Medical Device Labeling Regulations

0910-0485

ABSTRACT FOR USE IN ROCIS

This ICR collects information from manufacturers, importers, and distributors of medical devices to disclose to health professionals and consumers specific information about themselves or their devices on the label or labeling of their devices. The primary users of the information disclosed on the label or in the labeling of devices are the health professionals who use or prescribe the device or the lay consumers who use the device. The labeling should contain sufficient information for these persons to use the device safely and effectively. FDA may use the information to determine whether there is reasonable assurance of the safety and effectiveness of the device for its intended use.

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SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 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:

Processing, labeling, or repacking agreement--§ 801.150(a)(2)—(Recordkeeping) 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.

Impact resistant lenses; invoices, shipping documents, and records of sale or distribution and impact tests--§ 801.410(e) and (f)—(Recordkeeping)
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.

Hearing aid records--§ 801.421(d)—(Recordkeeping)
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.

Menstrual tampons, sampling plan for measuring absorbency--§ 801.430(f)—(Recordkeeping)
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).

Latex condoms; justification for the application of testing data to the variation of the tested product--801.435(g)—(Recordkeeping)
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:

Contact lens cleaning solution labeling--§ 800.10(a)(3) and 800.12(c)—(Third-party disclosure)
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.

Liquid ophthalmic preparation labeling--§ 800.10(b)(2)—(Third-party disclosure)
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.

Manufacturer, packer, or distributor information--§ 801.1—(Third-party disclosure)
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.

Adequate directions for use--§ 801.5—(Third-party disclosure)
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.

Statement of identity--§ 801.61—(Third-party disclosure)
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.

Declaration of net quantity of contents--§ 801.62—(Third-party disclosure)
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.

Prescription device labeling--§ 801.109—(Third-party disclosure)
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.

Retail exemption for prescription devices--§ 801.110—(Third-party disclosure)
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.

Processing, labeling, or repacking; non-sterile devices--§ 801.150(e)—(Third-party disclosure)
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.

Labeling of articles intended for lay use in the repairing and/or refitting of dentures--§ 801.405(b)(1)—(Third-party disclosure)
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.

Dentures; information regarding temporary and emergency use--§ 801.405(c)—(Third-party disclosure)
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.

Labeling requirements for hearing aids--§ 801.420(c)(1)—(Third-party disclosure)
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.

Technical Data for hearing aids--§ 801.420(c)(4)—(Third-party disclosure)
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.

Hearing aids, opportunity to review User Instructional Brochure--§ 801.421(b)—(Third-party disclosure)
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.

Hearing aids, availability of User Instructional Brochure--§ 801.421(c)—(Third-party disclosure)
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.

User labeling for menstrual tampons--§ 801.430(d)—(Third-party disclosure)
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).

Menstrual tampons, ranges of absorbency--§ 801.430(e)(2)—(Third-party disclosure)
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.

User labeling for latex condoms--§ 801.435(b), (c), and (h)—(Third-party disclosure)
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.

Labeling for IVDs--§ 809.10(a) and (b)—(Third-party disclosure)
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.

Labeling for general purpose laboratory reagents--§ 809.10(d)(1)—(Third-party disclosure)
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.

Labeling for analyte specific reagents--§ 809.10(e)—(Third-party disclosure)
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.

Labeling for OTC test sample collection systems for drugs of abuse testing--§ 809.10(f)—(Third-party disclosure)
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.

Advertising and promotional materials for ASRs--§ 809.30(d)—(Third-party disclosure)
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.

Labeling of sunlamp products--§ 1040.20(d)—(Third-party disclosure)
Section 1040.20(d) provides that manufacturers of sunlamp products and ultraviolet lamps are subject to the labeling regulations under part 801 as well as the labeling requirements of § 1040.20(d) specific to sunlamp products and ultraviolet lamps.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

The primary users of the information disclosed on the label or in the labeling for devices are the health professionals who use or prescribe the device or the lay consumers who use the device. The intent of these rules is that the labeling should contain sufficient information for these persons to use the device safely and effectively. FDA may use the information to determine whether there is reasonable assurance of the safety and effectiveness of the device for its intended use. Failure of the manufacturer, packer, or distributor to label its products in accordance with section 502 of the act may result in the product being misbranded under the act and the firm and the product subject to regulatory action. Respondents are private sector for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

Manufacturers, packers, and distributors may use any appropriate information technology to develop and distribute the required labeling. In general, the statute requires paper copies for labeling accompanying a device. Manufacturers may use appropriate information technology to keep records required by these regulations.

Section 206 of the Medical Device User Fee and Modernization Act (MDUFMA) amended Section 502(f) of the Federal Food, Drug, and Cosmetic Act (the Act) to authorize the use of electronic labeling, rather than the traditional paper labeling, under specified circumstances. Upon enactment, distributors of prescription devices who intend those devices to be used within the confines of a health care facility may provide labeling for those devices solely in electronic form, so long as they afford users the opportunity to request the labeling in paper form and promptly provide such labeling to requestors without additional cost. On March 31, 2003, FDA issued the document entitled, "Section 206 of the Medical Device User Fee and Modernization Act (MDUFMA) (New section 502(f) of the Federal Food, Drug, and Cosmetic Act) Electronic Labeling for Prescription Devices Intended for Use in Health Care Facilities - #G03-1," which describes how FDA plans to implement this provision.

FDA estimates that approximately 5% of the respondents use electronic means to fulfill the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

The information required to be disclosed by these regulations is available only from the manufacturer, packer, and distributors of these devices and is not otherwise available to the user of the devices.

5. Impact on Small Businesses or Other Small Entities

   Using the guidelines set by the Small Business Administration on what constitutes a small business (for manufacturing, a small business cannot exceed 500 employees), we estimate that approximately 95% of U.S. medical device manufacturing establishments are considered small businesses.

   The requirements in these regulations are the minimum requirements for complying with the provisions of the act. In most cases, the information that is required to be disclosed is information that is available to the firm, including a small business, as a normal course of its doing business.

   FDA aids small business and manufacturers to comply with applicable statutes and regulations by providing guidance and information through the Division of Industry and Consumers Education (DICE) within the Center for Devices and Radiological Health. DICE provides workshops, onsite evaluations and other technical and nonfinancial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device establishment and listing requirements. DICE also maintains a toll-free 800 telephone number and a website that firms may use to obtain regulatory compliance information.
6. Consequences of Collecting the Information Less Frequently

   The statutes and regulations generally require that labeling accompany each shipment of a device (occasionally). If this were not done, the device user may not have the necessary information for the safe and effective use of the device.
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances for this collection of information.
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 08/01/2014 (79 FR 44782). No comments were received.

   FDA regularly consults with representatives of industry to discuss various regulatory issues including labeling issues in general and with regard to specific devices. The labeling regulations are generally flexible and FDA is often able to work with industry to accommodate concerns without changing the regulations. FDA also regularly makes available guidance documents with device specific recommendations for conforming to labeling requirements. When FDA makes these guidance documents available, FDA provides an opportunity for interested persons to comment. FDA revises the guidance documents as the comments warrant.
9. Explanation of Any Payment or Gift to Respondents

   This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information that is made available in labeling is, by its nature, public information. Information that is trade secret or confidential is subject to FDA's regulations on the release of information, 21 CFR Part 20.

11. Justification for Sensitive Questions

This information collection does not include any questions that are of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Recordkeeping Burden[1]

Activity/ 21 CFR Section	No. of Recordkeepers	No. 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)	861	39,208	33,758,088	0.0008	27,006
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					2,240,929

Table 2.--Estimated Annual Third-Party Disclosure Burden[1]

Activity/ 21 CFR Section	No. of Respondents	No. 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

Table 2.--Estimated Annual Third-Party Disclosure Burden[1]

Activity/ 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Statement of identify--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
Labeling of sunlamp products--1040.20(d)	30	1	30	10	300
Total					8,437,318

These estimates are based on the FDA Uniform Registration and Listing System (FURLS) database for medical device establishments (OMB approval 0910-0625), FDA's Operational and Administrative System for Import Support (OASIS) data, communications with industry, and FDA's knowledge of and experience with medical device labeling. We have not estimated a burden for those requirements where the information to be disclosed is

information that has been supplied by FDA. Also, we have not estimated a burden for that information that is disclosed to third parties as a usual and customary part of a medical device manufacturer, distributor, or importer's normal business activities. We do not include any burden for time that is spent designing labels to improve the format or presentation.

Recordkeeping Burden

Processing, labeling, or repacking agreement--§ 801.150(a)(2)—(Recordkeeping)
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.

From its registration and listing database, FDA estimates that there are 4,870 contract manufacturers, each with an average of 739 agreements of this type. FDA believes the label requirements of section 801.150(e) can be met in 0.50 hours, imposing therefore a total annual burden of 1,799,465 hours.

Impact resistant lenses; invoices, shipping documents, and records of sale or distribution and impact tests--§ 801.410(e) and (f)—(Recordkeeping)
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.

FDA estimates the number of eyeglasses shipped annually to be 112 million lenses based on the steady average numbers of prescription and over-the-counter glasses sold between 2009 and 2012 (Statista.com 2009-2012 data, http://www.statista.com/statistics/256274/eyewear-sold-in-the-united-states-by-type/). Assuming that the glass/plastic lenses-produced ratio remained as in previous years (22% glass and 78% plastic) and that glass lenses must be tested individually and only 5% of the plastic lenses must be tested, then 29,008,000 lenses should be tested. This figure was derived by taking 22% of 112 million lenses (24,640,000 glass lenses) and adding it to 5% of the remaining plastic lenses (5% X 87,360,000 = 4,368,000) which then together result in 29,008,000 lenses tested (24,640,000 + 4,368,000 = 29,008,000). Additionally, 95 million lenses are sold in non-prescription sunglasses, which have plastic lenses, resulting in 4,750,000 lenses that need to be tested (5% x 95,000,000). The total number of lenses to be tested is therefore 33,758,000 (29,008,000 + 4,750,000).

Next, we divided the total tests (33,758,000) by 861 manufacturers (No. of Respondents based on 2015 FDA Establishment Registration and Listing (FURLS) data) to return the average No. of Records per Recordkeeper estimate of 39,208 (rounded). FDA and industry experts have estimated that, on average, each test could be completed and

recorded in 3 seconds (0.0008 hours). We estimate, therefore, that the total burden for this collection is 27,006 hours (861 respondents x 39,208 responses per respondent (rounded) = 33,758,088 estimated total annual responses x 0.0008 (3 seconds per record) = 27,006 estimated total burden hours).

Hearing aid records--§ 801.421(d)—(Recordkeeping)
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.

FDA estimates that 10,000 hearing aid dispensers dispense 1,600,000 hearing aids per year. Each record required by § 801.421(d) documents the dispensing of a hearing aid to a hearing aid user. FDA estimates that each recordkeeping entry requires approximately 15 minutes (0.25 hours). Therefore, the total burden estimate is 400,000 hours (1,600,000 X 0.25).

Menstrual tampons, sampling plan for measuring absorbency--§ 801.430(f)—(Recordkeeping)
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).

Latex condoms; justification for the application of testing data to the variation of the tested product--801.435(g)—(Recordkeeping)
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.

We estimate that there are 63 condom manufacturers, with an average of 6 unique brands each. We estimate that it will take approximately 1 hour per record to fulfill the requirement.

Third-Party Disclosure Burden

Contact lens cleaning solution labeling--§ 800.10(a)(3) and 800.12(c)—(Third-party disclosure)
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.

Seventeen establishments label an average of 8 different versions of contact lens cleaning solutions each. Each establishment would most likely have a similar tamper-resistant feature for each of their products. FDA believes that one hour per product is a reasonable estimate.

Liquid ophthalmic preparation labeling--§ 800.10(b)(2)—(Third-party disclosure)

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.

FDA estimates that it would take each establishment approximately one hour per device to develop and revise, when necessary, the labeling required by this section.

Manufacturer, packer, or distributor information--§ 801.1—(Third-party disclosure)
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.

From its registration and listing database, FDA estimates that there are 13,780 establishments that distribute approximately 96,460 devices.

Adequate directions for use--§ 801.5—(Third-party disclosure)
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.

This applies to over-the-counter devices. It does not apply to devices dispensed upon the prescription of a health professional for use by a lay person. Section 801.110 applies to labeling for those devices. Many of the devices that fall into this category would be fairly simple types of devices (dental floss, ice bags, canes, and crutches) that would require minimal labeling.

Statement of identity--§ 801.61—(Third-party disclosure)
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.

FDA estimates that there are 6,657 establishments distributing an average of 6 types of these devices each. FDA estimates that including the statement of identity in the labeling for these types of devices would require no more than 1 hour per type of device.

Declaration of net quantity of contents--§ 801.62—(Third-party disclosure)
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.

FDA estimates that this is a minimal requirement that imposes a burden of no more than one hour per year/per device.

Prescription device labeling--§ 801.109—(Third-party disclosure)

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.

The requirements of section 801.109 apply to prescription devices to be used by or on the order of a health care professional. The rule requires that the labeling provide adequate directions for use by health care professionals, but exempts establishments from this requirement for devices for which the directions, hazards, warnings, and other information are well known to health care professionals. FDA estimates that there are 7,558 manufacturers distributing 45,348 such types of devices. FDA estimates that approximately ninety percent of these devices are of the type that would require minimal labeling information, e.g., surgical instruments well known to the health professional. These would require about 10 hours per year to develop the labeling. The other ten percent of these devices would require somewhat more detailed labeling information. FDA estimates that firms would expend about 80 hours per device per year to develop the labeling. The weighted average hourly burden per device per year would be 17.77 hours. The annual burden then would be 805,834 hours (45,348 X 17.77).

Retail exemption for prescription devices--§ 801.110—(Third-party disclosure)
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.

FDA assumes that the manufacturer or distributor would provide this information to a pharmacy or medical equipment supplier who would pass it on to the patient. The information would be readily available to the manufacturer or distributor and could be quickly passed on to the patient. FDA estimates that there are approximately 30,000 retail facilities dispensing 20,010,000 such devices per year. FDA estimates that a retail facility would expend about 15 minutes (0.25 hours) per device processing this information and providing it to the patient. The total annual burden would be 5,002,500 hours (20,010,000 devices X 0.25 hours per device).

Processing, labeling, or repacking; non-sterile devices--§ 801.150(e)—(Third-party disclosure)
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.

Labeling of articles intended for lay use in the repairing and/or refitting of dentures--§ 801.405(b)(1)—(Third-party disclosure)
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.

From its FURLS database, FDA has determined that there are 31 establishments manufacturing, packing, or distributing the emergency denture kits covered by §801.405(b)(1). The requirements of this section are rather simple. FDA estimates that it will take each establishment 4 hours per year to meet these requirements.

Dentures; information regarding temporary and emergency use--§ 801.405(c)—(Third-party disclosure)
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.

Labeling requirements for hearing aids--§ 801.420(c)(1)—(Third-party disclosure)
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.

In estimating the burden for the requirement of preparing a User Instructional Brochure as required by §801.420(c), FDA has determined that there are approximately 86 manufacturers of hearing aids in the Unites States and that the average manufacturer develops 12 new models requiring a brochure each year. FDA estimates that the manufacturers expended approximately 40 hours developing each brochure. This results in an annual burden of 41,280 hours for this requirement (86 manufacturers x 12 brochures x 40 hours).

Technical Data for hearing aids--§ 801.420(c)(4)—(Third-party disclosure)
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.

FDA has determined that there are approximately 86 manufacturers of hearing aids in the Unites States and that the average manufacturer develops 12 new models requiring a

brochure each year. FDA estimates that the manufacturers expended approximately 80 hours developing each brochure. This results in an annual burden of 82,560 hours for this requirement (86 manufacturers x 12 brochures x 80 hours).

Hearing aids, opportunity to review User Instructional Brochure--§ 801.421(b)—(Third-party disclosure)

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.

FDA estimates that there are approximately 10,000 hearing aid dispensers who distribute 1,600,000 hearing aids each year. For all such sales, the dispenser must provide the prospective user a copy of the User Instructional Brochure and the opportunity to read and review the contents with him/her orally, or in the predominate method of communication used during the sale. FDA estimates that this exchange will involve 18 minutes (0.3 hours).

Hearing aids, availability of User Instructional Brochure--§ 801.421(c)—(Third-party disclosure)

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.

FDA estimates that approximately 10,000 hearing aid dispensers and manufacturers will provide copies of the User Instructional Brochure to any health care professional, user, or prospective user who requests a copy under §801.421(c). FDA estimates that each of these 10,000 firms will receive approximately 5 requests per year. FDA estimates that the firm will require about 10 minutes (0.17 hours) to complete each request. The effort consists of the hearing aid manufacturer or distributor or hearing aid dispenser locating the appropriate brochure and mailing it to the requestor. Thus, the total burden for this collection is 8,500 hours (10,000 firms x 5 requests per year x 0.17 staff hours).

User labeling for menstrual tampons--§ 801.430(d)—(Third-party disclosure)

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).

Menstrual tampons, ranges of absorbency--§ 801.430(e)(2)—(Third-party disclosure)

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.

User labeling for latex condoms--§ 801.435(b), (c), and (h)—(Third-party disclosure)

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.

Through its FURLS database, FDA determined that there are approximately 63 manufacturers of condoms that would have to provide the labeling for 378 product types. FDA estimated that it then would take each manufacturer approximately 100 hours per year to complete the tests required to establish an expiration date for their condoms, thus, the total annual burden is 37,800 hours (378 device types x 100 hours).

Labeling for IVDs--§ 809.10(a) and (b)—(Third-party disclosure)
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.

From its FURLS database, FDA has determined that there are 1,700 establishments distributing 10,200 devices subject to the labeling requirements of §809.10(a) and (b). FDA estimates that, for each of these devices, an establishment would expend approximately 80 hours per year/per device developing and revising the labeling. This would make the annual burden estimate 816,000 hours.

Labeling for general purpose laboratory reagents--§ 809.10(d)(1)—(Third-party disclosure)
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.

From its FURLS database, FDA has determined that there are approximately 300 establishments engaged in the manufacture and distribution of approximately 600 general purpose laboratory reagents subject to the labeling requirements in §809.10(d). FDA estimates that these establishments would expend about 40 hours per year/per device developing and maintaining the labeling required by this section. This would result in an annual burden of 24,000 hours.

Labeling for analyte specific reagents--§ 809.10(e)—(Third-party disclosure)
Section 809.10(e) provides that the labeling for "Analyte Specific Reagents" (ASRs) must provide information identifying the quantity or proportion of each reagent ingredient, instructions for use, lot or control number, and source.

FDA estimates for each ASR it would take approximately 1 hour to design a new label to conform with §809.10(e) and approximately 3 hours to review the new label through to chain of review, including legal and marketing people. As shown above, FDA estimates that the total hours to design/review labels is approximately 100 hours per respondent (25 x 4). The total hours to design/review labels are estimated at 30,000 (100 x 300). These estimates do not take into account economies of scale in designing and revising the labeling on ASRs. FDA estimates that entities work approximately 25% of

that time ascertaining that the labeling meets the new requirements. Consequently, FDA estimates that the total number of hour burden for designing/review of labeling is approximately 25 hours per respondent (100 X .25). FDA also estimates that the total hour burden for §809.10(e) is approximately 7,500 hours (30,000 X .25).

Labeling for OTC test sample collection systems for drugs of abuse testing--§ 809.10(f)—(Third-party disclosure)

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.

Based upon discussions with manufacturers, FDA estimates that it will take manufacturers of over-the-counter drugs of abuse test kits approximately 40 hours to gather the information required by §809.10(f), another 40 hours to design and prepare the labeling, and an additional 20 hours per year to review and revise the labeling, as necessary. Thus, the total burden hour for preparing and reviewing labeling will be 100 hours per manufacturer. FDA estimates that there are 20 manufacturers of these devices. This will result in a total burden of 2,000 hours.

Advertising and promotional materials for ASRs--§ 809.30(d)—(Third-party disclosure)

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.

FDA estimates for each ASR it would take approximately 1 hour to rewrite the professional materials to ascertain compliance with §809.30(d). FDA also estimates it would take approximately 4 hours to review rewritten materials through the chain of review, including legal and marketing people. As shown above, FDA estimates that the total number of hours to rewrite/review promotional materials is approximately 125 hours per respondent (25 x 5). The total hours for all ASR's is estimated at 37,500 (125 x 300). This estimate does not take into account economies of scale. Often the promotional materials are a catalogue of products. FDA estimates that entities work approximately 20% of that time ascertaining that the promotional materials meet the new requirements. Consequently, FDA estimates that the total number of hour burden for rewriting/reviewing promotional materials is approximately 25 (125 x .20) hours per respondent. FDA estimates that the total hour burden for promotional materials is approximately 7,500 (37,500 X .20).

Labeling of sunlamp products--§ 1040.20(d)—(Third-party disclosure)

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

12b. Annualized Cost Burden Estimate

FDA estimates the annualized cost to the respondent for the third-party disclosure and recordkeeping burden to be $373,569,665. This is based on an hourly salary of $35.00 and total burden hours of 10,678,247.

	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Respondent	10,678,247	$35.00	$373,738,645

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Generally, FDA would review labeling as part of a premarket notification submission or as part of a premarket approval application. These information collections are approved under OMB Control No. 0910-0120 and 0910-0231. FDA estimates from its time reporting system that it expends approximately 10 FTEs on other labeling reviews. Based on a cost of $283,487 per position (which is the agency's projected average cost of an FTE including their benefits*), the estimated annual Federal cost is $2,834,870.

*Based on the Department of Health and Human Services, Fiscal Year 2015, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 11-13).

15. Explanation for Program Changes or Adjustments

The estimated annual hourly burden, formerly estimated as 3,784,684 hours (422,207 recordkeeping and 3,362,477 third-party disclosure) has increased by 5,886,363 hours (811,522 recordkeeping and 5,074,841 third-party disclosure) to a total estimated annual hourly burden of 10,678,247 hours (2,240,929 recordkeeping and 8,437,318 third-party disclosure). The increase is due to adjustments reflecting updated data and to corrections made at Agency discretion to increase the accuracy of our estimate. As noted in section 8 of this document, we received no comments on the estimates. The specific changes are listed in the table below and a description of the changes follows:

Activity/ 21 CFR Section	Adjustment to Total Annual Records/ Disclosures	Adjustment to Average Burden per Recordkeeping/ Disclosure	Adjustment to Total Hours	Notes
Recordkeeping:				
Processing, labeling, or repacking agreement--801.150(a)(2)	+3,598,873	0	+1,799,436	Change described below

Activity/ 21 CFR Section	Adjustment to Total Annual Records/ Disclosures	Adjustment to Average Burden per Recordkeeping/ Disclosure	Adjustment to Total Hours	Notes
Impact resistant lenses; invoices, shipping documents, and records of sale or distribution--801.410(e) and (f)	+6,035,088	0	+4,828	Adjustment—updated; also corrects error in arithmetic; change described below
Hearing aid records--801.421(d)	0	0	0	No change
Menstrual tampons, sampling plan for measuring absorbency--801.430(f)	+86	0	+6,880	IC moved from third-party disclosure to recordkeeping; Adjustment—updated
Latex condoms; justification for the application of testing data to the variation of the tested product--801.435(g)	+378	+1	+378	IC not included in previous ICRs; see description below
Total change to recordkeeping:	+9,634,425	+1	+1,811,522	
Third-Party Disclosure:				
Contact lens cleaning solution labeling--800.10(a)(3) and 800.12(c)	-3,564	0	-3,564	Adjustment—updated
Liquid ophthalmic preparation labeling--800.10(b)(2)	-3,564	0	-3,564	Adjustment—updated
Manufacturer, packer, or distributor information--801.1	-43,898	0	-43,576	Adjustment—updated
Adequate directions for use--801.5	+22,442	0	+501,579	Adjustment—updated
Statement of identify--801.61	+22,442	0	+22,442	Adjustment—updated
Declaration of net quantity of contents--801.62	+34,942	0	+34,942	Adjustment—updated
Prescription device labeling--801.109	-17,652	0	-313,676	Adjustment—updated
Retail exemption for prescription devices--801.110	+19,510,000	0	+4,877,500	Change described below
Processing, labeling, or repacking; non-sterile devices--801.150(e)	+11,018	0	+44,072	Adjustment—updated
Labeling of articles intended for lay use in the repairing and/or refitting of dentures--801.405(b)(1)	-137	0	-549	Adjustment—updated
Dentures; information regarding temporary and emergency use--801.405(c)	-137	0	-549	Adjustment—updated
Labeling requirements for hearing aids--801.420(c)(1)	-343	0	-13,720	Adjustment—updated
Technical Data for hearing aids--801.420(c)(4)	-343	0	-27,440	Adjustment—updated
Hearing aids, opportunity to review User Instructional Brochure--801.421(b)	0	0	0	No change

Activity/ 21 CFR Section	Adjustment to Total Annual Records/ Disclosures	Adjustment to Average Burden per Recordkeeping/ Disclosure	Adjustment to Total Hours	Notes
Hearing aids, availability of User Instructional Brochure--801.421(c)	0	0	0	No change
User labeling for menstrual tampons--801.430(d)	+86	0	+172	Adjustment—updated
Menstrual tampons, ranges of absorbency--801.430(e)(2)	+86	0	+172	Adjustment—updated
Menstrual tampons, sampling plan for measuring absorbency--801.410(e) and (f)	-90	0	-7,200	IC moved to recordkeeping and adjusted/ updated
User labeling for latex condoms--801.435(b), (c), and (h)	+86	0	+8,600	Adjustment—updated
Labeling for IVDs--809.10(a) and (b)	0	0	0	No change
Labeling for general purpose laboratory reagents--809.10(d)(1)	0	0	0	No change
Labeling for analyte specific reagents--809.10(e)	0	0	0	No change
Labeling for OTC test sample collection systems for drugs of abuse testing--809.10(f)	0	0	0	No change
Advertising and promotional materials for ASRs--809.30(d)	0	0	0	No change
Labeling of sunlamp products--1040.20(d)	-80	0	-800	Adjustment—updated
Total change to third-party disclosure	+19,531,294	0	+5,074,841	

Adjustment—updated: The burden for several ICs (noted in the table above) was adjusted consistent with updated estimates of the number of respondents and/or the number of records or disclosures. The estimates are based on 2013 registration and listing data (FURLS database) and shipment information (OASIS database) unless otherwise stated. The average burden per recordkeeping/disclosure did not change for any of these ICs.

Processing, labeling, or repacking agreement--801.150(a)(2): Upon a detailed review of this IC, we have determined that the previous estimate did not accurately represent the burden associated with this provision. We believe the previous estimate of respondents was based on the number of device reprocessors. Reprocessing refers specifically to cleaning and sterilizing a device that was intended to be single-use and offering it for sale. However, 801.150(a)(2) applies to any device being shipped from one firm to another for further manufacturing steps and allows such devices to be exempt from having adequate labels and labeling. For example, a contract manufacturer ships devices in bulk to a firm that puts them in individual packages and applies the labels. Therefore, we believe the respondents to this IC are contract manufacturers. Under 801.150(a)(2), respondents must 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.

The previous estimate was for 57 respondents, one response each per year. Based on 2013 data, there are 4,870 contract manufacturers and approximately 3.6 million shipments (an average of 739 shipments per contract manufacturer) per year. The requirement itself has not changed, therefore the average burden per recordkeeping remains 30 minutes. The correction of this estimate increases the overall burden estimate by 3,598,873 records and 1,799,436 hours. Though this is a significant increase, we feel that the current estimate more accurately represents the burden of the recordkeeping requirement.

Impact resistant lenses; invoices, shipping documents, and records of sale or distribution and impact tests--§ 801.410(e) and (f): Upon OMB review and comment we have corrected the estimated burden associated with 801.410(e) and (f). We have determined that the estimated number of respondents was erroneous and that the estimated total annual records was outdated and did not include sunglass lenses subject to the requirement, which caused the resultant number of records per recordkeeper to also be innacurate. We updated the number of recordkeepers consistent with 2015 FDA establishment registration and listing data (FURLS database). We updated the estimated number of total annual records based on data from Statista.com and recalculated the number of records per recordkeeper based on the new estimates. Consequently, we have updated the narrative description of our method of calculation in section 12a of this supporting statement. Because the requirement in 801.410(e) and (f) has not changed, the average burden per recordkeeping is also unchanged. The updates have caused an adjusted increase of 6,035,088 records. Because the average burden per recordkeeping is only 3 seconds per record, the updates have only caused an increase of 4,828 total burden hours.

Menstrual tampons, sampling plan for measuring absorbency—801.430(f): The burden for this IC has been moved from third-party disclosure to recordkeeping. Upon review of this IC, FDA feels that regarding this portion of the burden as recordkeeping is more appropriate because manufacturers must devise and follow an ongoing sampling plan; there is no requirement under 801.430(f) to disclose information to a third-party. The burden estimate for this IC has also been adjusted consistent with updated respondent/response data as described above.

Latex condoms; justification for the application of testing data to the variation of the tested product--801.435(g): A burden estimate for 801.435(g) was not included in past versions of this ICR. We have corrected this oversight by adding an IC in the recordkeeping table. Specifically, 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. The addition of this IC increases the overall burden estimate by 378 respondents and 378 hours.

Retail exemption for prescription devices--801.110: Upon a detailed review of this IC, we have determined that the previous estimate did not accurately represent the burden associated with this provision. Section 801.110 permits a prescription device to be dispensed by or on the order of a physician without adequate instructions for (lay) use. It states: "A device subject to §801.109 shall be exempt at the time of delivery to the ultimate purchaser or user from section 502(f)(1) of the act if it is delivered by a licensed practitioner in the course of his

professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order." We believe the previous estimate of 500,000 annual responses (10,000 respondents; 50 devices per respondent annually) to be an underestimate of the burden associated with this provision.

We have therefore corrected our estimate to reflect that there are approximately 30,000 pharmacies (respondents) that sell 20,000,000 prescription devices (an average of 667 per pharmacy) per year. The average burden per disclosure, 15 minutes, has not changed. This adjustment increases the overall burden estimate by 19,510,000 disclosures and 4,877,500 hours. Though this is a significant increase, we feel that the current estimate more accurately represents the respondents and disclosures associated with this requirement.

16. Plans for Tabulation and Publication and Project Time Schedule

    Not applicable.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

    Not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.