

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Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm.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one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.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](mailto: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FDA is announcing the availability of a draft guidance for industry entitled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](mailto: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]

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## **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