TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR Section	Number of recordkeeper	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
120.8(b)(7) and 120.12(a)(4)(i) and (b)—Require a recordkeeping system that documents monitoring of the critical control points and other measurements as prescribed in the HACCP plan.	1,450	14,600	21,170,000	0.01	211,700
120.10(c) and 120.12(a)(4)(ii) and (b)—Require that all corrective actions taken in response to a deviation from a critical limit be documented.	1,840	12	22,080	0.1	2,208
120.11(a)(1)(iv) and (a)(2), and 120.12 (a)(5)—Require records showing that process monitoring instruments are properly calibrated and that end-product or in-process testing is performed in accordance with written procedures.	1,840	52	95,680	0.1	9,568
120.11(b) and 120.12(a)(5) and (b) - Require that every processor record the validation that the HACCP plan is adequate to control food hazards that are likely to occur.	1,840	1	1,840	4	7,360
120.14(a)(2), (c), and (d)—Require that importers of fruit or vegetable juices, or their products used as ingredients in beverages, have written procedures to ensure that the food is processed in accordance with our regulations in part 120.	308	1	308	4	1,232
120.11(c) and 120.12(a)(5) and (b)—Require documentation of revalidation of the hazard analysis upon any changes that might affect the original hazard analysis (applies when a firm does not have an HACCP plan because the original hazard analysis did not reveal hazards likely to occur.)	1,840	1	1,840	4	7,360
Total					358,466

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

Table 1 provides our estimate of the total annual recordkeeping burden of our regulations in part 120. We base our estimate of the average burden per recordkeeping on our experience with the application of HACCP principles in food processing. We base our estimate of the number of recordkeepers on our estimate of the total number of juice manufacturing plants affected by the regulations (plants identified in our official establishment inventory plus very small apple juice and very small orange juice manufacturers). These estimates assume that every processor will prepare sanitary standard operating procedures and an HACCP plan and maintain the associated monitoring records, and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice processors that, based upon their hazard analysis, determine that they are not required to have an HACCP plan under these regulations.

Dated: *November 15, 2013.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–27811 Filed 11–19–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0576]

Draft Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the draft guidance for industry entitled ''Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products'' that appeared in the **Federal Register** of July 2, 2013 (78 FR 39736). The draft guidance document provides sponsors of Investigational New Drug Applications for cellular therapy (CT) and gene therapy (GT) products (referred to collectively as CGT products) with recommendations to assist in designing early-phase clinical trials of CGT products. In the notice, we requested comments on the draft guidance. We are taking this action to allow interested persons additional time to submit comments and to allow for public discussion at the February 25–26, 2014, Cellular, Tissue, and Gene Therapies Advisory Committee meeting, where FDA will present the draft guidance document for review.

DATES: FDA is extending the comment period on the draft guidance. Submit either electronic or written comments by May 9, 2014.

ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov.* 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 written requests for single copies of the draft guidance to 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. Send one self-addressed adhesive label to assist the office in processing your request. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–

4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document

FOR FURTHER INFORMATION CONTACT: Melissa Reisman, 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

In the **Federal Register** of July 2, 2013 (78 FR 39736), FDA published a notice announcing the availability of a draft guidance document entitled ''Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products.'' The notice invited comments on the draft guidance by November 22, 2013.

We are extending the comment period for the draft guidance to May 9, 2014. We are taking this action to allow interested persons additional time to submit comments and to allow for public discussion at the April 10–11, 2014, Cellular, Tissue, and Gene Therapies Advisory Committee meeting, where FDA will present the draft guidance document for review.

The Agency believes that this extension will not significantly delay further FDA action on this guidance.

II. Request for 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.*

Dated: November 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–27769 Filed 11–19–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–D–4079]

Draft Guidance for Industry on Product Name Placement, Size, and Prominence in Advertising and Promotional 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 ''Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling.'' When finalized, the draft guidance will replace the guidance of the same title issued January 25, 2012. The draft guidance clarifies the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertising for prescription human drugs, including biological drug products, and prescription animal drugs and articulates the circumstances under which FDA intends to exercise enforcement discretion.

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 January 21, 2014.

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; or the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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: *Regarding human prescription drugs:* Cynthia Ng, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3278, Silver Spring, MD 20993–0002, 301–796–1200.

Regarding prescription human biological products: 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.

Regarding animal prescription drugs: Julie Garnier, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6878.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling.'' In the **Federal Register** of January 25, 2012 (77 FR 3779), FDA announced the availability of a guidance entitled ''Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling.'' The 2012 guidance discusses the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertising for prescription human and animal drugs and biological products. The draft guidance clarifies these requirements and articulates the circumstances under which FDA intends to exercise enforcement discretion.

The disclosure of the product name in promotional labeling and advertising for all prescription human and animal drug and biological products is important for the proper identification of such products to ensure their safe and effective use.

The placement, size, prominence, and frequency of proprietary and established names for human and animal prescription drug products are specified in labeling and advertising regulations (21 CFR 201.10(g) and (h); 202.1(b), (c), and (d)). These regulations are also applicable to biological product labeling and advertising materials.

The recommendations in the draft guidance pertain to product names in traditional print media promotion (e.g., journal ads, detail aids, brochures), audiovisual promotional labeling (e.g.,