using the travel cost rate for foreign travel, because we anticipate that the vast majority of onsite assessments made by FDA under this program will require foreign travel. In FY 2015, ORA spent a total of $2,521,216 on 269 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $9,373 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $9,373 per trip by 120 hours per trip results in a total and an additional cost of $78 per paid hour spent for foreign inspection travel costs in FY 2015. To adjust $78 for inflationary increases in FY 2016 and FY 2017, FDA must multiply it by the same inflation factor mentioned previously in this document (1.036047), which results in an estimated cost of $81 dollars per paid hour in addition to $204 for a total of $285 per paid hour ($204 plus $81) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2017 when travel is required for the third-party certification program.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2017

Fee category	Fee rates for FY 2017
Hourly rate without travel	$204
Hourly rate if travel is required	285

III. Application Fee for Accreditation Bodies Applying for Recognition in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

In FY 2017 (the first fiscal year in which the program will operate), the only fee that will be collected by FDA under section 808(c)(8) of the FD&C Act is the initial application fee for accreditation bodies seeking recognition. Section 1.705(a)(1) establishes an application fee for accreditation bodies applying for initial recognition that represents the estimated average cost of the work FDA performs in reviewing and evaluating initial applications for recognition of accreditation bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. We estimate that it would take, on average, 60 person-hours to review an accreditation body's submitted application, 48 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 45 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $204/hour, to calculate the portion of the user fee attributable to those activities: $204/hour × (60 hours + 45 hours) = $21,420. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most accreditation bodies are located in foreign countries. For this portion of the fee we use the fully supported FTE hourly rate for work requiring travel, $285/hour, to calculate the portion of the user fee attributable to those activities: $285 × 48 hours (*i.e.,* 2 fully supported FTEs × (2 travel days + 1 day onsite)) = $13,680. The estimated average cost of the work FDA performs in total for reviewing an initial application for recognition for an accreditation body based on these figures would be $21,420 + $13,680 = $35,100. Therefore the application fee for accreditation bodies applying for recognition in FY 2017 will be $35,100.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Fee Categories Not Applicable in FY 2017

The third-party certification program will also assess other application fees and annual fees in future years of this program. Section 1.705(a) also establishes application fees for recognized accreditation bodies submitting renewal applications, certification bodies applying for direct accreditation, and certification bodies applying for renewal of direct accreditation. Section 1.705(b) establishes annual fees for recognized accreditation bodies, certification bodies directly accredited by FDA, and certification bodies accredited by recognized accreditation bodies.

Although we will not be collecting these other fees in FY 2017, for transparency and planning purposes, we have provided an estimate of what these fees could have been for FY 2017 based on the fully supported FTE hourly rates for FY 2017 and estimates of the number of hours it would take FDA to perform relevant activities as outlined in the Final Regulatory Impact Analysis for the Third-Party Certification Regulation. Table 3 provides an overview of the estimated fees for other fee categories.

Fee category	Estimated fee rates for FY 2017
Renewal application fee for recognized accreditation body	$18,855
Initial application fee for certification body seeking direct-accreditation from FDA	35,100
Renewal application fee for directly-accredited certification body	26,460
Annual fee for recognized accreditation body	1,579
Annual fee for certification body directly-accredited by FDA	20,208
Annual fee for accredited certification body	1,974

V. How Must the Fee Be Paid?

Accreditation bodies seeking initial recognition must submit the application fee with the application.

VI. What Are the Consequences of Not Paying This Fee?

The consequence of not paying this fee is outlined in § 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete and FDA would not review the application.

Dated: *December 9, 2016.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30034 Filed 12–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4803]

Public Notification of Emerging Postmarket Medical Device Signals (''Emerging Signals''); Guidance for Industry and Food and Drug Administration Staff; 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 the guidance entitled ''Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals').'' FDA is issuing this guidance to describe the Center for Devices and Radiological Health's (CDRH) policy for notifying the public about medical device ''emerging signals.'' This guidance describes the

factors CDRH intends to consider in deciding whether to notify the public about an emerging signal and the processes and timelines it intends to follow in issuing and updating the notification. Timely notification about those emerging signals based on the factors described in this guidance document is intended to provide health care providers, patients, and consumers with access to the most current information concerning the performance and potential benefits and risks of marketed medical devices so that they can make informed patient management decisions about their treatment and diagnostic options.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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–2015–D–4803 for ''Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals').'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://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 *http://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 *http://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.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals')'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993–0002, 301–796–6527.

SUPPLEMENTARY INFORMATION:

I. Background

All medical devices have benefits and risks. FDA weighs probable benefit to health from the use of the device against any probable risk of injury or illness from such use in determining the safety and effectiveness of a device.[1] Once FDA has made its determination, health care providers, patients, and consumers must weigh these benefits and risks when making patient management decisions. However, not all information regarding benefits and risks for a given device may be known before the device reaches the market. New information about a device's safety and/or effectiveness, including unanticipated adverse events, may become available once the device is more widely distributed and used under real-world conditions and in broader patient populations than may have been studied in support of a marketing application. Also, subsequent changes made to the device, its manufacturing process, or supply chain might lead to new safety problems.

FDA is issuing this guidance to describe CDRH policy for notifying the public about medical device ''emerging signals.'' For the purposes of this guidance, an emerging signal is new information about a marketed medical device: (1) That supports a new causal association or a new aspect of a known association between a device and an adverse event or set of adverse events and (2) for which the Agency has conducted an initial evaluation and determined that the information has the potential to impact patient management decisions and/or the known benefit-risk profile of the device. Information that is

[1] See 21 U.S.C. 360c(a)(2) and 21 CFR 860.7.

unconfirmed, unreliable, or lacks sufficient strength of evidence is not an emerging signal.

This guidance describes the factors CDRH intends to consider in deciding whether to notify the public about emerging signals and the processes and timelines it intends to follow in issuing and updating the notification. Timely notification about those emerging signals based on the factors described in this guidance document is intended to provide health care providers, patients, and consumers with access to the most current information concerning the performance and potential benefits and risks of marketed medical devices so that they can make informed patient management decisions about their treatment and diagnostic options.

In the **Federal Register** of December 31, 2015 (80 FR 81829), FDA announced the availability of the draft of this guidance. Interested persons were invited to comment by February 29, 2016. In the **Federal Register** of January 27, 2016 (81 FR 4632), FDA extended the comment period to March 29, 2016. FDA received and considered 21 sets of public comments and revised the guidance as appropriate. CDRH also intends to provide periodic public updates on the implementation of this guidance.

II. Significance of Guidance

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 ''Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals').'' 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 interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals')'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500027 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR parts 801, regarding labeling, have been approved under OMB control number 0910–0485 and the collections of information in 21 CFR part 803, regarding medical device reporting, have been approved under OMB control numbers 0910–0291, 0910–0437, and 0910–0471.

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29989 Filed 12–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Requirements and Registration for ''Privacy Policy Snapshot Challenge''

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice.

SUMMARY: The Model Privacy Notice (MPN) is a voluntary, openly available resource designed to help health technology developers who collect digital health data clearly convey information about their privacy and security policies to their users. Similar to a nutrition facts label, the MPN provides a snapshot of a product's existing privacy practices, encouraging transparency and helping consumers make informed choices when selecting products. The MPN does not mandate specific policies or substitute for more comprehensive or detailed privacy policies. The Privacy Policy Snapshot Challenge is a call for designers, developers, and health data privacy experts to create an online MPN generator. The statutory authority for this Challenge is Section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358).

DATES:

- Submission period begins: December 13, 2016
- Submission period ends: April 10, 2017
- Winners announced: May-June, 2017

FOR FURTHER INFORMATION CONTACT: Adam Wong, *adam.wong@hhs.gov* (preferred), 202–720–2866.

SUPPLEMENTARY INFORMATION:

Award Approving Official

B. Vindell Washington, National Coordinator for Health Information Technology

Subject of Challenge

In 2011, the Office of the National Coordinator for Health Information Technology (ONC) collaborated with the Federal Trade Commission (FTC) and released a Model Privacy Notice (MPN) focused on personal health records (PHRs), which were the emerging technology at the time (view 2011 PHR MPN). The project's goals were to increase consumers' awareness of companies' PHR data practices and empower consumers by providing them with an easy way to compare the data practices of two or more PHR companies. In the last five years, the health information technology market has changed significantly and there is now a larger variety of products such as mobile applications and wearable devices that collect digital health data.

ONC recognized a need to update the MPN to make it applicable to a broad range of consumer health technologies beyond PHRs. More and more individuals are obtaining access to their electronic health information and using consumer health technology to manage this information. As retail products that collect digital health data directly from consumers are used, such as exercise trackers, it is increasingly important for consumers to be aware of companies' privacy and security policies and information sharing practices. Health technology developers can use the MPN to easily enter their information practices and produce a notice to allow consumers to quickly learn and understand privacy policies, compare company policies, and make informed decisions. Many consumer health technologies are offered by organizations that are not subject to the Health Insurance Portability and Accountability Act (HIPAA) privacy and security standards. This is detailed in the HHS report, Examining Oversight of the Privacy & Security of Health Data Collected by Entities Not Regulated by HIPAA, released in July 2016 by ONC's Office of the Chief Privacy Officer with the cooperation of the HHS Office for Civil Rights (OCR) and the FTC.

The Privacy Policy Snapshot Challenge leverages updated content developed recently by ONC, with feedback from OCR, FTC, and other private and public stakeholders. The