

fees equivalent to the additional fee burden associated with the submission of two marketing applications. This guidance does not address how FDA should determine whether a single or multiple marketing applications should be submitted for a combination product. Such guidance is in development and will be provided separately for public review and comment.

## II. Significance of Guidance

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 application user fees for combination products. 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 statute and regulations.

## III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance at any time. Submit two paper copies of any mailed comments, except that individuals may submit one 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.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/oc/combination> or by e-mailing the Office of Combination Products at [combination@fda.gov](mailto:combination@fda.gov). Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: April 15, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0041]

#### Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Content of Labeling; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Content of Labeling." This guidance is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. FDA's regulations require that the content of labeling for marketing applications be submitted in electronic format in a form that FDA can process, review, and archive. The guidance provides information on submitting the content of labeling in electronic format for review with new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biological license applications (BLAs) for biological products that meet the definition of drug in the Federal Food, Drug, and Cosmetic Act.

**DATES:** Submit written or electronic comments on agency guidances at any time. General comments on agency guidance documents are welcome 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 to 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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800-835-4709 or 301-827-1800.

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:

Randy Levin, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5411, e-mail:

[levinr@cder.fda.gov](mailto:levinr@cder.fda.gov), or

Robert Yetter, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of December 11, 2003 (68 FR 69009), FDA published a final regulation (the electronic labeling regulation), which requires the submission of the content of labeling in electronic format for marketing applications. The requirements of the electronic labeling rule can be found in § 314.50(l) (21 CFR 314.50(l)) for NDAs, § 314.94(d) for ANDAs, § 601.14(b) for BLAs, and § 314.81(b) for annual reports on marketing applications. The regulations specify that the content of labeling must be submitted electronically in a form that FDA can process, review, and archive. The regulations also state that FDA will periodically issue guidance on how to provide the electronic submission.

##### II. The Guidance

FDA is announcing the availability of a guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Content of Labeling." The guidance provides information on how to submit the content of labeling in electronic format.

In the preambles of the proposed and final rules on electronic labeling, FDA identified portable document format (PDF) as the only type of electronic file format that the agency has the ability to accept for processing, reviewing, and archiving. Recent recommendations from the Institute of Medicine and the National Committee on Vital and Health Statistics and mandates in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) have created a new role for electronic labeling information. Electronically formatted content of labeling will be used to support Federal health information management initiatives such as electronic prescribing; the electronic health record (EHR), which will provide health care providers, patients, and other authorized users access to patient information in electronic format; and

the DailyMed, a new way to distribute up-to-date and comprehensive medication information in a computerized format for use in health care information systems.

Because FDA's current procedures using PDF are not adequate to support these initiatives, the agency is changing the way it processes, reviews, and archives the content of labeling. We are adopting a new technology for exchanging information between computer systems developed by Health Level Seven (HL7), a standards development organization accredited by the American National Standards Institute. The new technology, based on Clinical Document Architecture (CDA), allows information to be exchanged in extensible markup language (XML) and is the standard being investigated for the EHR. FDA, working with other parties in HL7 (experts from HL7, industry, and technology solution providers), has adapted CDA for labeling in an HL7 standard called Structured Product Labeling (SPL).

FDA is developing an automated system using SPL for processing and managing labeling and labeling changes. FDA's Center for Drug Evaluation and Research has identified SPL in public docket number 1992S-0251 as a format that FDA can use to process, review, and archive the content of labeling. During our transition to the automated system, the agency is able to accept the content of labeling in either PDF or SPL file format. After the automated system is implemented, PDF will no longer be a format that we can use to process, review, and archive the content of labeling. At this time, it is our goal to complete the transition to SPL format for content of labeling submissions by fall 2005.

In the **Federal Register** of February 5, 2004 (69 FR 5552), FDA published a document announcing the availability of a draft guidance for industry and gave interested persons an opportunity to submit comments by April 5, 2004. Based on comments received on the draft guidance, the agency has taken the following actions:

- Lengthened the timeframe for the agency's implementation of the automated system using SPL;
- Developed a Web site (on the Internet at <http://www.fda.gov/oc/datacouncil/spl.html>) to provide technical support for the transition to SPL, including links to SPL-related documents and resources, stylesheet files for viewing SPL files, and example labels; and
- Revised the guidance to clarify the procedures for submitting content of labeling in electronic format.

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 providing the content of labeling in electronic format as required in 21 CFR parts 314 and 601. 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.

### III. Comments

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

### IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in this guidance have been approved under OMB control number 0910-0530, expiring November 30, 2006.

### V. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: April 15, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of Loan Repayment; Submission for OMB Review; Comment Request; National Institutes of Health Loan Repayment Programs

**Summary:** In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995,

the Office of Loan Repayment, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on December 10, 2004, and allowed 60 days for public comment. No responses to the notice were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number. The programs have existing data collections with an OMB control number (OMB No. 0925-0361, expiration date 12/31/2004). An extension has been granted until March 2005 due to an administrative delay caused by a change in office responsible for the LRPs.

### Proposed Collection

**Title:** National Institutes of Health Loan Repayment Programs.

**Type of Information Collection**

**Request:** Revision of a currently approved collection (OMB No. 0925-0361, expiration date 12/31/04, extension granted until 03/05).

**Form Numbers:** NIH 2674-1, NIH 2674-2, NIH 2674-3, NIH 2674-4, NIH 2674-5, NIH 2674-6, NIH 2674-7, NIH 2674-8, NIH 2674-9, NIH 2674-10, NIH 2674-11, NIH 2674-12, NIH 2674-13, NIH 2674-14, NIH 2674-15, NIH 2674-16, NIH 2674-17, NIH 2674-18, and NIH 2674-19.

**Need and Use of Information**

**Collection:** The NIH makes available financial assistance, in the form of educational loan repayment, to M.D., Ph.D., Pharm. D., D.D.S., D.M.D., D.P.M., D.C., and N.D. degree holders, or the equivalent, who perform biomedical or biobehavioral research in NIH intramural laboratories or who perform research that is supported by a domestic non-profit institution or a U.S. Government (Federal, state, local) entity for a minimum of 2 years (3 years for the General Research LRP) in research areas supporting the mission and priorities of the NIH.

The AIDS Research Loan Repayment Program (AIDS-LRP) is authorized by Section 487A of the Public Health Service Act (42 U.S.C. 288-1); the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP) is authorized by Section 487E (42 U.S.C.