approved for use in a regimen with misoprostol for the medical termination of early pregnancy. There are no approved drug applications pursuant to section 505 of the FD&C Act (21 U.S.C. 355) in effect for the mifepristone and misoprostol Ms. Wing imported and sold via her website. In addition to being unapproved, the drugs sold via Ms. Wing's website were also misbranded because they failed to bear adequate directions for their intended use (see 21 U.S.C. 352(f)(1) and 21 CFR 201.5) and are prescription medications that were dispensed without a prescription from a practitioner licensed by law to administer such drugs (21 U.S.C. 353(b)(1) and 331(k)).

Ms. Wing broke down the bulk shipments of unapproved and misbranded drugs she received from India and repackaged them into retail quantities which she then shipped to customers in the United States and around the world via U.S. mail. To disguise her sales, Ms. Wing created a fake company called ''Fatima's Bread Basket,'' which she listed as the shipper on the envelope going to the customer. Ms. Wing then inserted a piece of jewelry in the shipping envelope to serve as the cover piece of merchandise being mailed to the customer. She packaged the unapproved and misbranded prescription drugs in a smaller packet that was in a hidden panel and taped to the inside of the shipping envelope. Ms. Wing disguised the nature of the item being purchased by listing on the invoice alternate jewelry product names, each of which had a code to indicate the actual item (unapproved and misbranded drug(s)) being ordered.

As a result of this conviction, FDA sent Ms. Wing, by certified mail on October 15, 2020, a notice proposing to debar her for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Ms. Wing's conviction for one felony count under Federal law, for conspiracy to defraud the United States, was for conduct relating to the importation into the United States of any drug or controlled substance because she illegally smuggled unapproved and misbranded prescription drugs from India into the United States and then distributed those misbranded and unapproved drugs to consumers both in the United States and abroad.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Ms. Wing's offense, and concluded that this felony offense warranted the imposition of a 5-year period of debarment. The proposal informed Ms. Wing of the proposed debarment and offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Wing received the proposal and notice of opportunity for a hearing on October 19, 2020. Ms. Wing failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Ursula Wing has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Ms. Wing is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Ms. Wing is a prohibited act.

Any application by Ms. Wing for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2020–N–1682 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06258 Filed 3–25–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0273]

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 take place virtually on May 6, 2021, from 10 a.m. to 4:15 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings 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–2021–N–0273. The docket will close May 5, 2021. Submit either electronic or written comments on this public meeting by May 5, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 5, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 5, 2021. 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 22, 2021, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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–2021–N–0273 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, email: *AAC@fda.hhs.gov,* 301–796–2894, 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 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 meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss new drug application (NDA) 214487, for avacopan oral capsules, submitted by ChemoCentryx, Inc., for the treatment of anti-neutrophil cytoplasmic antibody-associated vasculitis.

FDA intends to make the meeting's background material and pre-recorded presentations available to the public no later than 2 business days before the meeting. The pre-recorded presentations will be viewed by the committee prior to the meeting and will not be replayed on meeting day. If FDA is unable to post the background material and/or pre-recorded presentations on its website prior to the meeting, the background material and/or pre-recorded presentations will be made publicly available on FDA's website at the time of the advisory committee meeting. The meeting will include brief summaries of the pre-recorded presentations. The pre-recorded presentations and brief summaries will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting. Background material and the link to the online teleconference meeting room will be 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 22, 2021, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 2:15 p.m. Eastern Time on May 6, 2021. 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 April 14, 2021. 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 15, 2021.

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 Moon Hee V. Choi (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 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06265 Filed 3–25–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Clinical Trials in Organ Transplantation in Children and Adults (CTOT–CA) (U01 Clinical Trial Optional).

Date: April 22–23, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31B, Rockville, MD 20852, (240) 669–5060, *james.snyder@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 22, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–06282 Filed 3–25–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Cancer Center Support Grant (P30).

Date: May 5, 2021.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W124, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: David G. Ransom, Ph.D., Chief, Special Review Branch, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W124, Rockville, Maryland 20850, 240–276–6351, *david.ransom@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Assay Validation of High-Quality Markers for Clinical Studies in Cancer (UH2/UH3).

Date: May 12, 2021.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W264, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Ombretta Salvucci, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W264, Rockville, Maryland 20850, 240–276–7286, *salvucco@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Engineered Biology for Cancer Applications.

Date: May 13, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W114, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, 9609 Medical Center Drive, Room 7W114, National Cancer Institute, NIH, Rockville, Maryland 20850, 240–276–6371, *decluej@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Cancer Intervention and Surveillance Modeling Network (CISNET) Incubator Program for New Cancer Sites (U01).

Date: May 17, 2021.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Shree Ram Singh, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, 9609 Medical Center Drive, Room 7W248, National Cancer Institute, NIH, Rockville, Maryland 20850, 240–672–6175, *singhshr@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SPORE (P50) Review I.

Date: May 25–26, 2021.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W244, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: John Paul Cairns, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W244, Rockville, Maryland 20850, 240–276–5415, *paul.cairns@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SPORE (P50) Review II.

Date: May 26–27, 2021.