

Regulatory Secretariat (MVCB), 1800 F Street NW., 2nd Floor, Washington, DC 20405–0001, telephone 202–501–4755. ATTN: Hada Flowers/IC 3090–00xx; MyUSA. Please cite OMB Control No. 3090–XXXX; MyUSA, in all correspondence.

Dated: August 8, 2013.

**Casey Coleman,**

*Chief Information Officer.*

[FR Doc. 2013–19633 Filed 8–12–13; 8:45 am]

BILLING CODE 6820–34–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2012–N–0892]

#### **Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Communicating Composite Scores in Direct-to-Consumer Advertising**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Communicating Composite Scores in Direct-to-Consumer (DTC) Advertising” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

#### **FOR FURTHER INFORMATION CONTACT:**

Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, [daniel.gittleston@fda.hhs.gov](mailto:daniel.gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On May 16, 2013, the Agency submitted a proposed collection of information entitled “Communicating Composite Scores in Direct-to-Consumer (DTC) Advertising” 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 0910–0743. The approval expires on July 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: August 5, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–19523 Filed 8–12–13; 8:45 am]

BILLING CODE 4160–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2013–D–0880]

#### **Draft Guidance for Industry on Frequently Asked Questions About Medical Foods; Second Edition; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of the draft guidance for industry entitled “Frequently Asked Questions About Medical Foods; Second Edition.” The draft guidance, when finalized, will provide responses to additional questions regarding the definition, labeling, and availability of medical foods and updates to some of the existing responses.

**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 15, 2013.

**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 two self-addressed adhesive labels to assist that office in processing your request. 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:** Shawne Suggs-Anderson, Center for Food Safety and Applied Nutrition (HFS–850), Food and Drug Administration, 5100 Paint Branch

Pkwy., College Park, MD 20740, 240–402–1783.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

We are announcing the availability of a draft guidance for industry entitled “Frequently Asked Questions About Medical Foods; Second Edition.” This draft guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA’s current thinking on medical foods. 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.

We originally issued this guidance in May 2007. This draft guidance provides responses to additional questions regarding the definition, labeling, and availability of medical foods and updates to some of the existing responses.

##### **II. Paperwork Reduction Act of 1995**

This draft 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 PRA). The collections of information in sections 101.3, 101.4, 101.5, 101.15, and 101.105 of 21 CFR part 101 have been approved under OMB control number 0910–0381.

The labeling provisions recommended in this draft guidance in response to Question 13 are not subject to review by OMB because they do not constitute a “collection of information” under the PRA. Rather, the recommended labeling is a “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

##### **III. Comments**

Interested persons may submit either electronic comments regarding this draft guidance to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

#### IV. Electronic Access

Persons with access to the Internet may obtain this draft guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: August 7, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-19532 Filed 8-12-13; 8:45 am]

**BILLING CODE 4160-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2013-N-0001]

##### Pediatric Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Pediatric Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on September 19, 2013, from 10 a.m. to 5:30 p.m. and September 20, 2013, from 8 a.m. to 1 p.m.

*Location:* Doubletree Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910, 301-589-5200 or visit the hotel's Web site at <http://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-hotel-washington-dc-silver-spring-DCASSDT/index.html>.

*Contact Person:* Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993, 301-796-0885, email [walter.ellenberg@fda.hhs.gov](mailto:walter.ellenberg@fda.hhs.gov) or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://>

[www.fda.gov/AdvisoryCommittees/default.htm](http://www.fda.gov/AdvisoryCommittees/default.htm) and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On September 19, 2013, and September 20, 2013, the Pediatric Advisory Committee (PAC) will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109) and the for Pediatric Research Equity Act (Pub. L. 108-155).

On September 19, 2013, the PAC will meet to discuss Cervarix (human papillomavirus Bivalent (Types 16 and 18) vaccine); Gammagard Liquid (Immune Globulin Infusion (human)); Hemacord (hematopoietic progenitor cells, cord blood); Copegus and Pegasys (rivabirin and peginterferon alfa-2a); Chantix (varenicline tartrate); Isentress (raltegravir potassium); Intuniv (guanfacine), Topamax (topiramate); Faslodex (fulvestrant); Ixempra Kit (ixabepilone); and Plavix (clopidogrel bisulfate). An update on the drug program for KidNet will be provided. On September 20, 2013, the PAC will meet to discuss the Berlin Heart EXCOR Pediatric Ventricular Assist Device; Melody Transcatheter Pulmonary Heart Valve (TPV); and Elana Surgical Kit (HUD). On September 20, 2013, the committee will also receive and discuss a report on the September 9 and 10, 2013, meeting of the Pediatric Ethics Subcommittee of the PAC concerning their discussion of the ethical issues involved in the development of pediatric medical countermeasures.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 30, 2013. Oral presentations from the public will be scheduled on September 19, 2013, between approximately 11:30 a.m. and 12 noon, and on September 20, 2013,

between 10:30 a.m. and 11 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 22, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 26, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Walter Ellenberg at 301-796-0885, email [walter.ellenberg@fda.hhs.gov](mailto:walter.ellenberg@fda.hhs.gov), at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 6, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-19522 Filed 8-12-13; 8:45 am]

**BILLING CODE 4160-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2013-N-0001]

##### Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.