

NIOSH recognizes this opportunity will raise many questions for prospective partners. In order to give all involved the greatest opportunity to understand the process and project expectations, the NTEA-AMD, our collaborative partner and host standards setting body, has agreed to provide a meeting room for us to hold an informational meeting to present a broad overview of the effort and answer any resulting questions.

To provide us with the best opportunity to meet the needs of all prospective partners at each of these meetings, we request that all interested parties contact Jim Green, NIOSH Project Officer, by email at [JGreen@cdc.gov](mailto:JGreen@cdc.gov); or telephone (304) 285-5857, by Thursday, March 17, 2011.

**CONTACT PERSON FOR MORE INFORMATION:** Jim Green, NIOSH Project Officer, e-mail: [JGreen@cdc.gov](mailto:JGreen@cdc.gov); telephone (304) 285-5857.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 7, 2011.

**Tanja Popovic,**

*Deputy Associate Director for Science, Centers for Disease Control and Prevention.*

[FR Doc. 2011-5733 Filed 3-11-11; 8:45 am]

**BILLING CODE 4163-19-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0447]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Devices; Third Party Review Program Under the Food and Drug Administration Modernization Act

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Medical Devices; Third Party Review Program Under the Food and Drug Administration Modernization Act" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**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](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 28, 2010 (75 FR 81616), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0375. The approval expires on February 28, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: March 8, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-5738 Filed 3-11-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0116]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Labeling Regulations

**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 medical device labeling regulations.

**DATES:** Submit either electronic or written comments on the collection of information by May 13, 2011.

**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, PI50-400B, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto: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.

#### Medical Device Labeling Regulations—(OMB Control Number 0910-0485)—(Extension)

Section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded and subject to a

regulatory action. Certain provisions under section 502 require manufacturers, importers, and distributors of medical devices to disclose information about themselves or the devices, on the labels or labeling for the devices. Section 502(b) of the FD&C Act requires that for packaged devices, the label must bear the name and place of business of the manufacturer, packer, or distributor as well as an accurate statement of the quantity of the contents. Section 502(f) of the FD&C Act requires that the labeling for a device must contain adequate directions for use. FDA may however, grant an exemption, if the Agency determines that the adequate directions for use labeling requirements are not necessary for the particular case, as it relates to protection of the public health.

FDA regulations under parts 800, 801, and 809 (21 CFR parts 800, 801, and 809) require disclosure of specific information by manufacturers, importers, and distributors of medical devices about themselves or the devices, on the label or labeling for the devices to health professionals and consumers. FDA issued these regulations under the authority of sections 201, 301, 502, and 701 of the FD&C Act (21 U.S.C. 321, 331, 352, and 371). Most of the regulations under parts 800, 801, and 809 are derived from requirements of section 502 of the FD&C Act, which provides in part, that a device shall be misbranded if among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular way, or fails to contain adequate directions for use.

#### *Reporting Burden*

Sections 800.10(a)(3) and 800.12(c) require that the label for contact lens cleaning solutions bear a prominent statement alerting consumers of the tamper-resistant feature. Further, § 800.12 requires that packaged contact lens cleaning solutions contain a tamper-resistant feature, to prevent malicious adulteration.

Section 800.10(b)(2) requires that the labeling for liquid ophthalmic preparations packed in multiple-dose containers provide information on the duration of use and the necessary warning information to afford adequate protection from contamination during use.

Section 801.1 requires that the label for a device in package form, contain the name and place of business of the manufacturer, packer, or distributor.

Section 801.5 requires that labeling for a device include information on

intended use as defined under § 801.4 and provide adequate directions to assure safe use by the lay consumers.

Section 801.61 requires that the principal display panel of an over-the-counter (OTC) device in package form must bear a statement of the identity of the device. The statement of identity of the device must include the common name of the device followed by an accurate statement of the principal intended actions of the device.

Section 801.62 requires that the label for an OTC device in package form must bear a statement of declaration of the net quantity of contents. The label must express the net quantity in terms of weight, measure, numerical count, or a combination of numerical count and weight, measure, or size.

Section 801.109 establishes labeling requirements for prescription devices, in which the label for the device must describe the application or use of the device, and contain a cautionary statement restricting the device for sale by, or on the order of an appropriate professional.

For prescription by a licensed practitioner, § 801.110 establishes labeling requirements for a prescription device delivered to the ultimate purchaser or user. The device must be accompanied by labeling bearing the name and address of the licensed practitioner, directions for use, and cautionary statements if any, provided by the order.

Section 801.150(e) requires a written agreement between firms involved when a nonsterile device is assembled or packaged with labeling that identifies the final finished device as sterile, for which the device is ultimately introduced into interstate commerce to an establishment or contract manufacturer to be sterilized. When a written agreement complies with the requirements under § 801.150(e), FDA takes no regulatory action against the device as being misbranded or adulterated. In addition, § 801.150(e) requires that each pallet, carton, or other designated unit, be conspicuously marked to show its nonsterile nature when introduced into interstate commerce, and while being held prior to sterilization.

Section 801.405(b)(1) provides for labeling requirements for articles, including repair kits, re-liners, pads, and cushions, intended for use in temporary repairs and refitting of dentures for lay persons. Section 801.405(b)(1) also requires that the labeling contain the word “emergency” preceding and modifying each indication-for-use statement for denture repair kits and the word “temporary”

preceding and modifying each indication-for-use statement for re-liners, pads, and cushions.

Section 801.405(c) provides for labeling requirements that contain essentially the same information described under § 801.405(b)(1). The information is intended to enable a lay person to understand the limitations of using OTC denture repair kits, and denture re-liners, pads, and cushions.

Section 801.420(c)(1) requires that manufacturers or distributors of hearing aids develop a user instructional brochure to be provided by the dispenser of the hearing aid to prospective users. The brochure must contain detailed information on the use and maintenance of the hearing aid.

Section 801.420(c)(4) establishes requirements that the user instructional brochure or separate labeling, provide for technical data elements useful for selecting, fitting, and checking the performance of a hearing aid. In addition, § 801.420(c)(4) provides for testing requirements to determine that the required data elements must be conducted in accordance with the American National Standards Institute’s (ANSI) “Specification of Hearing Aid Characteristics,” ANSI S3.22–1996 (ASA 70–1996); (Revision of ANSI S3.22–1987), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

Section 801.421(b) establishes requirement for the hearing aid dispenser to provide prospective users with a copy of the user instructional brochure along with an opportunity to review comments, either orally or by the predominant method of communication used during the sale.

Section 801.421(c) establishes requirements for the hearing aid dispenser to provide a copy of the user instructional brochure to the prospective purchaser of any hearing aid upon request or, if the brochure is unavailable, provide the name and address of the manufacturer or distributor from which it may be obtained.

Section 801.430(d) establishes labeling requirements for menstrual tampons to provide information on signs, risk factors, and ways to reduce the risk of Toxic Shock Syndrome (TSS).

Section 801.430(e)(2) requires menstrual tampon package labels to provide information on the absorbency term based on testing required under § 801.430(f) and an explanation of selecting absorbencies that reduce the risk of contracting TSS.

Section 801.430(f) establishes requirements that manufacturers of

menstrual tampons devise and follow an ongoing sampling plan for measuring the absorbency of menstrual tampons. Further, manufacturers must use the method and testing parameters described under § 801.430(f).

Section 801.435(b), (c), and (h) establishes requirements for condom labeling to bear an expiration date that is supported by testing that demonstrates the integrity of three random lots of the product.

Section 809.10(a) and (b) establishes requirements that a label for an in vitro diagnostic device and the accompanying labeling (package insert), must contain information identifying its intended use, instructions for use and lot or control number, and source.

Section 809.10(d)(1) provides that the labeling requirements for general purpose laboratory reagents may be exempt from the requirements of § 809.10(a) and (b), if the labeling contains information identifying its intended use, instructions for use, lot or control number, and source.

Section 809.10(e) provides that the labeling for “Analytic Specific Reagents” (ASRs) must provide information identifying the quantity or proportion or each reagent ingredient, instructions for use, lot or control number, and source.

Section 809.10(f) provides that the labeling for OTC test sample collection systems for drugs of abuse must include

information on the intended use, specimen collection instructions, identification system, and information about use of the test results. In addition, § 809.10(f) requires that this information be in a language appropriate for the intended users.

Section 809.30(d) requires that advertising and promotional materials for ASRs include the identity and purity of the ASR and the identity of the analyte.

Section 1040.20(d) provides that manufacturers of sunlamp products and ultraviolet lamps are subject to the labeling regulations under part 801.

#### Recordkeeping Burden

Section 801.150(a)(2) establishes recordkeeping requirements for reproprocessors, relabelers, or repackagers to retain a copy of the agreement containing the specifications for the processing, labeling, or repacking of the device for 2 years after the shipment or delivery of the device. Section 801.150(a)(2) also requires that the subject respondents make copies of this agreement available for inspection at any reasonable hour to any officer or employee of the Department of Health and Human Services (HHS), upon their request.

Section 801.421(d) establishes requirements for hearing aid dispensers to retain copies of all physician

statements or any waivers of medical evaluation for 3 years after dispensing the hearing aid.

Section 801.410(e) requires copies of invoices, shipping documents, and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, be maintained for 3 years by the retailer and made available upon request by any officer or employee of FDA or by any other officer or employee acting on behalf of the Secretary of HHS.

Section 801.410(f) requires that the results of impact tests and description of the test method and apparatus be retained for a period of 3 years.

Section 801.421(d) requires hearing aid dispensers to retain a copy of any written statement from a physician required under § 801.421(a)(1), or any written statement waiving medical evaluation required under § 801.421(a)(2)(iii) for 3 years after the dispensing the hearing aid.

Section 801.435(g) requires latex condom manufacturers to document and provide, upon request, an appropriate justification for the application of the testing data from one product on any variation of that product to support expiration dating in the user labeling.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	Number of respondents	Annual frequency of response	Total annual responses	Hours per response	Total hours
800.10(a)(3) and 800.12(c) .....	37	100	3,700	1	3,700
800.10(b)(2) .....	37	100	3,700	1	3,700
801.1 .....	23,393	6	140,358	.1	140,036
801.5 .....	5,000	3.5	17,500	22.35	391,125
801.61 .....	5,000	3.5	17,500	1	17,500
801.62 .....	1,000	5	5,000	1	5,000
801.109 .....	18,000	3.5	63,000	17.77	1,119,510
801.110 .....	10,000	50	500,000	0.25	125,000
801.150(e) .....	90	20	1,800	4	7,200
801.405(b)(1) .....	99	1.7	168	4	673
801.405(c) .....	99	1.7	168	4	673
801.420(c)(1) .....	275	5	1,375	40	55,000
801.420(c)(4) .....	275	5	1,375	80	110,000
801.421(b) .....	10,000	160	1,600,000	0.30	480,000
801.421(c) .....	10,000	5	50,000	0.17	8,500
801.430(d) .....	45	2	90	2	180
801.430(e)(2) .....	45	2	90	2	180
801.430(f) .....	45	2	90	80	7,200
801.435(b), (c), and (h) .....	86	3.4	292	100	29,200
809.10(a) and (b) .....	1,700	6	10,200	80	816,000
809.10(d)(1) .....	300	2	600	40	24,000
809.10(e) .....	300	25	7,500	1	7,500
809.10(f) .....	20	1	20	100	2,000
809.30(d) .....	300	25	7,500	1	7,500
1040.20(d) .....	110	1	110	10	1,100
Total .....					3,362,477

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

TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per record	Total hours
801.150(a)(2) .....	57	1	57	0.50	29
801.410(e) and (f) .....	30	924,100	27,723,000	0.0008	22,178
801.421(d) .....	10,000	160	1,600,000	0.25	400,000
<b>Total</b> .....					<b>422,207</b>

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

The medical device labeling regulations also refer to previously approved collections of information found in FDA regulations. The collections of information under § 800.12(d) and 801.437(i) have been approved under OMB control number 0910–0183; the collections of information under § 800.12(e) have been approved under OMB control number 0910–0231; and the collections of information under § 801.435(g) have been approved under OMB control number 0910–0073.

Further, FDA concludes that labeling statements under §§ 801.63, 801.405(b)(2) and (b)(3), 801.420(c)(2) and (c)(3), 801.430(c) and (e)(1), 801.433, 801.437(d) through (g), and 809.30(d)(2), (d)(3), and (e) do not constitute a “collection of information” under the PRA. Rather, these labeling statements are “public disclosure” of information originally supplied by the Federal Government to the recipient for the purpose of “disclosure to the public” (5 CFR 1320.3(c)(2)).

*Reporting*

These estimates are based on FDA’s registration and listing database for medical device establishments and FDA’s knowledge of and experience with device labeling.

*Recordkeeping*

These estimates are based on FDA’s registration and listing database for medical device establishments, Agency communications with industry, and FDA’s knowledge of and experience with device labeling.

The medical device labeling regulations also refer to previously approved collections of information. The collections of information under §§ 800.12(d) and 801.437(i) have been approved under OMB control number 0910–0183; and the collections of information under § 800.12(e) have been approved under OMB control number 0910–0231.

The information collection requirements under §§ 801.63, 801.405(b)(2) and (b)(3), 801.420(c)(2) and (c)(3), 801.430(c) and (e)(1),

801.433, 801.437(d) through (g), and 809.30(d)(2), (d)(3), (e) are not considered information collection because the public information is originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)).

Dated: March 4, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–5739 Filed 3–11–11; 8:45 am]

**BILLING CODE 4160–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2011–N–0129]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Comparing Nutrition Knowledge, Attitude, and Behavior Among English-Dominant Hispanics, Spanish-Dominant Hispanics, and Other Consumers**

**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 a study entitled “Comparing Nutrition Knowledge, Attitude, and Behavior Among English-Dominant Hispanics, Spanish-dominant Hispanics, and Other Consumers.”

**DATES:** Submit either electronic or written comments on the collection of information by May 13, 2011.

**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:** Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

**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