This guidance provides important recommendations to sponsors, applicants, and potential applicants in the approaches to collecting data that should comprise the abuse potential assessment submitted in the marketing application to FDA if one is required pursuant to § 314.50(d)(5)(vii).

In the **Federal Register** of January 27, 2010 (75 FR 4400), FDA issued the draft guidance for industry ''Assessment of Abuse Potential of Drugs.'' Based on the 2010 draft guidance, and consideration of comments received from the public, this guidance provides the Agency's current thinking with respect to the scientific methods recommended to assess abuse potential. The guidance also adds more detailed discussion about key questions and decision points to consider during drug development that will likely determine the appropriate studies for sponsors and applicants to conduct to address the abuse potential of their new drug, inform appropriate labeling of the product upon its approval, and allow a thorough scientific and medical evaluation to support scheduling decisions in accordance with the CSA. In addition, this guidance takes into consideration other guidance issued and legislation enacted since 2010.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on assessment of abuse potential of drugs. 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.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in part 314, including § 314.50(d)(5)(vii), has been approved under OMB control number 0910–0001. The collection of information in 21 CFR part 312 for investigational drugs has been approved under OMB control number 0910–0014. The collection of information in the guidance ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' has been approved under OMB control number 0910–0429. The collection of information in 21 CFR 201.56 and 201.57, prescription drug labeling, has been approved under OMB control number 0910–0572. The collection of information in 21 CFR part 58, Good Laboratory Practice for Nonclinical Studies, has been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: January 12, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–01024 Filed 1–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–0113]

The Prohibition of Distributing Free Samples of Tobacco Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''The Prohibition of Distributing Free Samples of Tobacco Products; Draft Guidance for Industry.'' The draft guidance, when finalized, would provide information intended to assist manufacturers, distributors, and retailers in complying with the regulations prohibiting the distribution of free samples of tobacco products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 17, 2017.

ADDRESSES: 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2017–D–0113 for ''The Prohibition of Distributing Free Samples of 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 Division of Dockets Management 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 Division of Dockets

Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paul Hart or Samantha Loh Collado, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''The Prohibition of Distributing Free Samples of Tobacco Products; Draft Guidance for Industry.'' Title 21 of the Code of Federal Regulations (CFR) section 1140.16(d)(1) prohibits, with a limited exception, tobacco product manufacturers, distributors, and retailers from distributing or causing to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products. The draft guidance describes, among other things, how the prohibition of distributing free samples of tobacco products applies to non-monetary exchanges, coupons and discounts, membership and rewards programs, contests and games of chance, and the business-to-business exchange of free samples. FDA requests that interested parties submit comments concerning its draft interpretation of the prohibition of distributing free samples.

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 ''The Prohibition of Distributing Free Samples of Tobacco Products.'' 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.

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 *http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: January 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00969 Filed 1–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; NURSE Corps Loan Repayment Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB).

DATES: Comments on this ICR should be received no later than March 20, 2017.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N–39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: NURSE Corps Loan Repayment Program OMB No. 0915–0140—Revision

Abstract: The NURSE Corps Loan Repayment Program (NURSE Corps LRP), formerly known as the Nursing Education Loan Repayment Program, assists in the recruitment and retention of professional Registered Nurses (RNs), including advanced practice RNs (*e.g.,* nurse practitioners, certified registered nurse anesthetists, certified nurse-midwives, clinical nurse specialists), dedicated to working at eligible health care facilities with a critical shortage of nurses (*i.e.,* a Critical Shortage Facility) or working as nurse faculty in eligible, accredited schools of nursing, by decreasing the financial barriers associated with pursuing a nursing education. The NURSE Corps LRP provides loan repayment assistance to these nurses to repay a portion of their qualifying educational loans in exchange for full-time service at a public or private nonprofit Critical Shortage Facility or in an eligible, accredited school of nursing.

Need and Proposed Use of the Information: The need and purpose of this information collection is to obtain information for NURSE Corps LRP applicants and participants. The information is used to consider an applicant for a NURSE Corps LRP contract award and to monitor a participant's compliance with the service requirements. Individuals must submit an application to participate in the program. The application asks for personal, professional, educational, and financial information required to determine the applicant's eligibility to participate in the NURSE Corps LRP. The semi-annual employment verification form asks for personal and employment information to determine if a participant is in compliance with the service requirements. The Authorization to Release Employment Information form is now a self-certification within the NURSE Corps LRP application process with applicants clicking a box. This decreases the overall time burden by eliminating a form and not increasing