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

SUPPLEMENTARY INFORMATION: On August 25, 2011, the Agency submitted a proposed collection of information entitled ''Premarket 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.

[FR Doc. 2011–29836 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–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