FDA's mission to protect the public health. The workshop will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. The public workshop's agenda is available at *http://www.afdo.org/conference.* Topics for discussion include the following:

- FDA Associate Commissioner for Regulatory Affairs Update
- Health Canada: Single Audit Program
- Enforcement Trends in Drug, Devices, and Compounding Pharmacy Inspections
- FDA Compliance Questions Panel
- International Compliance—Industry Perspective
- Puerto Rico Emergency Response Update
- Artificial Intelligence
- Supply Chain Control
- Dermal Abyss: Tattoos as Medical Condition Monitors
- Design Controls for Combination Products
- Benefit Risk—Using Benefit Risk in Making Post-Market Decisions

III. Participating in the Public Workshop

Registration: You are encouraged to register by May 1, 2018. Registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space-available basis on the day of the public workshop beginning at 7:30 a.m. The cost of registration is as follows:

Category	Cost of registration
AFDO Members	$550
AFDO Non-Members	650
Additional Fee for Registration Postmarked After May 1, 2018	100

To register online, please visit *http://www.afdo.org/conference* (FDA has verified the website address, but is not responsible for subsequent changes to the website after this document publishes in the **Federal Register**.) For alternative registration, please complete and submit an AFDO Conference Registration Form, available at *http://burlington.afdo.org/registration.html,* along with a check or money order payable to AFDO. Please mail your completed registration form and payment to: AFDO, 155 West Market St., 3rd Floor, York, PA 17401. The registrar will also accept payment through Visa, MasterCard, and American Express credit cards. For more information on the public workshop, or for questions about registration, please contact AFDO at 717–757–2888, *afdo@afdo.org,* or *http://www.afdo.org/conference.*

If you need special accommodations due to a disability, please contact Krystal Reed (see **FOR FURTHER INFORMATION CONTACT**) at least 21 days in advance of the workshop.

Dated: March 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05389 Filed 3–15–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. During the April meeting, the Clinical Care Subcommittee will be taking charge of the theme, focusing on advancing consensus on dementia care elements to