accompanying technical and/or professional codes, combination of codes billed), and costs must be submitted to us.

II. Provisions of This Notice

This notice informs interested parties of an opportunity to participate in the section 3113 Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration. The authorizing legislation requires us to conduct a Demonstration for a period of 2 years subject to a $100 million ($100,000,000) limit. The Demonstration will allow a direct payment to a laboratory for certain complex diagnostic laboratory tests in situations where, under the date of service rule (see 42 CFR 414.510(b)(2)(i)(A)), Medicare pays the hospital or CAH and the hospital or CAH, in turn, pays the laboratory (''under arrangement'') for laboratory tests.

This notice also serves to notify interested parties that they must obtain a temporary G code from CMS for tests currently billed using NOC codes that would otherwise meet the criteria set forth in section 3113(a)(2). Information about these tests is due to CMS no later than August 1, 2011. The purpose of the August deadline is to allow time for CMS to determine whether the test meets the criteria for a complex clinical laboratory test and to determine appropriate payment amounts for tests paid under the Demonstration. Payment under the Demonstration will begin on January 1, 2012.

For specific details regarding the section 3113 Demonstration, please refer to the CMS Web site at: *http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS1240611*.

III. Collection of Information Requirements

The burden discussed in this notice pertains to the time and effort necessary for interested parties to obtain a temporary G-code from CMS for tests currently billed using NOC codes that would otherwise meet the criteria set forth in section 3113(a)(2) for being a complex diagnostic laboratory test under the Demonstration. However, we believe that no more than nine entities will be eligible to meet those criteria, and therefore, while the aforementioned requirement is subject to the Paperwork Reduction Act (PRA) of 1995, the associated burden is exempt under 5 CFR 1320.3(c)(4). This will affect less than 10 entities in a 12-month period. Consequently, notice need not be reviewed by the Office of Management and Budget under the authority of the PRA.

Dated: May 4, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–16721 Filed 7–1–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0376]

Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; 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 ''Dietary Supplements: New Dietary Ingredient Notifications and Related Issues.'' The draft guidance, when finalized, will assist industry in deciding when a premarket safety notification for a dietary supplement containing a new dietary ingredient (NDI) is necessary and in preparing premarket safety notifications (also referred to as ''NDI notifications'').

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 the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 3, 2011.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. 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.

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: Corey Hilmas, Center for Food Safety and Applied Nutrition (HFS–850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2375.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Dietary Supplements: New Dietary Ingredient Notifications and Related Issues.'' This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115(g)(2)).

This draft guidance is intended to assist industry in deciding when a premarket safety notification for a dietary supplement containing an NDI is necessary and in preparing NDI notifications. The draft guidance discusses in question and answer format FDA's views on what qualifies as an NDI, when an NDI notification is required, the procedures for submitting an NDI notification, the types of data and information that manufacturers and distributors should consider when they evaluate the safety of a dietary supplement containing an NDI, and what should be included in an NDI notification. In addition, the draft guidance contains questions and answers about parts of the dietary supplement definition that can affect whether a particular substance may be marketed as a dietary ingredient in a dietary supplement.

On October 25, 1994, the Dietary Supplement Health and Education Act of 1994 (DSHEA) (Pub. L. 103–417) was signed into law. DSHEA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, among other provisions, (1) Section 201(ff) (21 U.S.C. 321(ff)), which defines the term ''dietary supplement'' and (2) section 413 (21 U.S.C. 350b), which defines the term ''new dietary ingredient'' and requires the manufacturer or distributor of an NDI, or of the dietary supplement that contains the NDI, to submit a premarket notification to FDA at least 75 days before introducing the supplement into interstate commerce or delivering it for introduction into interstate commerce, unless the NDI and any other dietary ingredients in the dietary supplement ''have been present in the food supply as an article used for food in a form in which the food has not been chemically altered'' (section 413(a)(1)). The notification must contain the information, including any citation to published articles, which is the basis on which the manufacturer or distributor of the NDI or dietary supplement has concluded that the dietary supplement containing the NDI will reasonably be

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.

[FR Doc. 2011–16711 Filed 7–1–11; 8:45 am]

BILLING CODE 4160–01–P

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.*

Dated: June 28, 2011,

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011–16717 Filed 7–1–11; 8:45 am]

BILLING CODE 4165–15–P