108.35(d) and (e). The report is expected to take 4 hours per response, for a total of 4 hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
108, 113, and 114	10,392	1	10,392	250	2,598,000

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

FDA bases its estimate of 10,392 recordkeepers in table 2 on its records of the number of registered firms, excluding firms that were inactive or out of business, yet still registered. To avoid double-counting, we have not included estimates for §§ 108.25(g), 108.35(c)(2)(ii), and 108.35(h) because they merely cross-reference recordkeeping requirements contained in parts 113 and 114 and have been accounted for in the recordkeeping burden estimate. We estimate that 10,392 firms will expend approximately 250 hours per year to fully satisfy the recordkeeping requirements in parts 108, 113 and 114, for a total of 2,598,000 hours.

Finally, our regulations require that processors mark thermally processed low-acid foods in hermetically sealed containers (§ 113.60(c) and acidified foods (§ 114.80(b)) with an identifying code to permit lots to be traced after distribution. We seek OMB approval of the third party disclosure requirements in §§ 113.60(c) and 114.80(b). However, we have not included a separate table to report the estimated burden of these regulations. No burden has been estimated for the third party disclosure requirements in §§ 113.60(c) and 114.80(b) because the coding process is done as a usual and customary part of normal business activities. Coding is a business practice in foods for liability purposes, inventory control, and process control in the event of a problem. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

II. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (We have verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.)

1. FDA 2012. ''Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format''. Available at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/ucm309376.htm.*

2. Form FDA 2541a. Food Process Filing for All Methods Except Low-Acid Aseptic. Available at *http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM076784.pdf.*

3. Form FDA 2541c. Food Process Filing for Low-Acid Aseptic Systems. Available at *http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM123687.pdf.*

4. Draft Form 2541d. Food Process Filing for Low-Acid Retorted Method. Available at *http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM365066.pdf.*

5. Draft Form 2541e. Food Process Filing for Acidified Method. Available at *http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM365058.pdf.*

6. Draft Form 2541f. Food Process Filing for Water Activity/Formulation Control Method. Available at *http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM365059.pdf.*

7. Draft Form 2541g. Food Process Filing for Low-Acid Aseptic Systems. Available at *http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM365060.pdf.*

8. Draft Instructions for Paper Submission of Form FDA 2541d. Available at *http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM366881.pdf.*

9. Draft Instructions for Paper Submission of Form FDA 2541e. Available at *http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM366882.pdf.*

10. Draft Instructions for Paper Submission of Form FDA 2541f. Available at *http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM366884.pdf*

11. Draft Instructions for Paper Submission of Form FDA 2541g. Available at *http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM366885.pdf.*

Dated: September 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–22674 Filed 9–17–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1067]

Draft Guidance for Industry on Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products—Content and Format; 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 ''Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' The recommendations in the draft guidance are intended to help ensure that the labeling is clear, useful, informative, and to the extent possible, consistent in content and format.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 18, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jonas Santiago, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6358, Silver Spring, MD 20993–0002, 301–796–5346; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' This draft guidance provides recommendations for the ''Patient Counseling Information'' section on the following: How to decide what topics to include in the section, how to present information within the section, and how to format and organize section contents.

This guidance is one of a series of guidances FDA is developing, or has developed, to assist applicants with the content and format of the labeling for human prescription drug and biological products. In the **Federal Register** of January 24, 2006 (71 FR 3922), FDA published a final rule on labeling for human prescription drug and biological products. The final rule and additional guidances can be accessed at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm*. The labeling requirements and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's current thinking on the content and format of the ''Patient Counseling Information'' section of labeling for human prescription drug and biological 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 statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

III. The Paperwork Reduction Act of 1995

This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information 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 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov*.

Dated: September 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–22644 Filed 9–17–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0643]

Guidance for Industry on Electronic Source Data in Clinical Investigations; 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 ''Electronic Source Data in Clinical Investigations.'' This document provides guidance to sponsors, contract research organizations (CROs), clinical investigators, and others involved in the capture, review, and retention of electronic source data in FDA-regulated clinical investigations. This guidance promotes capturing source data in electronic form, and it is intended to assist in ensuring the reliability, quality, integrity, and traceability of data from electronic source to electronic regulatory submission.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448 (the guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800); or the Division of Small Manufacturers, International and