

ACTION: Notice.

SUMMARY: In this document the Federal Communications Commission (FCC) provides a detailed agenda for the workshop scheduled for March 18, 2013 in Washington, DC. This event is the first in a planned series of workshops to analyze technology transitions from narrowband to broadband; from time-division multiplexing (TDM) to Internet Protocol (IP); from copper to fiber; from only wireline services to greater use of wireless and their implications for modernizing Commission policy.

DATES: The workshop information is as follows:

Date: March 18, 2013.

Time: 9:30 a.m.–4:00 p.m. (EST).

Location: Commission Meeting Room, Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

9:30 a.m.–10:00 a.m. Welcome and Opening Remarks.

10:00 a.m.–11:30 a.m. Technological Capabilities—This panel will discuss the technological capabilities of wireless and wireline (copper, fiber and coax) technologies today and in the future.

11:30 a.m.–12:30 p.m. Lunch Break.

12:30 p.m.–2:00 p.m. Usage and Adoption—This panel will examine the adoption and use of various technologies across the diverse demographics of our nation.

2:00 p.m.–2:30 p.m. Break.

2:30 p.m.–4:00 p.m. Network Evolution—transition for different wireline and wireless. This panel will examine the timing of the technological networks as well as examine drivers for the timing of the technology transition.

ADDRESSES: Federal Communications Commission, Commission Meeting Room, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: For additional information about the meeting, please contact Rebekah Goodheart, Deputy Director, Technology Transitions Policy Task Force, at (202) 418-1438 or rebekah.goodheart@fcc.gov.

SUPPLEMENTARY INFORMATION: The FCC will attempt to accommodate as many attendees as possible; however, admittance will be limited to seating availability. The Commission will provide audio and/or video coverage of the meeting over the Internet from the FCC's Web page at <http://www.fcc.gov/live>. Open captioning will be provided for this event. Other reasonable accommodations for people with

disabilities are available upon request. Requests for such accommodations should be submitted via email to fcc504@fcc.gov or by calling the Consumer & Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (tty). Such requests should include a detailed description of the accommodation needed. In addition, please include a way the FCC can contact you if it needs more information. Please allow as much advance notice as possible; last-minute requests will be accepted, but may be impossible to fill.

We also take this opportunity to remind the public that presentations to decision-making personnel that go to the merits of the Commission's pending permit-but-disclose proceeding in GN Docket No. 13-5 regarding the work of the Technology Transitions Policy Task Force, *see Ex Parte Meetings with the Technology Transitions Policy Task Force*, Public Notice, 28 FCC Rcd 105 (2013), must comply with the Commission's *ex parte* rules, *see, e.g.*, 47 CFR.1.1200 *et seq.* Interested parties are also invited to submit written comments in this public docket.

Attendance—This Workshop is open to the public. In order to ensure space availability and expedite the security check-in process, please submit name and company affiliation ahead of time by sending an email to susan.fisenne@fcc.gov. All attendees are advised to arrive approximately 30 minutes prior to the start of the workshop to allow time to go through our security process.

Lunch: Attendees may pre-order lunch, to be picked up by FCC staff, from the Potbelly Sandwich Shop. To place your order online, go to <http://www.potbelly.com/Shops/OrderOnline.aspx> and follow these instructions:

- Which Shop?, enter the FCC's address at 445 12th Street SW., Washington, DC, and then select the Potbelly Shop located at 1240 Maryland Ave. SW., Washington
- Carryout or Delivery?: Carryout
- Pickup Date?: March 18, 2013
- Pickup Time?: 10:30 a.m.
- Make your lunch and beverage selections
- Who is this Item for?: First and last name followed by "FCC," i.e., John Smith FCC
- Contact Information: Complete your contact information and after your last name, include "-FCC"
- Credit Card Information: Provide your credit card information and submit your order.

Federal Communications Commission.

Sean Lev,

General Counsel.

[FR Doc. 2013-06287 Filed 3-14-13; 4:15 pm]

BILLING CODE 6712-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0194]

Agency Information Collection Activities; Proposed Collection; Comment Request; Draft Guidance for Industry and FDA Staff; Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on "Guidance for Industry and FDA Staff; Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions."

DATES: Submit either electronic or written comments on the collection of information by May 17, 2013.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under 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 and FDA Staff; Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions—0910–NEW

This draft guidance is intended to assist industry in preparing premarket notification submissions for infusion pumps and to identify device features that manufacturers should address throughout the total product life cycle. The draft guidance is available at

(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm206153.htm>).

In the **Federal Register** of March 26, 2010 (75 FR 21632), FDA published a notice seeking comment on the proposed information collection activity. Given the lapse in time since its publication, FDA is reissuing this notice, responding to a single comment and providing the public and additional opportunity to comment on this proposed information collection activity, prior to the issuance of the final guidance document.

In the March 26, 2010, notice, the FDA estimated “it will receive 31 infusion pump submissions annually. The Agency reached this estimate by averaging the number of premarket notifications for infusion pumps submitted to FDA over the past 5 years. The draft guidance identifies 56 potential hazards FDA recommends addressing if applicable to a particular device. Although there may be additional hazards identified by a manufacturer, the Agency believes these hazards may offset FDA identified hazards not applicable to a particular device. FDA estimates it will take infusion pump manufactures approximately 56 hours (approximately 1 hour per hazard) to complete the case assurance report described in section 6 of the draft guidance. FDA reached this estimate based on its expectation of the amount of information that will be contained in the report.”

However, based on a single public comment provided to FDA, related to the FDA burden estimate, we are adjusting the burden associated with this collection. The public comment is summarized as follows: It will take significantly longer than one hour to conduct assurance case reports for each of the 56 potential hazards identified

* * *. For instance, due to the iterative nature of the assurance case report process, each of the applicable hazards will need to be re-evaluated at multiple stages of the development process. In addition, it will be difficult to estimate the time required to conduct an assurance case report without specific guidance on the assurance case reports.

While the commenter believes the reporting burden is greater than 1 hour, and FDA agrees, it is also important to note that the burden associated with this new recommendation to present data is the time and effort necessary to comply with submitting a new 510(k) or 510(k) supplements for legally marketed infusion pumps for which no assurance case exists. The Agency has revised the burden estimate, by averaging the number of premarket notifications for infusion pumps submitted to FDA over the past 5 years. The draft guidance identifies 56 potential hazards FDA recommends addressing if applicable to a particular device. Although there may be additional hazards identified by a manufacturer, the Agency believes the reporting of these hazards may be offset by FDA identified hazards not applicable to a particular device. FDA has revised the estimate of time it will take infusion pump manufactures from approximately 56 hours to 112 hours (approximately 2 hours per hazard) to submit the case assurance report described in section 6 of the draft guidance. FDA reached this estimate based on its expectation of the amount of information that will be contained in the report and the public comment received.

The respondents to this collection of information are infusion pump manufacturers subject to FDA’s laws and regulations.

The Agency estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| Guidance title: Infusion pumps—premarket notification 510(k) submissions | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Guidance Section 6—Assurance Case Report | 31 | 1 | 31 | 112 | 3,472 |

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

The premarket notification procedures discussed in the draft guidance (21 CFR 807, subpart E) have been approved under OMB control number 0910–0120. The proposed information collection seeks to add clinical or scientific data demonstrating that new or changed infusion pumps are as safe and effective as those legally marketed and do not raise different

questions of safety and effectiveness than predicate devices in this generic device type. In this way manufacturers of infusion pumps may demonstrate substantial equivalence and receive premarket clearance for their devices.

This draft guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21

CFR part 803 are approved under OMB control number 0910–0437; the collections of information in 21 CFR part 801 are approved under OMB control number 0910–0485; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts B and E are approved

under OMB control number 0910–0231; the collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR part 822 are under OMB control number 0910–0449; and the collections of information in 21 CFR 56.115 are approved under OMB control number 0910–0130.

Dated: March 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06128 Filed 3–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0190]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on submission of rotational plans for health warning label statements for smokeless tobacco products.

DATES: Submit either electronic or written comments on the collection of information by May 17, 2013.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All

comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, Daniel.Gittleston@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under 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, including each proposed extension of an existing 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.

Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act (OMB Control Number 0910–0671)—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law.

Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act) (15 U.S.C. 4402), as amended by section 204 of the Tobacco Control Act, requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements. Section 3(b)(3)(A) of the Smokeless Tobacco Act requires that the warnings be displayed on packaging and advertising for each brand of smokeless tobacco “in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer” to, and approved by, FDA.

This information collection—the submission to FDA of warning plans for smokeless tobacco products—is statutorily mandated. The warning plans will be reviewed by FDA, as required by the Smokeless Tobacco Act, to determine whether the companies’ plans for the equal distribution and display of warning statements on packaging and the quarterly rotation of warning statements in advertising for each brand of smokeless tobacco products comply with section 3 of the Smokeless Tobacco Act, as amended.

Based on the Federal Trade Commission’s (FTC’s) previous experience with the submission of warning plans and FDA’s experience with smokeless tobacco companies (e.g., correspondence associated with user fees under section 919 of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act (21 U.S.C. 387s)), FDA estimates that there are 36 companies affected by this information collection. To account for the entry of new smokeless tobacco companies that may be affected by this information collection, FDA is estimating the total number of respondents to be 100.

When the FTC requested an extension of their approved information collection in 2007, based on over 20 years implementing the warning plan requirements and taking into account increased computerization and improvements in electronic communication, the FTC estimated submitting an initial plan would take 60 hours. Based on FDA’s experience over the past several years, FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be reasonable.

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