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 December 31, 2002 (67 FR 79939), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs.'' The notice gave interested persons an opportunity to submit comments by January 24, 2003.

After consideration of the comments received and revisions to the draft guidance, a final draft of the guidance was submitted to the ICH steering committee and endorsed by the three participating regulatory agencies in February 2003.

This guidance provides additional information on the objectives, general principles, and model for PSURs specified in the ICH E2C guidance, including clarification of the following topics:

- When separate PSURs will be considered appropriate,
- Synchronization of National Birthdates with the International Birthdates,
- Reporting frequency and time for submission changes, and
- Use of the reference safety information.

In addition, this guidance includes information on the following topics not previously addressed in the ICH E2C guidance.

- Summary bridging reports and addendum reports,
- Executive summaries, and
- Information on risk management programs and risk-benefit analyses.

The document should be used in conjunction with the ICH E2C guidance.

This 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, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written comments on the guidance. Two copies of any 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 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/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: January 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–2314 Filed 2–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0041]

Draft 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 draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Content of Labeling.'' This draft guidance is one in a series of guidance documents on providing regulatory submissions to the FDA in electronic format. In the **Federal Register** of December 11, 2003 (68 FR 69009), FDA published a final regulation (the electronic labeling rule) requiring that the content of labeling for marketing applications be submitted in electronic format in a form that FDA can process, review, and archive. The draft 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).

DATES: Submit written comments on the draft guidance by April 5, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft 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 draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Randy Levin, Center for Drug Evaluation and Research (HFD–140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5411, e-mail: *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 December 2003, FDA published 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 21 CFR 314.50(l) for NDAs, 21 CFR 314.94(d) for ANDAs, 21 CFR 601.14(b) for BLAs, and 21 CFR 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 Draft Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Content of Labeling.'' The draft 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 health information management initiatives such as electronic prescribing and the electronic health record (EHR).

Because FDA's current procedures using PDF are not adequate to support these initiatives, the agency is proposing to change the way it processes, reviews, and archives the content of labeling. We are proposing to adopt 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, 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 interested parties in HL7, has adapted CDA for labeling in a proposed HL7 standard called Structured Product Labeling (SPL).

FDA is developing an automated system using SPL for processing and managing labeling and labeling changes. When the draft guidance is finalized, absent significant objections, FDA is likely to identify SPL in public docket number 92S–0251 as a format that we can use to process, review, and archive the content of labeling. During our transition to the automated system, the agency would be able to accept the content of labeling in either PDF or SPL file format. After the automated system is implemented, PDF would 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 the end of 2004.

This draft guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on providing in electronic format the content of labeling 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 draft guidance. 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 draft 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

The information requested for human drug and biological products in this guidance is already covered by the collection of information in ''Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format'' (Office of Management and Budget 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 at *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 25, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–2536 Filed 2–3–04; 9:39 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute Proposed Collection; Comment Request Exam 2—The Jackson Heart Study, Annual Follow-Up Component

Summary: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 9, 2003, pages 53177–53178, and allowed 60-days for public comment. No public comments 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.

Proposed Collection: Title: The Jackson Heart Study: Annual Follow-up with Third Party Respondents. *Type of Information Collection Request:* Revision of a currently approved collection (OMB 0925–0491). *Need and Use of Information Collection:* This project involves follow-up by telephone of participants in the JHS study, review of their medical records, and interviews with doctors and family to identify disease occurrence. Interviewers will contact doctors and hospitals to ascertain participants' cardiovascular events. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in African American men and women. The continuation of the study will allow continued assessment of subclinical coronary disease, left ventricular dysfunction, progression of carotid atherosclerosis and left ventricular hypertrophy, and responses to stress, racism, and discrimination as well as new components such as renal disease, body fat distribution and body composition, and metabolic consequences of obesity. *Frequency of Response:* One-time. *Affected Public:* Individuals or families; businesses or other for profit; not-for-profit institutions. *Affected Public:* Third party respondents (next-of-kin decedents and physicians). *Type of Respondents:* Middle aged and elderly adults; doctors and staff of hospitals and nursing homes. *Estimated Number of Respondents:* 600; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 0.50; and *Estimated Total Annual Burden Hours Requested:* 300. The annualized cost to respondents is estimated at: $6,500. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.