TABLE 2.—ESTIMATED SUBSEQUENT YEARS ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.22(a)	Form 2891 Initial Establishment Registration	2,245	1	2,245	0.25	561
807.22(b)	Form 2892 Device Listing—initial and updates	3,650	1	3,650	0.50	1,825
807.22(a)	Form 2891(a)—Registration Update	18,500	1	18,500	0.25	4,625
807.31(e)		200	1	200	0.50	100
Total year 2 and year 3 burden hours						7,111

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

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Recordkeeper	Total Hours
807.31	9,900	10	99,000	0.50	49,500
Total burden hours					49,500

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

This year's submission has broken out annual costs into two distinct phases, and the tables above summarized the estimated annual reporting burden hours for medical device establishments to report in compliance with the provisions imposed by this regulation.

Hospital Reprocessing of Single-Use Medical Devices

On August 14, 2001, hospitals who reprocess single-use devices will be required to register their establishments and list those devices they reprocess. FDA has estimated that there will be approximately 2,000 such establishments that will fall into this category. The first year of the requirement will cause a one-time bolus of information to be submitted. FDA has separated the burden estimates into two tables to indicate year 1 (table 1 of this document) and subsequent year's estimates (table 2 of this document). Year 1 will include burden hours based on this bolus of submissions during the first year and subsequent year's estimates will indicate an adjustment for the new registrants for year 2 and beyond.

Burden Hour Explanation

The annual reporting burden hours to respondents for registering establishments and listing devices is estimated to be 16,961 hours, and recordkeeping burden hours for respondents is estimated to be 49,500 hours. The estimates cited in the tables above are based primarily upon the annual FDA accomplishment report, which includes actual FDA registration and listing figures from fiscal year (FY) 2000. These estimates are also based on FDA estimates of FY 2000 data from current systems, conversations with industry and trade association representatives, and from internal review of the documents referred to in the previous tables.

According to 21 CFR part 807, all owners/operators are required to list, and establishments are required to register. Each owner/operator has an average of two establishments, according to statistics gathered from FDA's registration and listing database. The database has 16,500 active establishments listed in it. Based on past experience, the agency anticipates that approximately 4,045 registrations will be processed during the first year (because of hospitals who reprocess single-use), and 2,045 registrations thereafter. The agency also anticipates that approximately 5,450 initial and update device listings will be submitted the first year (due to hospitals who reprocess single-use devices), and 3,450 thereafter. FDA anticipates reviewing 200 historical files annually. Finally, because initial importers (currently estimated at 6,200) do not have to maintain historical files and because of the addition of 2,000 hospitals who reprocess single-use medical devices, FDA estimates that the number of recordkeepers required to maintain the initial historical information will be 9,900.

Dated: October 9, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–25920 Filed 10–15–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0267]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Device Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written or electronic comments on the collection of information by November 15, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Labeling—21 CFR Parts 800, 801, and 809

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), 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 of the act 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) of the act 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) of the act 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.

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 required by § 800.12.

Section 800.10(b)(2) 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.

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

Section 801.5 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 § 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.

Section 801.61 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.

Section 801.62 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.

Section 801.109 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 which it is intended, including all purposes for which it is advertised or represented.

Section 801.110 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.

Section 801.405(b) establishes labeling requirements for articles intended for lay use in repairing and refitting dentures.

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

Section 801.420(c) requires that the manufacturer or distributor of the hearing aid develop a user instructional brochure, which accompanies the device and is provided to the user by the dispenser of the hearing aid.

Section 801.421(b) requires that the hearing aid dispenser provide the user a copy of the user instructional brochure.

Section 801.421(c) requires the hearing aid dispenser to provide, upon request, to the purchaser of any hearing aid dispensed a copy of the a user instructional brochure or the name and address of the manufacturer of distributor from whom the brochure may be obtained.

Section 801.421(d) requires the hearing aid dispenser to retain for 3 years from the time of dispensing copies of all physician statements or any waivers of medical evaluation.

Section 801.435(b) 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.

Section 809.10(a) and (b) provide labeling requirements for in vitro diagnostic products including the label and a package insert.

Section 809.10(d) provides that labeling for general purpose laboratory reagents may be exempt from the labeling requirements in 809.10(a) and (b) under certain conditions.

Section 809.10(e) requires manufacturers of analyte specific reagents (ASRs) include specific information in their labeling.

Section 809.10(f) requires that labeling for over-the-counter test collection systems for drugs of abuse testing include specific information in their labeling.

Section 809.30(d) requires that manufacturers of ASRs assure that advertising and promotional materials for ASRs contain specific information.

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.

From its registration and listing databases, FDA has determined that there are approximately 20,000 registered device establishments. About 2,000 of these are distributing over-the-counter devices. About 18,000 are distributing prescription devices. About 1,700 establishments are distributing in vitro diagnostic products.

In the **Federal Register** of July 11, 2001 (66 FR 36285), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	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					2,772,080

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.410(f)	30	769,000	23,070,000	0.0008	19,225
801.421(d)	9,900	162,160	1,600,000	0.25	400,000
Total					419,225

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

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

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 1 hour per product is a reasonable estimate.

These same four 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.

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.

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 = 17,500) and that the other half would require an expenditure of approximately 40 hours per device/per year (3,500 x 40 = 140,000).

The requirements of § 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.

The requirements of § 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 1 hour per year/per device.

The requirements of § 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 90 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 10 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).

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).

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.

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).

Under provisions of § 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 or 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).

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 requester. Thus, the total burden for this collection is 8,500 hours (10,000 firms x 5 requests per year x .17 staff hours).

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).

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.

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.

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 percent 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.

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 hours 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.

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 ASRs 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 percent 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

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 percent 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.

TABLE 3.—ANNUAL PERCENTAGE SALES IN EYEGLASS SHIPMENTS

Year	Sales (Millions)	Percent 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 percent glass and 78 percent plastic), that glass lenses must be tested individually, and only 5 percent of the plastic lenses must be tested, then 23,070,000 lenses should be tested. This figure was derived by taking 22 percent of 89 million glass lenses (19,600,000) and adding it to 5 percent 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).

Under provisions of § 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).

Dated: October 10, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–25943 Filed 10–15–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0186]

International Conference on Harmonisation; Guidance on M4 Common Technical Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of guidance entitled ''M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use'' (M4 CTD). The guidance was developed under the auspices of the International Conference on Harmonisation of