SUPPORTING STATEMENT
Medical Device Labeling Regulations
21 CFR Parts 800, 801, and 809

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.

21 CFR 800.10(a)(3) and 800.12(c) – Third Party Disclosure

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) – Third Party Disclosure

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 – Third Party Disclosure

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 – Third Party Disclosure

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 – Third Party Disclosure

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 – Third Party Disclosure

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 – Third Party Disclosure

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.

The label of the device must include: (1) The statement "Caution: Federal law restricts this device to sale by or on the order of a _____." The blank is to be filled in by a term such as "physician," "dentist," or other appropriate term.; and (2) the method of its application or use.

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 - Third Party Disclosure

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 801.405(b) – Third Party Disclosure

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 801.410(f) – Recordkeeping

This regulation requires that results of impact tests and description of the test method and apparatus be kept for a period of three years.

The regulation is designed to protect the eyeglass wearer from potential eye injury resulting from shattering of ordinary eyeglass lenses and requires that eyeglasses and sunglasses be fitted with impact-resistant lenses. Examination of data available on the frequency of eye injuries resulting from the shattering of ordinary crown glass lenses indicates that the use of such lenses constitutes an avoidable hazard to the eye of the wearer. According to the Vision Council of America, 60% of the population, or 161 million Americans, wear prescription eyewear; 81% have eyeglasses, 3% have contact lenses only and 16% have both eyeglasses and contact lenses

21 CFR 801.420(c) – Third Party Disclosure

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) - Third Party Disclosure

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) – Third Party Disclosure

This section requires the hearing aid dispenser to provide, upon request, to the prospective purchaser of any hearing aid (s)he 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.

21 CFR 801.421(d) - Third Party Disclosure

This section requires the hearing aid dispenser to retain for three years from the time of dispensing copies of all physician statements or any waivers of medical evaluation.

21 CFR 801.435 – Third Party Disclosure

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) – Third Party Disclosure

Paragraph (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.

Paragraph (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) – Third Party Disclosure

This paragraph 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) - Third Party Disclosure

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) 4. A statement of warnings or precautions for users.

5) 5. Appropriate storage instructions.

6) 6. A declaration of the net quantity of contents.

7) 7. Name and place of business of the manufacturer, packer, or distributer.

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) - Third Party Disclosure

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) – Third Party Disclosure

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.

OMB has approved the information collections in the following sections under the stated approval number. The burden hours are included in section 12 below. FDA will ask OMB to cancel the approvals listed below when OMB approves this information collection.

21 CFR Section	**Hours**	**OMB No.**	**Expiration Date**
801.410(f)	19,225	0910-0182	4/30/04
801.420(c)	8,000	0910-0171	1/31/03
801.421(b)	480,000	0910--171	1/31/03
801.421(c)	8,449	0910-0171	1/31/03
801.421(d)	400,000	0910-0171	1/31/03
801.435	4,320	0910-0352	11/30/03
809.10(e)	7,500	0910-0361	3/31/04
809.10(f)	2,000	0910-0368	4/30/01

809.30(d)	7,500	0910-0361	3/31/04

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 forms of information to develop and distribute the required labeling.

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. Small Business

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. The Center for Devices and Radiological Health (CDRH) has a Division of Small Manufacturers Assistance that provides assistance to manufacturers and others to comply with the applicable statutes and regulations.

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

The information collection is consistent with 5 CFR 1320.5.

8. Outside Consultation

FDA consulted with some members of industry to obtain information to assist in the development of the supporting statement. In the Federal Register of July 11, 2001, FDA requested comment on the information collection requirements. FDA did not receive any comments.

9. Gifts

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

10. Confidentiality

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. Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

12. Respondent Hour Burden and Annualized Burden Hour Cost Estimates

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

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

21 CFR part/section	No. of Respondents	Annual Responses Per Respondent	Total Annual Responses	Hours per Response	Total Hours
800.10(a)(3) and 800.12(c)	4	10	40	1	40
800.10(b)(2)	4	10	40	40	1,600
801.1	20,000	3.5	70,000	0.1	7,000
801.5	2,000	3.5	7,000	22.35	156,450
801.61	1,000	3.5	3,500	1	3,500
801.62	200	5	1,000	1	1,000
801.109	18,000	3.5	63,000	17.77	1,119,510
801.110	10,000	50	500,000	0.25	125,000
801.405(b)	40	1	40	4	160
801.420(c)	40	5	200	40	8,000
801.421(b)	10,000	160	1,600,000	0.30	480,000

801.421(c)	10,000	5	50,000	0.17	8,500
801.435	45	1	45	96	4,320
809.10(a) and (b)	1,700	6	10,200	80	816,000
809.10(d)	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
Total Burden Hours					2,772,080

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

Table 2 – Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total hours
801.410(f)	30	769,000	23,070,000	641	19,225
801.421(d)	9,900	162	1,600,000	0.25	400,000
Total Hours					419,225

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

Reporting

§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. Four establishments label 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 4 establishments would be subject to the requirements of §800.10(b)(2). FDA estimates that it would take each establishment approximately 40 hours per year/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. Obviously, this is information readily available to the establishment and easily supplied. From its registration and listing databases, FDA estimates that there are 20,000 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. On the average, FDA estimates that approximately half of

these devices would require minimal labeling with a burden of 5 hours per year per device (3,500 x 5 = 16,500) and that the other half would require an expenditure of approximately 40 hours per device per year (3,500 x 40 = 140,000).

§ 801.61. The requirements of section 801.61 apply to over-the-counter devices in package form. FDA estimates that there are 1,000 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 form 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). From its registration and listing databases, FDA has determined that there are 40 establishments manufacturing, packing, or distributing the emergency denture kits covered by §801.405(b). The requirements of this section are rather simple. FDA estimates that it will take each establishment 4 hours per device/ per year to meet these requirements.

§801.420(c). In estimating the burden for the requirement of preparing a User Instructional Brochure as required by §801.420(c), FDA determined that there were 40 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 8,000 hours for this requirement (40 manufacturers **X** 5 brochures **X** 40 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 registration database, FDA determined that there are approximately 45 manufacturers of condoms that would have to provide the labeling required by §801.435. FDA then determined that it would take a manufacturer 10 staff hours to check the individual data points that it needs to check in order to complete the tests. Based upon comments from manufacturers in response to the proposed rule, FDA

estimated that it would take each manufacturer approximately 96 hours per year to complete the tests required to establish an expiration date for their condom. Thus, the total burden is 4,320 hours (45 manufacturers **X** 96 hours).

§809.10(a) and (b). From its registration and listing databases, 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 registration and listing databases, 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 reporting hour burden for designing/review of labeling is approximately 25 hours per respondent (100 X .25). FDA also estimates that the total reporting 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 reporting 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 reporting hour burden for rewriting/reviewing promotional materials is approximately 25 (125 X

.20) hours per respondent. FDA estimates that the total reporting hour burden for promotional materials is approximately 7,500 (37,500 X .20).

Recordkeeping

§801.410(f). The Vision Council of America provided sales figures that were used to estimate the burden for §801.410(f). Beginning in 1998, the vision industry has experienced a steady but declining growth rate of 2.6% for the distribution of lenses. It is assumed that this growth rate continued in 1999 and 2000. This resulted in an increase in the number of eyeglasses shipped annually to 89 million lenses shipped by the year 2000. The following sales figures were based on the above assumptions:

Year	Sales (Millions)	% Change	Eyeglass Shipments
1998	15.8	+ 2.6%	84.51
1999	16.2	+ 2.6%	86.7
2000	16.6	+ 2.6%	89.0

By also 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 23,070,000 lenses should be tested. This figure was derived by taking 22% of 89 million glass lenses (19,600,000) and adding it to 5% of the remaining plastic lenses (5% **X** 69,400,000 = 3,470,000).

Next, divide the total tests (23,070,000) by 30 manufacturers to return the annual frequency of recordkeeping figure of 769,000. 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. It is estimated that the total burden for this collection is 19,225 hours, which is calculated by dividing the total records figure (23,070,000) by tests per hour (1,200). The hours per recordkeeper is calculated by dividing the total number of hours (19,225) by the number of manufacturers (30).

§ 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 reporting burden to be $92,546,366. This is based on an hourly salary of $29.00.

13. Annual Cost Burden to Respondent

There are no capital or operating or maintenance costs associated with this information collection. Establishments would label their devices in some form as part of their usual and customary business practices.

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 (premarket approval. 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 $100,000 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. Changes or Adjustments in Burden

FDA is seeking approval under the Paperwork Reduction Act for these information collection requirements for the first time. Therefore, there are no changes or adjustments in burden.

16. Statistical Analysis, publication Plans, and Schedule

Not applicable

17. Approval Not to Display Expration Date

Not applicable

18. Exceptions to the Certification Statement Identified in Item 19

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

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS.

There are no plans to publish the information collected under the provision of this proposed regulation for statistical use. The collections of information for which FDA is seeking approval do not employ statistical methods.

Tab A – 21 CFR Parts 800, 801, and 809