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

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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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 an NSE order. This policy primarily involves provisional tobacco products that become subject to NSE orders issued under section 910(a)(2)(B) of the FD&C Act (21 U.S.C. 387j(a)(2)(B)). This policy extends to new tobacco products created by modifying the quantity of a provisional tobacco product in a pending SE Report that become subject to NSE orders. The draft guidance also provides information on FDA's enforcement policy for when FDA receives from an applicant a request for supervisory review under 21 CFR 10.75 within 30 calendar days of the issue date of the NSE order. The draft guidance provides that for these new tobacco products, FDA intends to offer copies of those final scientific reviews that supported the basis of the Agency's decision to the applicant concurrent with the NSE order for provisional tobacco products.

II. Significance of Draft Guidance

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Enforcement Policy for Certain Marketed Tobacco Products,'' and will supersede ''Enforcement Policy for Certain (Provisional) Tobacco Products That the Food and Drug Administration Finds Not Substantially Equivalent; Guidance for Industry and Tobacco Retailers'' (the availability of which was announced in the **Federal Register** (80 FR 55124, September 14, 2015)). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at either *https://www.regulations.gov* or *https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: February 25, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03657 Filed 2–28–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Retail Pharmacy Interest in Utilization of Innovative Educational Technology To Increase Human Papillomavirus (HPV) Vaccination Rates in Rural Areas; Correction

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The Department of Health and Human Services published a document in the **Federal Register** of February 15, 2019, concerning a request for information (RFI) for informational and planning purposes only. We would like to extend the deadline in order to provide more time to the public to submit their response.

FOR FURTHER INFORMATION CONTACT: Kara Elam, National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services; telephone (202) 690–5566; email: *nvpo@hhs.gov*.

SUPPLEMENTARY INFORMATION:

Correction

In the Federal of February 15, 2019, in FR Doc. 2019–02548, on page 4483, in the first column, correct the **DATES** caption to read:

DATES: Information from retail pharmacies with greater than 100 stores in geographic areas considered to be rural by the census definition (<50,000 population) should submit responses to this RFI as described in the addresses section below no later than midnight, 12:00 a.m. EDT on March 15, 2019.

Dated: February 25, 2019.

Tammy Beckham,

Acting Director, National Vaccine Program Office.

[FR Doc. 2019–03698 Filed 2–28–19; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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