(*e.g.,* fentanyl) opioid substances. *Para*-fluorobutyrfentanyl has no currently accepted medical use in treatment in the United States. The abuse of *para*-fluorobutyrfentanyl carries public health risks similar to that of heroin, fentanyl, and prescription opioid analgesics. On February 1, 2018, *para*-fluorobutyrfentanyl was temporarily placed into Schedule I of the CSA. As such, additional permanent controls will be necessary to fulfill U.S. obligations if *Para*-fluorobutyrfentanyl is controlled under Schedule I of the 1961 Single Convention.

Ortho-fluorofentanyl has a pharmacological profile similar to fentanyl and other related μ-opioid receptor agonist. *Ortho*-fluorofentanyl has no currently accepted medical use in treatment in the United States. *Ortho*-fluorofentanyl has been encountered by law enforcement and public health officials. The DEA has received reports for at least 13 confirmed overdose deaths involving *ortho*-fluorofentanyl abuse in the United States. On October 26, 2017, *ortho*-fluorofentanyl was temporarily placed into Schedule I of the CSA. As such, additional permanent controls will be necessary to fulfill U.S. obligations if *Ortho*-fluorofentanyl is controlled under Schedule I of the 1961 Single Convention.

N-ethylnorpentylone (other name: *N*-ethylpentylone) is a synthetic cathinone with stimulant and psychoactive properties similar to cathinone, a Schedule I substance. *N*-Ethylpentylone abuse has been associated with adverse health effects leading to emergency department admissions, and deaths. *N*-Ethylpentylone has no currently accepted medical use in treatment in the United States. On August 31, 2018, *N*-ethylnorpentylone was temporarily controlled as a Schedule I substance under the CSA. As such, additional permanent controls will be necessary to fulfill U.S. obligations if *N*-ethylnorpentylone is controlled under Schedule II of the 1971 Convention on Psychotropic Substances.

FDA, on behalf of the Secretary of HHS, invites interested persons to submit comments on the notifications from the United Nations concerning these drug substances. FDA, in cooperation with the National Institute on Drug Abuse, will consider the comments on behalf of HHS in evaluating the WHO scheduling recommendations. Then, under section 201(d)(2)(B) of the CSA, HHS will recommend to the Secretary of State what position the United States should take when voting on the recommendations for control of substances under the Psychotropic Convention at the CND meeting in March 2019.

Comments regarding the WHO recommendations for control of Cyclopropyl fentanyl; Methoxyacetyl fentanyl; *Ortho*-fluorofentanyl; *Para*-fluorobutyrfentanyl; under the 1961 Single Convention will also be forwarded to the relevant Agencies for consideration in developing the U.S. position regarding narcotic substances at the CND meeting.

Dated: February 25, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03663 Filed 2–28–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0077]

Patient Perspectives on the Impact of Rare Diseases: Bridging the Commonalities; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public meeting and an opportunity for public comment on ''Patient Perspectives on the Impact of Rare Diseases: Bridging the Commonalities.'' This public meeting is intended to obtain patients' and caregivers' perspectives on impacts of rare diseases on daily life and to assess commonalities that may help the Agency and medical product developers further understand and advance the development of treatments for rare diseases. Developing a treatment for a rare disease can present unique challenges, such as the small number of individuals affected and heterogenous etiologies and manifestations. While the differences between rare diseases are critically important, it is also important to assess commonalities to synergize product development in rare diseases. The goal of this meeting is to identify common issues and symptoms in rare diseases to help advance medical product development, potentially through the creation of novel endpoints or trial designs that focus on commonalities across a variety of rare diseases.

DATES: The public meeting will be held on April 29, 2019, from 1 p.m. to 5 p.m. The online registration to attend must be received by April 15, 2019. Onsite registration on the day of the meeting will be based on space availability. Submit either electronic or written comments on the public meeting by May 30, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 30, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of May 30, 2019. 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.

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–2019–N–0077 for ''Patient Perspectives on the Impact of Rare Diseases: Bridging the Commonalities.'' 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.'' 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 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: Eleanor Dixon-Terry, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5163, Silver Spring, MD 20933, 301–796–7634, *OOPDOrphanEvents@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The development of drugs, biologics, and devices for rare diseases involves unique challenges. The goal of this meeting is to identify common issues across rare diseases to help address some of these challenges. Rare diseases, often referred to as orphan diseases, are defined based on rarity of occurrence. Although these diseases are individually rare, collectively they are not. According to the National Institutes of Health, there are approximately 7,000 rare diseases affecting an estimated 30 million people in the United States. Many of these rare diseases are serious or life-threatening and many affect children.

The combination of government incentives and scientific advances has fueled extraordinary development in orphan drugs. Since the Orphan Drug Act was passed in 1983, drugs and biologics for over 750 rare disease indications have been developed and approved for marketing. In addition to drugs and biologics, there has been progress in the development of devices for rare diseases. Since 1990, the FDA has approved 74 medical devices for orphan indications under the Agency's Humanitarian Device Exemption program. Despite these successes, we recognize that thousands of rare diseases still have no approved treatments.

Developing a treatment for a rare disease can present unique challenges. Potential challenges include the small number of individuals affected, lack of understanding of the natural history of the disease, phenotypic heterogeneity, and lack of validated endpoints for use in clinical trials. Overcoming these challenges requires collaboration between many stakeholders, including scientists, product developers, regulators, policy makers, and patients. FDA is committed to working with stakeholders to advance treatment options for patients with rare diseases.

This public meeting will focus on the perspective of those affected by rare diseases. Patients, family members, and caregivers will provide important input on the impact of rare diseases on daily life. While the differences between rare diseases are critically important, this meeting will assess commonalities. The specific goal of this meeting is to identify common issues and symptoms in rare diseases to help advance medical product development, potentially through the generation of novel endpoints or trial designs that focus on commonalities across a variety of rare disease.

FDA will provide a summary document from this public meeting. This meeting will include participants from FDA, the patient community, caregivers, and other interested stakeholders.

II. Topics for Discussion at the Public Meeting

This public meeting will consist of panels of patients/caregivers and facilitated discussions. The aim of the meeting is to hear directly from patients with rare diseases and their caregivers and family members. The meeting will include patients with any rare disease and their caregivers and family members. It is not restricted to a specific rare disease or group of rare diseases.

The meeting will focus on several related topics. Specifically, FDA would like to hear directly from patients with rare diseases and their caregivers and family members about disease symptoms, treatment considerations, and factors relevant to participating in a clinical study or registry. We invite the public to register and participate in our panel discussions. A detailed agenda and meeting topics will be posted on the following website in advance of the meeting: *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm628352.htm.*

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website by April 15, 2019: *https://patient-perspectives-rare-diseases.eventbrite.com.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by April 15, 2019, 5 p.m. Eastern Time. Early registration is recommended because seating is

limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when their registration has been received. If time and space permit, onsite registration on the day of the public meeting will be provided beginning an hour prior to the start of the meeting.

If you need special accommodations due to a disability, please contact Eleanor Dixon-Terry, at 301–796–7634, or *OOPDOrphanEvents@fda.hhs.gov* no later than April 15, 2019.

Requests for Oral Presentations: Patients and patient representatives who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients and patient representatives also must send to Eleanor Dixon-Terry (*OOPDOrphanEvents@fda.hhs.gov* or 301–796–7634) a brief summary of responses to the meeting topics by April 1, 2019. Details regarding the meeting agenda and topics will be available at *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm628352.htm.*

FDA will hold an open public comment period to give the public an opportunity to comment. Registration for open public comment will occur in the meeting registration and at the registration desk on the day of the meeting on a first-come, first-served basis.

Panelists and open public comment period speakers will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient representatives who wish to speak, either through the panel discussion, an open public comment period, or audience participation; however, the duration of comments may be limited by time constraints.

Streaming Webcast of the Public Meeting: For those unable to attend in person, FDA will provide a live webcast of the meeting. To register for the streaming webcast of the public meeting, please visit the following website by April 28, 2019: *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm628352.htm.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm628352.htm.*

Dated: February 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03675 Filed 2–28–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3244]

Enforcement Policy for Certain Marketed Tobacco Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Enforcement Policy for Certain Marketed Tobacco Products.'' FDA is issuing this draft guidance to provide information regarding FDA's enforcement policy for certain marketed tobacco products that become the subject of a not substantially equivalent (NSE) order. This policy primarily involves ''provisional'' tobacco products that become subject to NSE orders issued under the Federal Food, Drug, and Cosmetic Act (FD&C Act) (provisional tobacco products are tobacco products that were first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, and for which a substantial equivalence report (SE Report) was submitted no later than March 22, 2011). The draft guidance also provides information on FDA's enforcement policy when an applicant files a request for supervisory review of an NSE order.

DATES: Submit either electronic or written comments on the draft guidance by April 30, 2019 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–2018–D–3244 for ''Enforcement Policy for Certain Marketed Tobacco Products.'' 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