Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–7923 Filed 4–2–12; 8:45 am]

BILLING CODE 4184–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0508]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Blood Establishment Registration and Product Listing, Form FDA 2830

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Blood Establishment Registration and Product Listing, Form FDA 2830'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On January 4, 2012, the Agency submitted a proposed collection of information entitled ''Blood Establishment Registration and Product Listing, Form FDA 2830'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0052. The approval expires on March 31, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: March 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–7915 Filed 4–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0300]

Draft Guidance for Industry on Compliance Policy for Reporting Drug Sample Distribution Information; 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 ''Compliance Policy on Reporting Drug Sample Distribution Information Under the Affordable Care Act.'' This draft guidance is intended to provide information regarding the Agency's implementation of the drug sample transparency reporting provisions of section 6004 of the Patient Protection and Affordable Care Act. The draft guidance notifies entities covered by the reporting obligations in section 6004 that FDA does not intend to object until at least October 1, 2012, if manufacturers and authorized distributors of record (ADRs) do not submit information under those reporting provisions and that the Agency intends to provide notice before revising its exercise of discretion with respect to compliance.

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 electronic or written comments on the draft guidance by June 4, 2012.

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 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 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: Donovan F. Duggan, Jr., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4288, Silver Spring, MD 20993–0002, 301–796–0584; Paul Loebach, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4268, Silver Spring, MD 20993–0002, 301–796–2173; 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 ''Compliance Policy on Reporting Drug Sample Distribution Information.'' On March 23, 2010, the Affordable Care Act was signed into law. Among its many provisions, section 6004 of the Affordable Care Act amended the Social Security Act by adding section 1128H (42 U.S.C. 1320a–7i). This new section requires the submission of certain drug sample information to FDA not later than April 1 of each year, beginning April 1, 2012.

The draft guidance is intended to provide information regarding the Agency's implementation of section

6004. The draft guidance notifies entities covered by section 6004 that FDA does not intend to object until at least October 1, 2012, if manufacturers and ADRs do not submit information under section 6004 and that we intend to provide notice before revising our exercise of discretion with respect to compliance. The draft guidance also notifies covered entities that FDA plans to use its Electronic Submission Gateway (the Gateway) for submissions under section 6004 and that revisions to allow the Gateway to receive such submissions should be complete by April 1, 2012. Should covered entities wish to make such submissions notwithstanding FDA's compliance policy, the draft guidance provides information about accessing the Gateway. The Agency expects to issue further draft guidance concerning the requirements of section 6004 later in 2012.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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**) either electronic or written comments regarding this document. 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.

III. Paperwork Reduction Act of 1995

This draft guidance regarding Agency compliance policy refers to information collections under section 6004 that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). As noted, the Agency is also preparing a draft guidance for release later this year to provide additional information regarding submissions under section 6004. In accordance with the PRA, prior to publication of a final guidance document, FDA intends to solicit public comment and obtain OMB approval for any new information collections under section 6004.

IV. Electronic Access

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

Dated: March 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–7912 Filed 3–29–12; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0071]

Draft Guidance for Industry: Modified Risk Tobacco Product Applications; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

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 ''Modified Risk Tobacco Product Applications.'' The draft guidance provides information about submitting applications for modified risk tobacco products under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The draft guidance describes the information that the FD&C Act requires you to submit in your modified risk tobacco product application and the scientific evidence FDA recommends you submit to support your application. The draft guidance also permits the filing of a single application for any modified risk tobacco product that is also a new tobacco product under the FD&C Act.

DATES: Although you can submit written or electronic comments on this 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 electronic or written comments on the draft guidance by June 4, 2012. Submit electronic or written comments on the proposed collection of information by June 4, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Modified Risk Tobacco Product Applications'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance, including comments on the proposed collection of information, 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Gail Schmerfeld or Kristin Davis, Center for Tobacco Products, 9200 Corporate Blvd., Rockville, MD 20850–3229, 1–877–287–1373, *gail.schmerfeld@fda.hhs.gov* or *kristin.davis@fda.hhs.gov.*

With regard to the proposed collection of information: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act) into law. The Tobacco Control Act grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. Congress found that it is essential that, prior to marketing tobacco products for use to reduce harm or the risk of tobacco-related disease or to reduce exposure to harmful substances associated with tobacco products, manufacturers be required to ''demonstrate that such products * * * meet a series of rigorous criteria, and will benefit the health of the population as a whole'' (section 2(36) of the Tobacco Control Act). Thus, section 101 of the Tobacco Control Act added section 911 (21 U.S.C. 387k) to the FD&C Act to prohibit the introduction or delivery for introduction into interstate commerce of any modified risk tobacco product unless an order