SUPPORTING STATEMENT
FOR
MEDICAL DEVICE LABELING REGULATIONS
21 CFR PARTS 800, 801, AND 809
OMB NUMBER 0910-0485

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Section 502 (21 U.S.C. 352) of the Federal Food, Drug, and Cosmetic Act (the act), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. Certain of the provisions of section 502 require that manufacturers, importers, and distributors of medical devices disclose information about themselves or their devices on the labels or labeling of the devices. Section 502(b) requires that, if the device is in a package, the label must contain the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents. Section 502(f) provides that the labeling of a device must contain adequate directions for use. FDA may grant an exemption from the adequate directions for use requirement, if FDA determines that adequate directions for use are not necessary for the protection of the public health.

FDA regulations in parts 800, 801, and 809 (21 CFR parts 800, 801, and 809) require 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. FDA issued these regulations under the authority of sections 201, 301, 502, and 701 of the act (21 U.S.C. 321, 331, 352, and 371). Most of the regulations in parts 800, 801, and 809 derive from the requirements of section 502 of the 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, or fails to contain adequate directions for use.

THIRD-PARTY DISCLOSURE BURDEN

21 CFR 800.10(a)(3) and 800.12(c)
Section 800.12 requires that packages of contact lens cleaning solutions include a tamper-resistant feature to prevent malicious adulteration. Sections 800.10(a)(3) and 800.12(c) require that the label of contact lens cleaning solutions contain a prominent statement alerting consumers to the tamper-resistant feature.

21 CFR 800.10(b)(2)
This section requires that the labeling of liquid ophthalmic preparations packed in multiple-dose containers include information as to duration of use and necessary warnings to afford adequate protection from contamination during use.

21 CFR 801.1
This section requires that the label of a device in package form contain the name and place of business of the manufacturer, packer, or distributor.

21 CFR 801.5
This section requires that the labeling of devices include directions under which the layman can use a device safely and for the purposes for which it is intended. Section 801.4 defines intended use. Where necessary, the labeling should include: (1) statements of all conditions, purposes, or uses for which the device is intended, unless the device is a prescription device subject to the requirements of 21 CFR 801.109; (2) quantity of dose; (3) frequency of administration or application; (4) duration of administration or application; (5) time of administration, e.g. in relation to meals, onset of symptoms, etc.; (6) route of method or application; and (7) preparation for use.

21 CFR 801.61
This section requires that the principal display panel of an over-the-counter device in package form must include a statement of the identity of the device. The statement of the 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.

21 CFR 801.62
This section requires that the label of an over-the-counter device in package form must include a 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.

21 CFR 801.109
This section establishes labeling requirements for prescription devices. A prescription device is defined as a device which, because of its potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to use the device and, therefore, for which adequate directions for use by a lay person cannot be developed.

Labeling must include information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented. Information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device.

21 CFR 801.110
This section establishes a labeling requirement for a prescription device delivered to the

ultimate purchaser or user upon the prescription of a licensed practitioner. The device must be accompanied by labeling bearing the name and address of the licensed practitioner and the directions for use and cautionary statements, if any, contained in the order.

21 CFR 801.150(e)
This section requires a written agreement between the firms involved when a non-sterile device is assembled or packaged with labeling that identifies the final finished device as sterile, and is shipped in interstate commerce to an establishment or contract manufacturer to be sterilized. When the written agreement complies with the requirements of section 801.150(e), FDA will take no regulatory action against the device as misbranded or adulterated. In addition, section 801.150(e) requires that each pallet, carton, or other designated unit be conspicuously marked to show its nonsterile nature when it is introduced into and is moving in interstate commerce, and while it is being held prior to sterilization.

21 CFR 801.405(b)(1)
This section establishes labeling requirements for articles intended for lay use in repairing and refitting dentures. The labeling must: (1) limit directions for use for denture repair kits to emergency repair pending unavoidable delay in obtaining professional reconstruction of the denture; (2) limit directions for use for denture reliners, pads, and cushions to temporary refitting pending unavoidable delay in obtaining professional reconstruction of the denture; (3) 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 reliners, pads and cushions.

21 CFR 801.405(c)
This section establishes that the labeling requirements for adequate directions require full information of the temporary and emergency use recommended in order for the layman to understand the limitations of usefulness, the reasons therefore, and the importance of adhering to the warnings.

21 CFR 801.420(c)(1) and (4)
This section requires that the manufacturer or distributor of the hearing aid develop a User Instructional Brochure, which accompanies the device and is provided to the prospective user by the dispenser of the hearing aid. The brochure must contain detailed information on the use and maintenance of the hearing aid.

21 CFR 801.421(b-c)
This section requires the hearing aid dispenser to provide the prospective user a copy of the User Instructional Brochure and an opportunity to review the comments with him/her orally or in the predominant method of communication used during the sale.

21 CFR 801.421(c)
This section requires the hearing aid dispenser to provide, upon request, to the prospective purchaser of any hearing aid he or she dispenses a copy of the User Instructional Brochure or the name and address of the manufacturer or distributor

from whom the brochure may be obtained.

801.430(d)
This section requires that the labeling of menstrual tampons shall contain consumer information prominently and legibly in such terms as to render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

801.430(e)(2)
This section requires that the package label shall include an explanation of the ranges of absorbency and a description of how users can use a range of absorbency, and its corresponding absorbency term to make comparisons of absorbency needed to control menstrual flow in order to reduce the risk of contracting Toxic Shock Syndrome (TSS).

21 CFR 801.430(f)
This section 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 section 801.430(f).

21 CFR 801.435(b-c) and (h)
This section requires condom manufacturers to include an expiration date in the labeling of the condom. The manufacturer must support the expiration date by data from quality control tests demonstrating physical and mechanical integrity of three random lots of the same product which were stored under accelerated and real time conditions.

21 CFR 809.10(a) and (b)
Section (a) provides that a label for an in vitro diagnostic product must contain the following information:

1) The proprietary and established name.
2) The intended use or uses of the product.
3) For a reagent, a declaration of the established name, if any, and the quantity, proportion, and concentration of each reactive ingredient.
4) A statement of warnings and precautions for users.
5) For a reagent, appropriate storage instructions.
6) For a reagent, a means by which the user may be assured that the product meets the appropriate standards of identity, strength, quality, and purity.
7) For a reagent, a declaration of the net quantity of contents.
8) Name and place of business of the manufacturer, packer, and distributor.
9) A lot or control number.

Section (b) of this section provides that the labeling (package insert) accompanying the device must contain the following:

1) Proprietary name and established name, if any.

2) The intended use or uses.
3) A summary and explanation of the test.
4) The chemical, physical, physiological, or biological principles of the procedure.
5) Information about the reagents.
6) Information about the instruments,
7) Information about the specimen collection and preparation for analysis.
8) Information about the procedure.
9) Information about the results.
10) Information about the limitations of the procedure.
11) Expected values.
12) Specific performance characteristics.
13) A bibliography of pertinent references.
14) Date of issuance of the last revision of the labeling.

21 CFR 809.10(d)(1)
This section provides that the labeling for general purpose laboratory reagents may be exempt from the labeling requirements in 809.10(a) and (b), if the labeling contains the following:

1) The proprietary name and established name of the reagent.
2) The established name and the quantity, proportion, and concentration of the reagent ingredient.
3) A statement of the purity and quality of the reagent.
4) A statement of warnings and precautions for users.
5) Appropriate storage instructions.
6) A declaration of the net quantity of contents.
7) Name and place of business of the manufacturer, packer, or distributor
8) A lot or control number.

21 CFR 809.10(e)
This section requires manufacturers of analyte specific reagents to include the following in the labeling:

1) The proprietary name and established name, if any, of the reagent.
2) A declaration of established name, if any, and quantity, proportion or concentration of the reagent ingredient.
3) A statement of the purity and quality of the reagent.
4) A statement of warnings or precautions for users.
5). Appropriate storage instructions.
6) A declaration of the net quantity of contents.
7) Name and place of business of the manufacturer, packer, or distributor.
8) A lot or control number.
9) The statement, “For analyte specific reagent use only. Analytical and performance characteristics are not established.”

21 CFR 809.10(f)
This section requires that the labeling for over-the-counter (OTC) test sample collection

systems for drugs of abuse testing bear the following information in a language appropriate for the intended users:

1) Adequate instructions for specimen collection and handling.
2) An identification system to ensure that specimens are not mixed up or otherwise misidentified at the laboratory.
3) The intended use or uses of the product.
4) A statement that confirmatory testing will be conducted on all samples that initially test positive.
5) A statement of warnings or precautions for users.
6) Adequate instructions on how to obtain test results from a person who can explain their meaning, including the probability of false positive and false negative results, as well as how to contact a trained health professional if additional information on interpretation of test results or follow-up counseling is desired.
7) Name and place of business of the manufacturer, packer, or distributor.

21 CFR 809.30(d)
This section requires that manufacturers of analyte specific reagents assure that advertising and promotional materials for ASRs:

1) Include the identity and purity of the ASR and the identity of the analyte.
2) Do not include any statement regarding analytical or clinical performance.

RECORDKEEPING BURDEN

Section 801.150(a)(2)
This section requires a reprocessor, relabeler, or repackager to retain a copy of the agreement containing the specifications for the processing, labeling, or repacking of the device for two years after the shipment or delivery of the device. Section 801.150(a)(2) also requires a reprocessor, relabeler, or repackager to make copies of the agreement available for inspection at any reasonable hour to any officer or employee of the Department of Health and Human Services who requests them.

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

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

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

2. Purpose and Use of the Information

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.

3. Use of 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.

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 Business or Other Small Entities

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 Small Manufacturers, International, and Consumers Assistance (DSMICA) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DSMICA provides workshops, on-site 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. The Division also maintains a toll-free 800 telephone number and a website which 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. 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

This information collection is consistent with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

8a. Publication in the FEDERAL REGISTER.

On March 14, 2011, (76 FR 13623) FDA published a notice in the Federal Register soliciting comments for 60 days on this information collection prior to its submission to the Office of Management and Budget (OMB) as required by 5 CFR 1320.8(d). In response to that notice, one comment was received. The comment questioned the accuracy of FDA's estimate of the number of respondents under 21 CFR 1040.20(d) regarding sunlamp labeling requirements. Specifically, the comment suggested that the Agency provided a low estimate, however the commenter did not provide a basis by which FDA may make an alternative estimate. FDA based its estimate on the number of sunlamp manufacturers currently registered in FDA's Uniform Registration and Listing System (FURLS) database (OMB approval 0910-0625).

8b. Outside Consultation.

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 Respondent

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 involve any questions of a sensitive nature.

12. Estimate of Hour Burden Including Annualized Hourly Costs

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

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

21 CFR Section	No. of Respondents	Annual Frequency of Response No. of Responses per Respondent	Total Annual Responses	Hours per Response Average Burden per Response (in hours)	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	125000
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

21 CFR Section	No. of Respondents	Annual Frequency of Response No. of Responses per Respondent	Total Annual Responses	Hours per Response Average Burden per Response (in hours)	Total Hours
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

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

Table 2. - Estimated Average Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping No. of Records per Recordkeeper	Total Annual Records	Hours per Record Average Burden per Recordkeeping (in hours)	Total Hours
801.150(a)(2)	57	1	57	0.50	29
801.410(e) and (f)	1,136	924,100	27,723,000	0.0008	22,178
801.421(d)	10,000	160	1,600,000	0.25	400,000
TOTAL					422,207

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

These estimates are based on the FDA Uniform Registration and Listing System (FURLS) database for medical device establishments (OMB approval 0910-0625), 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.

Third-Party Disclosures

§800.10(a)(3) and 800.12(c). FDA believes that the labeling requirements of §800.10(a)(3) and 800.12(c) impose a minimal burden. The label must alert consumers as to the tamper-resistant feature of the packaging. Thirty-seven establishments label approximately 40 different versions of contact lens cleaning solutions. Each manufacturer 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.

§800.10(b)(2). These same establishments would be subject to the requirements of §800.10(b)(2). 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.

§801.1. The requirements of §801.1 also impose a minimal burden. This section only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This is information readily available to the establishment and easily supplied. From its registration and listing database, FDA estimates that there are 23,393 establishments that distribute approximately 70,000 devices.

§801.5. Section 801.5 requires adequate directions for lay use of a device. 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. FDA estimates that the total hours per year has remained constant.

§**801.61.** The requirements of section 801.61 apply to over-the-counter devices in package form. FDA estimates that there are 5,000 establishments distributing 3,500 types of these devices. 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.

§**801.62.** The requirements of section 801.62 also apply to over-the-counter devices in package form. Again, FDA estimates that this is a minimal requirement that imposes a burden of no more than one hour per year/per device.

§**801.109.** 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 18,000 manufacturers distributing 63,000 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 1,119,510 hours (63,000 X 17.77).

§**801.110.** Section 801.110 applies to the dispensing of a prescription device to a lay person by a health care professional. 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 10,000 retail facilities dispensing 500,000 such devices per year. FDA estimates that a retail facility would expend about 15 minutes per device processing this information and providing it to the patient. The total annual burden would be 125,000 hours (500,000 devices X .25 hours per device).

§801.405(b)(1). From its FURLS database, FDA has determined that there are 99 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.

§801.420(c)(1). In estimating the burden for the requirement of preparing a User Instructional Brochure as required by §801.420(c), FDA determined that there were 275 manufacturers of hearing aids in the Unites States and that the average manufacturer developed 5 new models requiring a brochure each year. FDA also determined that the manufacturer expended approximately 40 hours developing each brochure. This results in an annual burden of 55,000 hours for this requirement (275 manufacturers X 5 brochures X 40 hours). Under §801.420(c)(4) requiring technical data be provided in the brochure, FDA estimates manufacturers expend 80 hours.

§801.421(b). 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 staff hours).

§801.421(c). 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 (.17 staff 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 .17 staff hours).

§801.435. Through its FURLS database, FDA determined that there are approximately 86 manufacturers of condoms that would have to provide the labeling for 292 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 29,200 hours (292 device types X 100 hours).

§809.10(a) and (b). 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 816,000 hours.

§809.10(d). 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.

§809.10(e). 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).

§809.10(f). 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.

§809.30(d). 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).

Recordkeeping

§801.150(a)(2). Under this section, a device reprocessor, relabeler, or repackager must retain a copy of the agreement containing the specifications for the processing, labeling, or repacking of the device for two years after the shipment or delivery of the device. In addition, the device reprocessor, relabeler, or repackager must make copies of the agreement available for inspection at any reasonable hour to any officer or employee of the Department of Health and Human Services who requests them. From its registration and listing databases, FDA estimates that there are 57 establishments with 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 28 hours (57 x 0.5).

§ 801.410(e) and (f). 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, to be maintained for three years by the retailer and made available upon request by any officer or employee of the FDA or by any other officer or employee acting on behalf of the Secretary of Health and Human Services. FDA assumes this rate has remained constant and therefore estimates the number of eyeglasses shipped annually to be 107 million lenses. Assuming that the glass/plastic lenses-produced ratio remained as in previous years (22% glass and 78% plastic), that glass lenses must be tested individually and only 5% of the plastic lenses must be tested, then 27,723,000 lenses should be tested. This figure was derived by taking 22% of 107 million glass lenses (23,540,000) and adding it to 5% of the remaining plastic lenses (5% X 83,460,000 = 4,173,000) which then together result in 27,723,000 lenses tested (23,540,000 + 4,173,000 = 27,723,000).

Next, divide the total tests (27,723,000) by 30 manufacturers to return the annual frequency of recordkeeping figure of 924,100. Previously, FDA and industry experts estimated that, on average, each test could be completed and recorded in 3 seconds. Industry, therefore, could complete and record 1,200 tests per hour. We estimate, therefore, that the total burden for this collection is 23,103 hours, which is calculated by dividing the total records figure (27,723,000) by tests per hour (1,200). The estimate of 1200 tests per hour results in hours per recordkeeper of 0.0008 by dividing 1 hour by 1200 tests, 1/1200 = 0.0008.

§ **801.421(d).** 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 0.25 staff hours. The total burden, then, is 400,000 hours (1,600,000 X 0.25).

Estimated Annualized Cost for the Burden Hours

FDA estimates the annualized cost to the respondent for the third-party disclosure and recordkeeping burden to be $126,735,945. This is based on an hourly salary of $35.00 and total hours of 3,621,027 (3,197,416 + 423,611).

13. Estimate of the Other Total Annual Cost Burden to Respondent or Recordkeepers

There are no capital costs or 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 an average person-year cost of $180,000 and including an allowance for overhead, FDA estimates that this amount of time translates to a cost to the Federal government of approximately $1,800,000.

15. Explanation for Program Changes or Adjustments

There was an adjustment in burden, increasing by 164,582 hours, 10,091 respondents, and 45,149 annual responses. Additionally after review, the reporting burden was also moved to third party disclosure burden. The burden increase is due to an update in the number of manufacturers and distributors of the various products as reflected in the FURLS database (OMB approval 0910-0625). This database was implemented in 2008 in response to the 2007 reauthorization of Medical Device User Fees to include the electronic registration and listing of device establishments. Previously, while medical device establishments were required to register and list under the regulations, they were not required to pay fees and their submissions were submitted in hard copy, whereupon the data was entered into a "Registration and Listing Database." Upon authorization of associated fees, however, establishments were not only required to register and list, but to do so electronically. In 2008, therefore, an electronic medical device registration and listing database was created as part of FDA's Uniform Registration and Listing System (FURLS), which previously applied only to food product facilities. In this way, users must first establish an account, provide the requisite information, and then fees are assessed and associated with that account holder. The database does provide for and, in fact, is intended for industry use, but what we suspect is that some establishments were not previously registered properly, but are so now under the electronic system. We believe, therefore, that the information is now more easily verifiable and reliable regarding the number of both establishments and product listings.

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

FDA has not identified any exceptions to the certification statement identified in Item 19 of the Instructions for completing OMB Form 83-I.