

400B, Rockville, MD 20850, (301) 796-3793.

**SUPPLEMENTARY INFORMATION:** On August 25, 2011, the Agency submitted a proposed collection of information entitled "Pre-market Notification for a New Dietary Ingredient" 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 0910-0330. The approval expires on November 30, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: November 14, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-29837 Filed 11-17-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0099]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Followup Study for Infant Feeding Practices Study II

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Followup Study for Infant Feeding Practices Study II" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, (301) 796-3793.

**SUPPLEMENTARY INFORMATION:** On August 2, 2011, the Agency submitted a proposed collection of information entitled "Followup Study for Infant Feeding Practices Study II" 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 0910-0696. The approval expires on November 30, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: November 14, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0074]

#### Guidance for Industry on Medication Guide Distribution Requirements and Inclusion of Medication Guides in Risk Evaluation and Mitigation Strategies; 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 "Medication Guides—Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)." This guidance addresses two topics pertaining to Medication Guides for drug and biological products. First, the guidance addresses when FDA intends to exercise enforcement discretion regarding when a Medication Guide must be provided with a drug or biological product that is dispensed to a health care professional for administration to a patient instead of being dispensed directly to the patient for self-administration or to the patient's caregiver for administration to the patient. Second, the guidance addresses when a Medication Guide will be required as part of a REMS. The guidance is intended to answer questions that have arisen concerning these topics.

**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, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-(800) 835-4709 or (301) 827-1800. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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:

Kristen E. Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, (301) 796-5400;

or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, (301) 827-6210.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Medication Guides—Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)." This guidance provides information for industry, health care providers, and authorized dispensers of prescription drug products. The guidance addresses two topics pertaining to Medication Guides for drug and biological products.

Medication Guides are primarily for prescription drug and biological products used on an outpatient basis without direct supervision by a health care professional. Questions have arisen concerning when a Medication Guide must be provided with a drug or biological product that is dispensed to a health care professional for administration to a patient in certain situations, for example, in an inpatient setting or an outpatient setting such as a clinic or infusion center. This guidance is intended to articulate the circumstances under which FDA intends to exercise enforcement discretion regarding Medication Guide distribution.

The second topic addressed by the guidance is when a Medication Guide

will be required as part of a REMS. Under section 505–1(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355–1(e)), FDA may require that a REMS for a drug include one or more of the elements described in section 505–1(e), including the requirement for an applicant to develop a Medication Guide for distribution to each patient when the drug is dispensed (when the criteria in part 208 (21 CFR part 208) are met). Since the enactment of the Food and Drug Administration Amendments Act of 2007, FDA has, as a matter of policy, considered any new Medication Guide (or safety-related changes to an existing Medication Guide) to be part of a REMS. However, the Agency has the authority to determine, based on the risks of a drug and public health concern, how a Medication Guide should be required when the standard in part 208 is met. Based on the risks and public health concern, the Agency may require: (1) A Medication Guide in accordance with part 208 that is not an element of a REMS or (2) A Medication Guide in accordance with part 208 and section 505–1 of the FD&C Act that is an element of a REMS, which may include other elements of a REMS (such as elements to assure safe use).

In the **Federal Register** of February 28, 2011 (76 FR 10908), FDA announced the availability of a draft guidance for industry entitled “Medication Guides—Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS).” The notice gave interested parties the opportunity to comment by May 31, 2011. The Agency considered all of the comments received and made minor editorial and clarifying changes to the guidance.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on when FDA intends to exercise enforcement discretion regarding Medication Guide distribution and inclusion of Medication Guides in REMS. 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. It is no longer necessary to

send two copies of mailed 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 guidance 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 314.70 and 601.12 have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively; the collections of information in part 208 have been approved under OMB control number 0910–0393.

## IV. Electronic Access

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

Dated: November 14, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To obtain a copy of the clearance requests submitted to OMB for review, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

#### **Proposed Project: National Survey of Organ Donation Attitudes and Practices (OMB No. 0915–xxxx)—[New]**

The Division of Transplantation (DoT), Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), is planning to conduct a telephone survey of public knowledge, perceptions, opinion, and behaviors related to organ donation. Two key missions of the DoT are (1) to provide oversight for the Organ Procurement and Transplantation Network and policy development related to organ donation and transplantation and (2) to implement efforts to increase public knowledge about the need for increased organ donation.

With a constantly growing deficit between the number of Americans needing donor organs (currently approximately 112,000) and the annual number of donors (14,505 in 2010), raising the American public’s willingness to donate becomes increasingly critical. Effective education and outreach campaigns need to be based on knowledge of the public’s attitudes and perceptions about, and perceived impediments to, organ donation. Two national surveys using nearly identical survey instruments to identify public views and behaviors related to organ donation were conducted in 1993 and 2005.

The proposed study will identify current organ donation views and practices of the American public and various population subgroups using a survey instrument similar to the two earlier studies in order to track changes over time. It will measure issues such as public knowledge about and attitudes toward organ donation, public commitment to or willingness to donate, impediments to public willingness to donate, and attitudes toward living donation, donation practices, policy issues, allocation policy, presumed consent, and financial incentives for donation. Demographic information also will be collected. The randomly drawn sample will consist of 3,250 adults (age 18 and over), including an oversample of Asians, Hispanics, African Americans, and Native Americans, and will be geographically representative of the United States. The survey instrument will be administered in both English and Spanish through computer-assisted telephone interviews.

In addition to being useful to the DoT (especially in its donation outreach initiatives), results of this survey also will be of assistance to the donation and transplant community, DoT grantees and other research efforts, and to the