TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Guidance for industry: Fast track drug development programs: Designation, development, and application review	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					15,700

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

Dated: July 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18168 Filed 7–31–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1048]

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 the information collection associated with the medical device labeling regulations.

DATES: Submit either electronic or written comments on the collection of information by September 30, 2014.

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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Medical Device Labeling Regulations—21 CFR 800, 801, and 809 (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.

Recordkeeping Burden

Section 801.150(a)(2) establishes recordkeeping requirements for manufacturers of devices 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) who requests them.

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

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.

Third-Party Disclosure 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 requirements 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 801.435(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 (IVD) 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 of 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 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) (21 CFR 1040.20) provides that manufacturers of sunlamp products and ultraviolet lamps are subject to the labeling regulations under part 801.

The burden estimates are based on FDA's current registration and listing data and shipment information.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Processing, labeling, or repacking agreement—801.150(a)(2)	4,870	739	3,598,930	0.50	1,799,465
Impact resistant lenses; invoices, shipping documents, and records of sale or distribution—801.410(e) and (f)	1,136	924,100	27,723,000	0.0008	22,178
Hearing aid records—801.421(d)	10,000	160	1,600,000	0.25	400,000
Menstrual tampons, sampling plan for measuring absorbency—801.430(f)	22	8	176	80	14,080
Latex condoms; justification for the application of testing data to the variation of the tested product—801.435(g)	63	6	378	1	378
Total					2,236,101

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Contact lens cleaning solution labeling—800.10(a)(3) and 800.12(c)	17	8	136	1	136
Liquid ophthalmic preparation labeling—800.10(b)(2)	17	8	136	1	136
Manufacturer, packer, or distributor information—801.1	13,780	7	96,460	1	96,460
Adequate directions for use—801.5	6,657	6	39,942	22.35	892,704
Statement of identity—801.61	6,657	6	39,942	1	39,942
Declaration of net quantity of contents—801.62	6,657	6	39,942	1	39,942
Prescription device labeling—801.109	7,558	6	45,348	17.77	805,834
Retail exemption for prescription devices—801.110	30,000	667	20,010,000	0.25	5,002,500
Processing, labeling, or repacking; non-sterile devices—801.150(e)	377	34	12,818	4	51,272
Labeling of articles intended for lay use in the repairing and/or refitting of dentures—801.405(b)(1)	31	1	31	4	124
Dentures; information regarding temporary and emergency use—801.405(c)	31	1	31	4	124
Labeling requirements for hearing aids—801.420(c)(1)	86	12	1,032	40	41,280
Technical data for hearing aids—801.420(c)(4)	86	12	1,032	80	82,560
Hearing aids, opportunity to review user instructional brochure—801.421(b)	10,000	160	1,600,000	0.30	480,000
Hearing aids, availability of user instructional brochure—801.421(c)	10,000	5	50,000	0.17	8,500
User labeling for menstrual tampons—801.430(d)	22	8	176	2	352
Menstrual tampons, ranges of absorbency—801.430(e)(2)	22	8	176	2	352
User labeling for latex condoms—801.435(b), (c), and (h)	63	6	378	100	37,800
Labeling for IVDs—809.10(a) and (b)	1,700	6	10,200	80	816,000
Labeling for general purpose laboratory reagents—809.10(d)(1)	300	2	600	40	24,000
Labeling for analyte specific reagents—809.10(e)	300	25	7,500	1	7,500
Labeling for OTC test sample collection systems for drugs of abuse testing—809.10(f)	20	1	20	100	2,000
Advertising and promotional materials for ASRs—809.30(d)	300	25	7,500	1	7,500

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Labeling of sunlamp products—1040.20(d)	30	1	30	10	300
Total					8,437,318

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

Dated: July 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18197 Filed 7–31–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0505]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle

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 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision 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 existing FDA regulations concerning FDA-regulated human food, including dietary supplements, and cosmetics manufactured from, processed with, or otherwise containing material derived from cattle.

DATES: Submit either electronic or written comments on the collection of information by September 30, 2014.

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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 revision 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.

Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle—21 CFR 189.5 and 700.27 (OMB Control Number 0910–0623)—Revision

FDA's regulations in §§ 189.5 and 700.27 (21 CFR 189.5 and 700.27) set forth bovine spongiform encephalopathy (BSE)-related restrictions applicable to FDA-regulated human food and cosmetics. The regulations designate certain materials from cattle as ''prohibited cattle materials,'' including specified risk materials (SRMs), the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, and mechanically separated (MS) beef. Sections 189.5(c) and 700.27(c) set forth the requirements for recordkeeping and records access for FDA-regulated human food, including dietary supplements, and cosmetics manufactured from, processed with, or otherwise containing material derived from cattle. The FDA issued these recordkeeping regulations under the adulteration provisions in sections 402(a)(2)(C), (a)(3), (a)(4), (a)(5), 601(c), and 701(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(2)(C), (a)(3), (a)(4), (a)(5), 361(c), and 371(a)). Under section 701(a) of the FD&C Act, the FDA is authorized to issue regulations for the FD&C Act's efficient enforcement. With regard to records concerning imported human food and cosmetics, the FDA relied on its authority under sections 701(b) and 801(a) of the FD&C Act (21 U.S.C. 371(b) and 381(a)). Section 801(a) of the FD&C Act provides requirements with regard to imported human food and cosmetics and provides for refusal of admission of human food and cosmetics that appear to be adulterated into the United States. Section 701(b) of the FD&C Act authorizes the Secretaries of Treasury and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801 of the FD&C Act.