The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–02915 Filed 2–20–19; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1939]

Use of Investigational Tobacco Products; Revised Draft Guidance for Industry and Investigators; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry and investigators entitled ''Use of Investigational Tobacco Products.'' The revised draft guidance replaces the draft guidance of the same title announced in the **Federal Register** of September 24, 2015 (September 2015 draft guidance). The revised draft guidance, when finalized, will describe FDA's current thinking regarding the definition of ''investigational tobacco product'' and will discuss the kind of information FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations governing the use of investigational tobacco products become effective or FDA provides written notice of its intent to change its enforcement policy.

DATES: Submit either electronic or written comments on the draft guidance by April 22, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information by April 22, 2019.

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–2014–D–1939 for ''Use of Investigational Tobacco Products; Revised Draft Guidance for Industry and Investigators; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request.'' 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, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., 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:

With regard to the draft guidance: Laura Rich or Samantha LohCollado,

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, email: *AskCTP@fda.hhs.gov.*

With regard to the proposed collection of information: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Use of Investigational Tobacco Products.'' This revised draft guidance replaces the September 2015 draft guidance and, when final, will describe FDA's current thinking regarding the definition of ''investigational tobacco product'' and discuss the kind of information FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations are issued and become effective or FDA provides written notice of its intent to change its enforcement policy. It is intended to provide guidance to persons who currently intend to submit study information on tobacco products to FDA as well as to persons who conduct investigations using investigational tobacco products.

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act), enacted on June 22, 2009, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and provided FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

To introduce or deliver for introduction into interstate commerce a new tobacco product, there must be in effect a marketing authorization order issued by FDA for the tobacco product under section 910(c)(1)(A)(i) of the FD&C Act (21 U.S.C. 387j(c)(1)(A)(i)) unless:

- The manufacturer has submitted a substantial equivalence report for the tobacco product under section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) and obtained from FDA a substantial equivalence order under section 910(a)(2)(A)(i) of the FD&C Act;
- The manufacturer has submitted, under 21 CFR 1107.1, a request for an exemption for the tobacco product from the requirement to obtain a substantial equivalence order, FDA has granted the exemption request, and the manufacturer has made the required submission under section 905(j)(1)(A)(ii) of the FD&C Act and waited 90 days before introducing its product to the market; or
- The manufacturer has submitted a substantial equivalence report in accordance with section 910(a)(2)(B) of the FD&C Act and there is no order finding that the tobacco product is not substantially equivalent.

To introduce or deliver for introduction into interstate commerce a modified risk tobacco product, there must be in effect an order under section 911(g) of the FD&C Act (21 U.S.C. 387k(g)) and the applicant must satisfy any applicable premarket review requirements under section 910 of the FD&C Act.

Furthermore, a tobacco product must conform in all respects with applicable tobacco product standards established under section 907 of the FD&C Act (21 U.S.C. 387g). Any tobacco product, including a tobacco product intended for investigational use, is deemed adulterated if it is subject to a tobacco product standard established under section 907 of the FD&C Act and does not in all respects conform with such standard.

Section 910(g) of the FD&C Act gives FDA the authority to issue regulations to exempt tobacco products intended for investigational use from the provisions of chapter IX of the FD&C Act, including premarket submission requirements. FDA intends to propose regulations establishing conditions for exempting investigational tobacco products from certain FD&C Act requirements. Until then, investigational tobacco products are not exempt from applicable FD&C Act requirements, including premarket submission requirements and tobacco product standards.

FDA recognizes that researchers may seek to study tobacco products that do not have marketing authorization or that do not comply with an applicable tobacco product standard. Until regulations governing the use of investigational tobacco products are issued and finalized, FDA intends to evaluate specific uses of investigational tobacco products according to potential human subject protection concerns or other impacts on public health. This revised draft guidance discusses the factors FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products.

FDA issued the September 2015 draft guidance in the **Federal Register** of September 24, 2015 (80 FR 57623). Interested parties were given an opportunity to submit comments by November 23, 2015. FDA received numerous comments on the September 2015 draft guidance. Based on careful review of these comments, FDA is issuing this revised draft guidance to clarify the Agency's thinking.

II. Significance of Draft Guidance

FDA is issuing this revised draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance replaces the September 2015 draft guidance. The draft guidance, when finalized, will represent the current thinking of FDA regarding the definition of ''investigational tobacco product'' and discuss the factors FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations are issued or FDA provides written notice of its intent to change its enforcement policy. 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 draft guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Industry: Use of Investigational Tobacco Products

OMB Control Number 0910–NEW

FDA is announcing the availability of the revised draft guidance entitled ''Use of Investigational Tobacco Products.'' This revised draft guidance supersedes the September 2015 draft guidance and, when final, will describe FDA's current thinking regarding the definition of ''investigational tobacco product'' and discuss the kind of information FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations are issued and become effective or FDA provides written notice of its intent to change its enforcement policy. The revised draft guidance is intended to provide guidance to persons who currently intend to submit study information on tobacco products to FDA and to persons who conduct investigations using investigational tobacco products. Such persons may include sponsors, investigators, sponsor-investigators, and contract research organizations (CROs). This revised draft guidance is also intended to provide recommendations to committees or groups formally designated to oversee human subject research (*e.g.,* institutional review boards) involving investigational tobacco products.

FDA recognizes that researchers may seek to study tobacco products that do not have marketing authorization or that do not comply with an applicable tobacco product standard. Until regulations governing the use of investigational tobacco products are issued and finalized, as discussed in the guidance, FDA intends to evaluate specific uses of investigational tobacco products according to potential human subject protection concerns or other impacts on public health.

FDA has identified the following recommendations in the revised draft guidance as collections of information.

In the revised draft guidance, FDA provides examples of information that may help FDA to evaluate specific proposed uses of investigational tobacco products and encourages persons who intend to study investigational tobacco products to meet with FDA to discuss certain topics in connection with investigations. FDA does not recommend that investigators engaging in nonclinical laboratory investigations correspond with FDA about use of investigational tobacco products in nonclinical studies in all situations. However, sponsors of nonclinical studies may elect to meet with FDA early in the development process to discuss what, if any, animal testing is appropriate and the suitability and acceptability of non-animal tests for a particular tobacco product.

For clinical investigations, FDA encourages sponsors to submit information regarding a proposed use of an investigational tobacco product to FDA for review prior to enrolling subjects in the planned investigation. FDA has created a form entitled ''Proposed Use of an Investigational Tobacco Product'' to assist sponsors in submitting information. Although use of this form is voluntary, its use will likely reduce the burden hours and will help ensure that sponsors provide complete information for FDA's consideration, processing, and review. The amount of information the revised draft guidance recommends that a sponsor submit depends on the scope of the investigation. For example, the revised draft guidance encourages persons conducting studies with investigational tobacco products that involve minor modifications to legally marketed products to meet with FDA before making a submission. This is because in such cases, it may be appropriate to submit less information. Although the submission of information is voluntary, FDA encourages it, so that sponsors can ensure their investigations account for the factors FDA considers in making enforcement decisions.

Regardless of whether a sponsor intends to consult with FDA in conducting research with an investigational tobacco product, the revised draft guidance contains recommendations for information to include within the study protocol. This information may be considered should FDA assess the enforcement priority of a particular investigation.

Furthermore, to help ensure that studies are conducted in a manner that protects human subjects, the revised draft guidance contains recommendations for procedures sponsors can implement to keep FDA and the committee or group formally designated to oversee research involving human subjects informed about any changes relating to the conduct of, and issues that arise during, the study. In the revised draft guidance, FDA further recommends that the sponsor ensure that clinical investigators maintain complete and accurate records to account for receipt, use, and disposition of investigational tobacco products. FDA also recommends that the sponsor keep clinical investigators and any committee or group formally designated to oversee research involving human subjects informed of new information on the product, particularly adverse experience information.

In addition, FDA recommends that if there are changes to the current investigational use, sponsors consult with the Office of Science, Center for Tobacco Products (CTP), and any committee or group formally designated to oversee research involving human subjects to ensure that the sponsor's use of an investigational tobacco product continues to appropriately account for the factors FDA intends to consider in determining enforcement priorities. FDA recommends that sponsors also notify FDA if they choose to terminate a study, withdraw or inactivate a protocol, or want to withdraw studies of a product before completion. This information is relevant for FDA to consider in making decisions relating to future investigations involving the tobacco product that was the subject of the terminated study. Moreover, in the revised draft guidance, FDA recommends that under certain circumstances, sponsors also inform any clinical investigators who participated in the discontinued investigation of the reason(s) for discontinuing the clinical investigation.

FDA also makes recommendations related to clinical investigations using investigational tobacco products conducted outside of the United States, but intended for submission to FDA, and refers to section 801(e) of the FD&C Act (21 U.S.C. 381(e)) with respect to exported tobacco products intended for investigational use. The revised draft guidance also recommends that sponsors prepare and maintain certain records and reports for studies conducted outside of the United States but intended for submission to FDA to permit FDA to evaluate the conduct of a clinical investigation, including assessing the quality and integrity of the study data and protection of human subjects.

Finally, in the revised draft guidance, FDA recommends that sponsors, CROs, sponsor-investigators, and clinical investigators maintain documentation to permit evaluation of the conduct of a clinical investigation, including assessing the quality and integrity of the study data and protection of human subjects. The revised draft guidance recommends that records be maintained and available for inspection upon request for a period of at least 4 years after the date on which the investigation

is terminated or completed, or the date that the records are no longer considered necessary for supporting marketing of a product, or the later of the two dates if both apply.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity/FDA form for proposed use of an investigational tobacco product	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Capital and operating and maintenance costs
Initial Submission	20	1	20	35	700	
Protocol Amendments	30	1	30	4	120	
Information Amendments	20	1	20	15	300	
Administrative Amendments	1	1.5	1.5	0.5 (30 minutes)	0.75	
Other Information	3	1	3	0.5 (30 minutes)	1.5	
Serious or Unexpected Adverse Experience Reports.	75	3	75	2	150	
First year, electronic setup safety reporting portal.	15	1	15	0.5 (30 minutes)	7.5	
First year, Electronic Gateway setup and verification certificate (one-time burden).	2	1	2	42 [1]	84	37,800
First year, CTP Portal setup	18		18	3	54	
Electronic Gateway Submission (recurring).	2	1	2	3	6	2,700
Total Reporting Burden Hours					1,424	40,500

[1] Respondent may already have a valid WebTrader account established for other FDA electronic submissions.

Table 1 describes the annual reporting burden as a result of respondents submitting information regarding the use of investigational tobacco products in certain clinical investigations. FDA estimates that 20 respondents will submit study information to FDA annually. FDA estimates that it will take each respondent approximately 35 hours to prepare the study information necessary for FDA to issue a response to the proposed use of an investigational tobacco product in these clinical investigations. FDA's estimate includes the anticipated burden for completing the form for the initial submission, which will include the initial protocol, time for intracompany edits and approvals, as well as the burden for assembling additional information, as described in the revised draft guidance.

Since the initial publication of the September 2015 draft guidance, FDA has updated the estimated burden hours using current information. In addition, FDA has revised table 1 to clarify the types of submissions we anticipate receiving and to clarify what type of information may be included in the initial submission. Specifically, we now estimate that protocol submissions would be included with the initial submission. As such, the approximate burden on respondents is less than discussed in the original Notice of Availability (NOA) for the September 2015 draft guidance.

In response to the original NOA, FDA received one PRA-related comment.

(Comment) The comment stated that FDA has vastly underestimated the time and burden of preparing an initial submission. The comment contended that our estimate is not in line with the Agency's experience with respect to investigational new drug applications, which the comment also contends is an analogous context.

(Response) FDA does not agree with this comment. The Agency based its estimates on its understanding of the submissions it has received to date. The revised draft guidance announced in this notice also attempts to clarify the Agency's proposed recommendations regarding submissions.

Following the initial submission, sponsors may wish to provide protocol amendments to reflect certain changes to a protocol. FDA estimates that 30 respondents will submit a protocol amendment. The estimated time for submitting a protocol amendment is 4 hours per response. In addition, FDA estimates that 20 respondents will submit information amendments. Since this may take a little less than half the time of an initial submission, FDA estimates information amendments taking around 15 hours.

FDA estimates that respondents will infrequently need to report administrative amendments. The total number of respondents of this type of information is estimated to be one. FDA estimates administrative amendments taking around 30 minutes per response.

FDA estimates that approximately three respondents will report other types of submissions. These submissions are estimated to take 30 minutes per response.

FDA estimates that it will receive 75 reports of serious or unexpected adverse experiences. This submission will take an average of 2 hours per report. FDA further estimates that approximately 15 respondents will set up an account in the safety reporting portal for purposes of submitting serious or unexpected adverse experiences. The first year setup of the safety reporting portal for this purpose will take 30 minutes per respondent.

As referenced in the September 2015 draft guidance, FDA allows for three ways of submission. However, FDA strongly encourages the use of electronic format for submission because of its overall efficiency in transmitting information. To submit information through the Electronic Submissions Gateway (ESG), the submitter should first set up an account with WebTrader. FDA estimates from past experience with WebTrader that the first year to set up the account and to receive the verification certificate takes approximately 40 hours. This burden may be minimized if the respondent already has an established account in WebTrader for other electronic submissions to FDA, but FDA is assuming that all respondents for these products will be setting up a WebTrader account for the first time in the first year. In subsequent years, the burden hours are estimated at 1 hour to renew the yearly required Verification

Certification. In addition, to submit information through the ESG (or any other means of electronic submission), the submitter must package the information using the eSubmitter formatting software. FDA estimates that the gathering and scanning of information and related correspondence would take approximately 2 hours using the eSubmitter system.

Therefore, the first year will include 40 hours for the WebTrader system plus 2 hours for the eSubmitter process, resulting in 42 hours per response for the first year. For subsequent years, it is estimated that only 1 hour will be necessary for the WebTrader system plus the 2 hours for the eSubmitter process, resulting in 3 hours per response each year thereafter.

In addition to the ESG system, an alternative electronic method for respondents to submit electronic information is through the CTP Portal. Respondents with access to an Industry Account Manager (IAM) may contact the IAM directly for establishment of an account and access to the CTP Portal. Respondents without access to an IAM will be required to identify and establish an IAM. To establish an IAM with the CTP Portal, respondents should contact the CTP Portal Helpdesk and submit required administrative information. FDA estimates that the first-year setup for the CTP Portal is approximately 1 hour per respondent. After receiving access to the CTP Portal, respondents will submit information through the CTP Portal using the eSubmitter system. FDA estimates the gathering, scanning, and submission of information and related correspondence would take approximately 2 hours using the ESG system.

Additionally, there are capital and operating or maintenance costs associated with the ESG platform for the purpose of information collection. The costs are $30 per year to establish and maintain the ESG verification certificate. The total cost may be lower if the respondents already have a verification certificate for that year for other electronic submissions to FDA. However, for purposes of this estimate, FDA is assuming that all respondents for these products will be incurring this cost. The total costs are estimated to be $40,500.

The total reporting burden for this collection of information is estimated to be 1,424 hours. These burden estimates were computed using FDA staff expertise and by reviewing comments received from recent FDA information collections for other tobacco-related initiatives.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity records maintained	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records by Sponsors	20	1	20	10	200
Records by Sponsor-Investigators	10	1	10	20	200
Records by Investigators and CROs	15	1	15	15	225
Total Recordkeeping Burden Hours					625

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2 describes the annual recordkeeping burden of maintaining records relating to the investigational use of tobacco products. FDA has updated these numbers based on submissions received since the publication of the September 2015 draft guidance. Compared to FDA's original estimates, the recordkeeping burden has been decreased by 1,025 hours. In addition, FDA has revised table 2 to reflect that we have clarified which records we are recommending should be maintained. Consequently, FDA now anticipates that 20 sponsors, 10 sponsor-investigators, and 15 investigators and CROs (for a total of 45 respondents) will maintain records relating to the use of investigational tobacco products in clinical investigations. FDA estimates that it will take each sponsor approximately 10 hours per study annually to maintain these records. FDA further estimates that it will take each sponsor-investigator approximately 20 hours per study annually to maintain these records. Finally, FDA estimates that it will take investigators and CROs approximately 15 hours per study annually to maintain these records. The total reporting burden for recordkeeping is estimated to be 625 hours [200 hours for sponsors (20×10) + 200 hours for sponsor-investigators (10×20) + 225 for investigators and CROs (15×15)].

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Disclosures to Investigators	50	1	50	1	50
Disclosures to any Committee or Group	50	1	50	0.17 (10 minutes)	9
Disclosure to Study Subjects	50	2	100	0.5 (30 minutes)	50
Total					109

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3 describes the annual third-party disclosure burden.

FDA increased the number of anticipated disclosures based on submissions received since publication of the September 2015 draft guidance. Additionally, FDA recognizes that sponsors will need to make third-party disclosures to multiple individuals and groups including investigators, study subjects, as well as any committee or group designated to oversee research. FDA estimates that disclosing

information to investigators will take 1 hour per disclosure. FDA estimates that disclosing information to any committee or group formally designated to oversee research involving human subjects will average 10 minutes per disclosure.

The revised draft guidance also references examples of disclosing information to study subjects such as informed consent. On average, two disclosures per respondent will be provided to study subjects. FDA estimates this will take 30 minutes per disclosure.

The total burden for the collection of information under this revised draft guidance is estimated to be approximately 2,158 hours.

The revised draft guidance also refers to previously approved collections of information. The revised draft guidance includes a recommendation that persons who intend to study tobacco products meet with FDA to discuss research plans. Additional information about how to request meetings with FDA's CTP can be found in FDA's guidance ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products'' (*https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM305282.pdf*).

The collections of information in the guidance referenced have been approved under OMB control number 0910–0731. The collections of information in section 801(e) of the FD&C Act and 21 CFR 1.101(b) have been approved under OMB control number 0910–0482; the collections of information for the Safety Reporting Portal have been approved under OMB control number 0910–0645; the collections of information in section 905(j) of the FD&C Act have been approved under OMB control number 0910–0673.

IV. Electronic Access

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

Dated: February 15, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02971 Filed 2–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Migrant Health

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

ACTION: Notice.

SUMMARY: The Secretary's National Advisory Council on Migrant Health (NACMH) has scheduled a public meeting. Information about NACMH and the agenda for this meeting can be found on the NACMH website at *https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html.*

DATES: May 22, 2019, 9:00 a.m. to 5:00 p.m. Eastern Time (ET), and May 23, 2019, 9:00 a.m. to 5:00 p.m. ET.

ADDRESSES: The meeting will be held in-person. The address for the meeting is The College at Brockport, State University of New York (SUNY), Cooper Hall, 350 New Campus Drive, Brockport, New York 14420.

FOR FURTHER INFORMATION CONTACT: Esther Paul, Designated Federal Official, (DFO), Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 5600 Fishers Lane, 16N38B, Rockville, Maryland 20857; (301) 594–4300; or *epaul@hrsa.gov.*

SUPPLEMENTARY INFORMATION: NACMH provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under section 217 of Title 42 U.S.C. 218 of the Public Health Service (PHS) Act.

During the May 22–23, 2019, meeting, NACMH will hear presentations from a federal official and experts, and discuss issues facing migrant and seasonal agricultural workers, including the status of agricultural worker health at the local and national levels. Topics addressed at this meeting include health care for aging farmworkers, oral health, and sexual harassment in the agricultural industry. In addition, during the first day of the meeting, on May 22, 2019, the council will hear public comments from migratory and seasonal agricultural workers regarding matters affecting their health. Agenda items are subject to change as priorities dictate. Refer to the NACMH website for any updated information concerning the meeting at *https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html.*

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to NACMH should be sent to Esther Paul, DFO, using the contact information above at least three business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Esther Paul at the address and phone number listed above at least 10 business days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–02927 Filed 2–20–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

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

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault