

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](mailto: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.*

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**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. Mizrahi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-

400B, Rockville, MD 20850, 301-796-7726, [ila.mizrahi@fda.hhs.gov](mailto:ila.mizrahi@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]

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## 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