

expected to be safe. If the required premarket notification is not submitted to FDA, section 413(a) of the FD&C Act provides that the dietary supplement containing the NDI is deemed to be adulterated under section 402(f) of the FD&C Act (21 U.S.C. 342(f)). Even if the notification is submitted as required, the dietary supplement containing the NDI is adulterated under section 402(f) unless there is a history of use or other evidence of safety establishing that the NDI, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe.

To assist industry in complying with DSHEA, FDA issued a regulation, § 190.6 (21 CFR 190.6), to implement the FD&C Act's premarket notification requirements for dietary supplements that contain an NDI (62 FR 49886, September 23, 1997). The NDI regulation specifies the information the manufacturer or distributor must include in its premarket NDI notification (§ 190.6(b)) and establishes the administrative procedures for these notifications. FDA's goal in issuing the 1997 regulation was to ensure that NDI notifications contained the information that would enable FDA to evaluate whether a dietary supplement containing an NDI is reasonably expected to be safe.

On January 4, 2011, the President signed into law the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353). Section 113(b) of FSMA requires FDA to publish, not later than 180 days after the date of enactment, guidance that clarifies when a dietary supplement ingredient is an NDI, when the manufacturer or distributor of a dietary ingredient or dietary supplement should submit an NDI notification to FDA under section 413(a)(2) of the FD&C Act, the evidence needed to document the safety of an NDI, and appropriate methods for establishing the identity of an NDI. This draft guidance is being published to comply with section 113(b) of FSMA.

The draft guidance, when finalized, will represent the Agency's current thinking on NDIs and dietary supplements that contain NDIs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management

and Budget (OMB) for each collection of information they conduct or sponsor. This draft guidance contains proposed collections of information. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish a 60-day notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice on the proposed collections of information in this draft guidance in a future issue of the **Federal Register**.

This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR Part 111 have been approved under OMB control number 0901–0606, and the collections of information in § 190.6 have been approved under OMB control number 0910–0330.

## III. 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.

## IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>. Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: June 29, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

*Name:* Advisory Committee on Infant Mortality (ACIM).

*Dates and Times:* August 2, 2011, 9 a.m.–5 p.m. August 3, 2011, 9 a.m.–3 p.m.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814, (301) 657–1234.

*Status:* The meeting is open to the public with attendance limited to space availability.

*Purpose:* The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department of Health and Human Services' programs that focus on reducing infant mortality and improving the health status of infants and pregnant women; and factors affecting the continuum of care with respect to maternal and child health care. It includes outcomes following childbirth; strategies to coordinate the myriad of Federal, State, local and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start program and *Healthy People 2020* infant mortality objectives.

*Agenda:* Topics that will be discussed include the following: HRSA Update; MCHB Update; Healthy Start Program Update; Affordable Care Act and Infant Mortality; Quality Improvement in Perinatal Health Care; Patient Centered Medical Home; Centering Pregnancy, and Fetal Infant Mortality Review. Proposed agenda items are subject to change as priorities dictate.

Time will be provided for public comments limited to five minutes each. Comments are to be submitted in writing no later than 5 p.m. ET on July 19, 2011.

*For Further Information Contact:* Anyone requiring information regarding the Committee should contact Peter C. van Dyck, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration, Room 18–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, Telephone: (301) 443–2170.

Individuals who are submitting public comments or who have questions regarding the meeting and location should contact David S. de la Cruz, Ph.D., M.P.H., HRSA, Maternal and Child Health Bureau, telephone: (301) 443–0543, e-mail: [David.delaCruz@hrsa.hhs.gov](mailto:David.delaCruz@hrsa.hhs.gov).

Dated: June 28, 2011,

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

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