Dated: March 29, 2005.

Patricia A. Morrissey,

Commissioner, Administration on Developmental Disabilities.

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BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0515]

Agency Information Collection Activities; Submission for Office of Management and Budget 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 a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 2, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (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 Regulations—21 CFR Parts 800, 801, and 809 (OMB Control Number 0910–0485)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded and subject to regulatory action. Certain provisions 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 way, or fails to contain adequate directions for use.

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.

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 (OTC) 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 OTC 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 potential for harmful effect, 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 layperson 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, 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.

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 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; and (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.

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 801.410(f) 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 percent of the population, or 161 million Americans, wear prescription eyewear; 81 percent have eyeglasses, 3 percent have contact lenses only; and 16 percent have both eyeglasses and contact lenses.

Section 801.420(c) requires that the manufacturers or distributors of hearing aids 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.

Section 801.421(b) 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.

Section 801.421(c) 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.

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

Section 801.435 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.

Section 809.10(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; and
9. A lot or control number.

Section 809.10(b) 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; and
14. Date of issuance of the last revision of the labeling.

Section 809.10(d) 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; and
8. A lot or control number.

Section 809.10(e) 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; and
9. The statement, ''For analyte specific reagent use only. Analytical and performance characteristics are not established.''

Section 809.10(f) requires that the labeling for 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 followup counseling is desired; and

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

Section 809.30(d) requires that manufacturers of analyte specific reagents (ASRs) assure that advertising and promotional materials for ASRs:

1. Include the identity and purity of the ASR and the identity of the analyte; and

2. Do not include any statement regarding analytical or clinical performance.

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.

In the **Federal Register** of December 14, 2004 (69 FR 74529), FDA published a 60-day notice requesting public comment on the information collection provisions. 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 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	30,000	3.5	105,000	0.1	10,500
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	125,000
801.405(b)	40	1	40	4	160
801.420(c)	275	5	1,375	40	55,000
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	135	1	135	96	12,960
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					3,083,895

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

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)	10,000	160	1,600,000	0.25	400,000
Total Hours					419,225

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

Dated: March 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6405 Filed 3–31–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0117]

International Conference on Harmonisation; Guidance on E2E Pharmacovigilance Planning; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''E2E Pharmacovigilance Planning.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance describes a method for summarizing the important potential and identified risks of a drug. It proposes a structure for a pharmacovigilance plan and sets out principles of good practice for the design and conduct of observational studies. The guidance is intended to aid in planning pharmacovigilance activities, especially in preparation for the early postmarketing period of a new drug.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Paul Seligman, Center for Drug Evaluation and Research (HFD–030), Food and Drug Administration, Rockville, MD 20857, 301–827–6276, or M. Miles Braun, Center for Biologics Evaluation and Research (HFM–220), 1401 Rockville Pike, Rockville, MD 20852, 301–827–3974.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of March 30, 2004 (69 FR 16579), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''E2E Pharmacovigilance Planning.'' The notice gave interested persons an opportunity to submit comments by May 19, 2004.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in November 2004.

The document provides guidance on summarizing the important identified risks of a drug, important potential risks, and important missing information, including the potentially at-risk populations and situations where the product is likely to be used that have not been studied prior to approval. The guidance proposes a structure for a pharmacovigilance plan and sets out principles of good practice for the design and conduct of observational studies.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/*