

[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.)

Dated: October 4, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-25976 Filed 10-6-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### General and Plastic Surgery Devices Panel of the Medical Devices 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:* General and Plastic Surgery Devices Panel of the Medical Devices 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 December 1, 2011, from 8 a.m. to 6 p.m.

*Location:* Hilton Washington, DC North/Gaithersburg, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD.

*Contact Person:* Avena Russell, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993-0002, 301-796-3805,

[Avena.Russell@fda.hhs.gov](mailto:Avena.Russell@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about

possible modifications before coming to the meeting.

*Agenda:* On December 1, 2011, the committee will discuss, make recommendations, and vote on information related to the premarket approval application, sponsored by Contura, Inc., for AQUAMID, a new material (polyacrylamide) for use as a dermal filler for aesthetic treatment of wrinkles in the face. The AQUAMID dermal filler is intended for use in mid-to-deep sub-dermal implantation for the aesthetic treatment of moderate to severe facial wrinkles and folds, such as the nasolabial folds. 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 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 November 22, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m., immediately following lunch. 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 November 14, 2011. 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 November 15, 2011.

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 AnnMarie Williams, Conference Management Staff, 301-796-5966, 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: October 4, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-25969 Filed 10-6-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0695]

#### Science of Abuse Liability Assessment; Public Workshop

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

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop to discuss the science of abuse liability assessment. The Controlled Substance Staff (CSS) in FDA's Center for Drug Evaluation and Research, Office of the Center Director; the National Institute on Drug Abuse (NIDA) at the National Institutes of Health; and the College on Problems of Drug Dependence (CPDD) at the Temple University School of Medicine are cosponsoring the 1-day workshop.

*Date and Time:* The public workshop will be held on Thursday, November 10, 2011, from 8 a.m. to 5 p.m.

*Location:* The public workshop will be held at The Legacy Hotel and Meeting Centre, 1775 Rockville Pike, Rockville, MD 20852, 301-881-2300, accessible on the Metro Red Line, Twinbrook Station.

*Contact Person:* Ellen B. Geller, CPDD, Temple University School of Medicine, 3400 North Broad Street, Philadelphia, PA 19140, 215-707-5307, e-mail: [ebgeller@temple.edu](mailto:ebgeller@temple.edu); or Corinne P. Moody, Center for Drug Evaluation and Research, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5144, Silver Spring, MD 20993-0002, 301-796-5402, e-mail: [Corinne.moody@fda.hhs.gov](mailto:Corinne.moody@fda.hhs.gov).

**Accommodations:** Attendees are responsible for their own accommodations. Reservations can be made on a space-available basis at The Legacy Hotel and Meeting Centre (see *Location*).

**Registration:** You are encouraged to register at your earliest convenience. A registration fee will be charged to help defray the costs of rental of the meeting spaces, meals and snacks provided, travel expenses incurred by invited speakers, and other costs. The registration fee is \$325. Registration fees will be waived for invited speakers and administrative personnel.

The registration process, including payment of the registration fee, will be handled by CPDD. Additional information on the workshop, program agenda, and registration procedures is available on the Internet at <http://www.seiservices.com/nida/1014102/>. (FDA has verified the NIDA Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

If you need special accommodations due to a disability, please contact Ellen B. Geller or Corinne Moody (see *Contact Person*) at least 7 days in advance of the workshop.

**Comments:** FDA is holding this public workshop to obtain information about the science of abuse liability assessment. The workshop will center on status, needs, new approaches, and paradigms regarding preclinical studies, challenges associated with human subject abuse potential studies, and adverse events that signal abuse potential during clinical trials. The deadline for submitting comments about this public workshop is January 10, 2012.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments regarding the issues presented at the workshop. Submit electronic comments 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. 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.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 27, 2010 (75 FR 4400), FDA announced the publication of a draft guidance for industry on "Assessment of Abuse Potential of Drugs," and requested comments on the draft guidance. There were 23 submissions to the docket with approximately 750 comments received from academia, industry, and the government. General and specific comments were received on every section of the draft guidance. The comment period has closed and FDA is gathering current information that may relate to some of the comments received. Questions remain, for example, about when abuse potential studies should be conducted, and about the signals of abuse or potential abuse observed in clinical trials. This workshop is another mechanism for continuation of discussion with interested stakeholders before FDA finalizes the draft guidance.

**Transcripts:** Please be advised that as soon as a transcript is available it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: October 3, 2011.

**David Dorsey,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2011-25918 Filed 10-6-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 76 FR 54236 dated August 31, 2011).

This notice reflects organizational changes to the Health Resources and

Services Administration. Specifically, this notice updates the Office of Information Technology (RB5) functional statement. The update to the functional statement will better align functional responsibility with improved security management capabilities and improved alignment of current security initiatives within the Office of Information Technology (RB5).

#### Chapter RB5—Office of Information Technology

##### Section RB5-10, Organization

The Office of Information Technology (RB5) is headed by the Director and Chief Information Officer, who reports directly to the Chief Operating Officer.

##### Section RB5-20, Functions

(1) Delete the functional statement for the Office of the Director (RB5) and replace in its entirety; and (2) delete the functional statement for the Division of IT Operational Support Services (RB58) and replace in its entirety.

##### Office of the Director (RB5)

The Chief Information Officer (CIO) is responsible for the organization, management, and administrative functions necessary to carry out the responsibilities of the CIO including: (1) Provides organizational development, investment control, budget formulation and execution, policy development, strategic and tactical planning, and performance monitoring; (2) provides leadership in the development, review and implementation of policies and procedures to promote improved information technology management capabilities and best practices throughout HRSA; and (3) coordinates IT workforce issues and works closely with the departmental Office of Human Resources Management on IT recruitment and training issues.

The Chief Information Security Officer (CISO), reporting to the CIO, provides leadership for, and collaborates with, Agency staff to oversee the implementation of security and privacy policy in the management of their IT systems, and plans all activities associated with Federal Information Security Management Act (FISMA) or other agency security and privacy initiatives, and also carries out the responsibilities including: (1) Implements, coordinates, and administers security and privacy programs to protect the information resources of HRSA in compliance with legislation, Executive Orders, directives of the Office of Management and Budget (OMB), or other mandated requirements e.g., Presidential Decision Directive 63,