DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0229]

Agency Information Collection Activities; Proposed Collection; Comment Request; Invitation to Manufacturers and Distributors to Voluntarily Submit Final Product Labeling and Information Electronically for all Devices Cleared by the Food and Drug Administration for Home Use; Notice of Pilot Program

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 regarding the request that manufacturers and distributors of all devices cleared by FDA for home use voluntarily submit final product labeling and information electronically as a part of a pilot program to be conducted by FDA's Center for Devices and Radiological Health (CDRH). FDA is requesting that manufacturers and distributors for these products submit final product labeling and information in a standard Structured Product Labeling (SPL) format that we intend to eventually place on a home use device product portal that will be accessible to the public.

DATES: Submit written or electronic comments on the collection of information by July 19, 2010.

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.

Invitation to Manufacturers and Distributors of Devices Cleared by FDA for Home Use to Voluntarily Submit Final Product Labeling and Information Electronically (OMB Control Number 0910—New)

For purposes of this pilot program, FDA generally considers a home use device to be a medical device intended for users in a non-clinical environment that is managed partly or wholly by the user, where the device may require adequate labeling for home use and may require training by a licensed heath care provider in order to be used safely and effectively.

In June 2001, FDA created the Center for Devices and Radiological Health (CDRH) Home Health Care Committee (HHCC) to review CDRH's involvement in addressing problems that arise when devices are used in the home environment. After meeting with various stakeholders, the HHCC agreed with the stakeholders' recommendation that promoting the safe use of medical devices presented a significant health challenge for which the HHCC could focus CDRH's educational outreach efforts. As a result, FDA is seeking manufacturers and distributors of devices cleared for home use to voluntarily participate in a pilot program involving the submission of final product labeling and additional product information electronically.

Section 510(j)(1)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(j)(1)(B)(i)), requires persons who register and list a restricted device to provide, among other things, a copy of all labeling to FDA. Section 510(j)(1)(B)(ii) of the act requires persons who register and list a device that is not restricted to provide the label and package insert and a representative sampling of any other labeling to FDA. For this pilot program, we are requesting manufacturers and distributors of medical devices cleared for home use to electronically submit final product labeling as well as the following information, if not included in product labeling:

Device Product Information
- Proprietary name
- Descriptive name
- Model or catalog number
- FDA listing number

Manufacturer Information
- Manufacturer name
- Manufacturer address
- Manufacturer 800 number
- Manufacturer Web site

Distributor Information
- Distributor name
- Distributor address
- Distributor 800 number
- Distributor Web site

Characteristics
- Allergens
- Single use or reusable
- Sterile
- Storage temperature
- Storage humidity
- Size
- Storage environment
- Picture of device
- MRI compatible

Marketing Information
- Status
- Prescription or OTC

Components and Accessories
- Components needed to operate the device
- Accessories compatible with the device
- Pictures of components and compatible accessories

Directions for Use
- Intended use of the device
- Indications for use
- Route, method, and frequency of administration

Summary of safety and effectiveness
Assembly or installation instructions
Calibration instructions
Instructions for use for the layperson
Warnings
Precautions
Contraindications
Side effects
Cleaning, disinfecting, and sterilization instructions
Safety information
In Vitro Diagnostic Devices
Test code
Value range
Special information for this test

If this information is not a part of your current final product labeling or information, FDA is requesting that you submit the information as a part of this pilot program. The purpose of the pilot program is twofold. First the pilot program will enable regulated industry to provide feedback that will assist FDA in developing guidance for industry on the electronic submission and availability of final labeling and product information for devices cleared for home use. Second, the pilot program will enable the public and regulated industry to view the information and instructions for use for such devices as a part of CDRH's planned medical device portal for devices cleared for home use. It is our expectation that the portal, established as a part of this pilot program, will increase the likelihood that users—home health nurses, patients, and caregivers—will have continuous access to home use labeling information and instructions for use to help ensure the safe and effective use of devices cleared for home use. In order for manufacturers and distributors to submit final labeling and product information they will need to do so in the SPL format. To create an SPL file and submit it to FDA, a respondent would need the following tools: A computer, appropriate software, access to the Internet, knowledge of terminology and standards, and access to FDA's Electronic Submissions Gateway (ESG) (*http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm*). The ESG is an agency-wide means for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of regulatory submissions. Instructions and information regarding the creation of an SPL file can be found at *http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm*. Most respondents have computers and Internet access available for their use. If a business does not have an available computer or access to the Internet, free use of computers and the Internet are usually available at public facilities, e.g. a community library. In addition there should be no additional cost associated with obtaining the software. In 2008, FDA collaborated with GlobalSubmit (*http://globalsubmit.com/home/Home/tabid/37/Default.aspx)* to make available free SPL authoring software that SPL authors may utilize to create new SPL documents or edit previous versions. After the SPL is created, the respondent would upload the file through the ESG. The Internet portal can be found at *http://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM162419.pdf*. Prior to uploading an SPL file, one must obtain a digital certificate. Instructions regarding obtaining a digital certificate used with FDA's ESG and uploading the SPL file for submission can be found at *www.fda.gov/esg/default.htm*. The digital certificate binds together the owner's name and a pair of electronic keys (a public and a private key) that can be used to encrypt and sign documents. A fee of up to approximately $20.00 is charged for the digital certificate. FDA is not calculating this small fee as cost of this information collection because manufacturers and distributors will have already secured a digital certificate as they are required to do so when they register and list.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
Collecting Final Labeling and Product Information	200	3	600	2	1,200
Conversion of Word or PDF Final Labeling and Product Information into SPL	200	3	600	2	1,200
Submission of SPL into ESG	200	3	600	1	600
Total					3,000

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

FDA estimates that the collection of final product labeling will take 1 hour per response. FDA estimates that the submission of final product information will also take 1 hour per response. The agency estimates that approximately 200 respondents will submit their device labeling and product information 3 times annually. The agency estimates that it will take respondents 2 hours to convert their word or PDF labeling and product information into an SPL format using SPL authoring software. The main task involved in this conversion is copying the content from one document (Word or PDF) to another (SPL). SPL authors may copy a paragraph from a Word or PDF document and paste the text into the appropriate section of an SPL document. In instances where an SPL author needs to create a table, the table text may be copied from Word or PDF document and pasted into each table cell in the SPL document. Conversion software vendors have designed tools that will import the Word or PDF version of the final labeling and product information, and within minutes, automatically generate the SPL documents. Once the document is in the SPL format device manufacturers can then submit their product labeling through FDA's ESG. The agency estimates the burden associated with entering the SPL labeling and product information into the ESG is 1 hour per response. The agency based its estimates on the number of premarket submissions cleared by FDA for home use from 1976 to the present as well as experience with the electronic submission process of registration and listing data elements.

Dated: May 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–11810 Filed 5–17–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Imaging and Radiation Therapy.

Date: June 8, 2010.

Time: 1 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Syed M. Quadri, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6210, MSC 7804, Bethesda, MD 20892, 301–435–1211, *quadris@csr.nih.gov*.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Vector Biology Study Section.

Date: June 9–10, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monticello, 1075 Thomas Jefferson Street, NW., Washington, DC 20007.

Contact Person: Liangbiao Zheng, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301–402–5671, *zhengli@csr.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Auditory System Study Section.

Date: June 9–10, 2010.

Time: 8:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, NW., Washington, DC 20037.

Contact Person: Lynn E. Luethke, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5166, MSC 7844, Bethesda, MD 20892, (301) 806–3323, *luethkel@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; ARRA: Somatosensory and Chemosensory Systems Competitive Revisions.

Date: June 9, 2010.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: M. Catherine Bennett, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7846, Bethesda, MD 20892, 301–435–1766, *bennettc3@csr.nih.gov*.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Chemo/Dietary Prevention Study Section.

Date: June 10–11, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: Sally A Mulhern, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6198, MSC 7804, Bethesda, MD 20892, (301) 408–9724, *mulherns@csr.nih.gov*.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biodata Management and Analysis Study Section.

Date: June 10–11, 2010.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Latham Hotel, 3000 M Street, NW., Washington, DC 20007.

Contact Person: Mark Caprara, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7844, Bethesda, MD 20892, 301–435–1042, *capraramg@mail.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Cell Death in Neurodegeneration Study Section.

Date: June 10–11, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Washington DC, 1250 22nd Street, NW., Washington, DC 20037.

Contact Person: Kevin Walton, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–435–1785, *kevin.walton@nih.hhs.gov*.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Pregnancy and Neonatology Study Section.

Date: June 10, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael Knecht, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6176, MSC 7892, Bethesda, MD 20892, (301) 435–1046, *knechtm@csr.nih.gov*.

Name of Committee: Biology of Development and Aging Integrated Review Group; Cellular Mechanisms in Aging and Development Study Section.

Date: June 10–11, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: John Burch, PhD, Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3213, MSC 7808, Bethesda, MD 20892, 301–408–9519, *burchjb@csr.nih.gov*.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Neurological, Aging and Musculoskeletal Epidemiology Study Section.

Date: June 10–11, 2010.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Guest Suites, 1707 Fourth Street, Santa Monica, CA 90401.

Contact Person: Heidi B. Friedman, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1012A, MSC 7770, Bethesda, MD 20892, 301–435–1721, *hfriedman@csr.nih.gov*.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Virology—A Study Section.

Date: June 10–11, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: Joanna M. Pyper, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, (301) 435–1151, *pyperj@csr.nih.gov*.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Neurotechnology Study Section.

Date: June 10, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Washington DC, 1515 Rhode Island Avenue, NW., Washington, DC 20005.

Contact Person: Robert C. Elliott, PhD, Scientific Review Officer, Center for