• Awards may be subject to federal income taxes and HHS will comply with IRS withholding and reporting requirements, where applicable.

Basis Upon Which Winner Will Be Selected

Winning solution proposals to this Challenge will at a minimum meet the following Requirements:

(1) System is capable of capturing essential data from durable medical equipment (DME), including, but not limited to:

• Loss of external power;
• Power level and status of internal battery, including remaining battery life time, if appropriate;
• Unique identifier of the DME or at minimum, brand and model;
• GPS location;
• Current time/date;
• Device diagnostic information to determine operational status of DME; and
• User identifying information.

(2) System is capable of securely sending all captured data over various spectrums:

• Send information over medical body area network (MBAN);
• Robustly transmit over at least two communication methods/technologies; e.g. Ethernet, Wi-Fi, Mobile (CDMA, GSM, LTE), Amateur Radio, ZigBee;
• Ability to switch between/rollover spectrum/technologies depending on resource availability;
• Ability to send data automatically or upon manual command (e.g. at specified intervals of time, on-demand, or when triggered by external events);
• No interference with the operation of the DME;
• Securely transmit ''read only'' data collected from DME; and
• Data need to be distributed to a predetermined list of responders in a format defined by ASPR.

(3) System is accessible to all in-home patients with DME:

• Easy to install and set up user defined characteristics;
• Simple registration process; and
• Simple to use, particularly for elderly or frail individuals.

A solution may include the use of a device(s). If this is the case, these additional specifications must be met:

(1) Low-power consumption transmitter

• Ideally be constructed of readily available open source components;
• Consumes low level of standby power;
• If integrated into DME, consumes minimal power with no impact upon DME performance; and
• Alternatively, has its own power source separate from the DME.

ASPR is currently working to develop a piece of open source hardware capable of executing these functionalities. While the hardware is near completion, coding software is still needed and additional methods (e.g., mobile and social media apps) are required to establish the infrastructure needed to support information transmission using multiple channels. Hence, ASPR is interested in additional types of hardware, a combination of hardware and software, or a non-technical solution.

Include in your submission a detailed description of the system (process and/or device) that will be used under routine and emergency conditions to:

• Uniquely identify DME;
• Report the current power status of the device, to include remaining battery time;
• Report the location of the device;
• Determine the operational status of DME; and
• Identify a way to contact the DME user.

Be sure to include the rationale for the solution and specific ideas to address the following questions.

• How would people obtain the system?
• How could they register?
• How will data be transferred to recipients?

The solution most likely includes a device, but ASPR is interested in a versatile submission that would benefit people from all socioeconomic backgrounds.

Submitted proposals along with all relevant supporting data should include the information described in the Detailed Description of the Challenge.

Submitted proposals should not include any personal identifying information the participants do not want to make public, or any information the participant may consider as their intellectual property that they do not want to share.

After the Challenge deadline, a review panel of technical advisers will complete the review process and make a decision with regards to the winning solution(s). All participants that submit a proposal will be notified about the status of their submissions; however, no detailed evaluation of individual submissions will be provided.

Additional Information

Ownership of intellectual property is determined by the following:

• Each entrant retains title and full ownership in and to their submission. Entrants expressly reserve all intellectual property rights not expressly granted under the challenge agreement. By participating in the challenge, each entrant hereby irrevocably grants to sponsor and administrator a perpetual, non-exclusive, royalty free, worldwide license and right to reproduce, publicly perform, publicly display, and use the submission to the extent necessary to administer the challenge, and to publicly perform and publicly display the submission, including, without limitation, for advertising and promotional purposes relating to the challenge.

About ASPR

ASPR leads HHS in preparing the nation to respond to and recover from adverse health effects of emergencies, supporting communities' ability to withstand adversity, strengthening health and response systems, and enhancing national health security. To learn more about ASPR and preparedness, response, and recovery from the health impacts of disasters, visit the HHS public health and medical emergency Web site, *www.phe.gov.*

Dated: October 22, 2013.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2013–25280 Filed 10–25–13; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1147]

Agency Information Collection Activities; Proposed Collection; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 the information collection provisions of our guidance

document entitled, ''Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition.''

DATES: Submit either electronic or written comments on the collection of information by December 27, 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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition (CFSAN) (OMB Control Number 0910–0541)—Extension

As an integral part of its decision making process, we are obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of our actions, including allowing notifications for food contact substances to become effective and approving food additive petitions, color additive petitions, Generally Recognized As Safe affirmation petitions, requests for exemption from regulation as a food additive, and actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, we amended our regulations in part 25 (21 CFR part 25) to provide for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment (62 FR 40570, July 29, 1997). As a result of that rulemaking, we no longer routinely require submission of information about the manufacturing and production of our regulated articles. We also have eliminated the previously required Environmental Assessment (EA) and abbreviated EA formats from the amended regulations. Instead, we have provided guidance that contains sample formats to help industry submit a claim of categorical exclusion or an EA to CFSAN. The guidance document entitled, ''Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition'' identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for our own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

The guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for submission to CFSAN. The following questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion? (2) What must a claim of categorical exclusion include by regulation? (3) What is an EA? (4) When is an EA required by regulation and what format should be used? (5) What are extraordinary circumstances? and (6) What suggestions does CFSAN have for preparing an EA?

Although CFSAN encourages industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if these approaches satisfy the requirements of the applicable statutes and regulations. We are requesting the extension of OMB approval for the information collection provisions in the guidance.

Description of Respondents: The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part 25; Environmental impact considerations	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 25.32(i)	42	1	42	1	42
§ 25.32(o)	1	1	1	1	1
§ 25.32(q)	2	1	2	1	2
Total					45

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

The above estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for § 25.32(i) and (q) that the Agency has received in the past 3 years. Please note that, in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, we have estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission.

To calculate the estimate for the hours per response values, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 1 hour per submission. For the information requested for the exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 1 hour per submission.

Dated: October 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25300 Filed 10–25–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0804]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 27, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0120. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Premarket Notification—(OMB Control Number 0910–0120)—Extension

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)) and the implementing regulation under part 807 (21 CFR part 807, subpart E) requires a person who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device, as defined in § 807.92(a)(3). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), product development protocol, humanitarian device exemption (HDE), petition for Evaluation of Automatic Class III Designation (de novo), or be reclassified into class I or class II before being marketed. FDA makes the final decision of whether a device is substantially equivalent or not equivalent.

Section 807.81 states when a premarket notification is required. A premarket notification is required to be submitted by a person who is:

(1) Introducing a device to the market for the first time;

(2) introducing a device into commercial distribution for the first time by a person who is required to register; and

(3) introducing or reintroducing a device which is significantly changed or modified in design, components, method of manufacturer, or the intended use that could affect the safety and effectiveness of the device.

Form FDA 3514, a summary cover sheet form, assists respondents in categorizing administrative 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs such as PMAs, investigational device exemptions, and HDEs. Under § 807.87(h), each 510(k) submitter must include in the 510(k) either a summary of the information in the 510(k) as required by § 807.92 (510(k) summary) or a statement certifying that the submitter will make available upon request the information in the 510(k) with certain exceptions as per § 807.93 (510(k) statement). If the 510(k) submitter includes a 510(k) statement in the 510(k) submission, § 807.93 requires that the official correspondent of the firm make available within 30 days of a request all information included in the submitted premarket notification on safety and effectiveness. This information will be provided to any person within 30 days of a request if the device described in the 510(k) submission is determined to be substantially equivalent. The information provided will be a duplicate of the 510(k) submission including any safety and effectiveness information, but excluding all patient identifiers and trade secret and commercial confidential information.

Section 204 of the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105–115) amended section 514 of the FD&C Act (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions including premarket notifications or other requirements. FDA has published and updated the list of recognized standards regularly since enactment of FDAMA and has allowed 510(k) submitters to certify conformance to recognized standards to meet the requirements of § 807.87. Form FDA 3654, the 510(k) Standards Data Form, standardizes the format for submitting information on consensus standards that a 510(k) submitter chooses to use as a portion of their premarket notification submission (Form FDA 3654 is not for declarations of conformance to a recognized standard). FDA believes that use of this form will simplify the 510(k)