Committee) is a Federal Advisory Committee established in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C., App 2. This notice announces the next GTAC meeting, which is open to the public via teleconference and webinar.

DATES: The upcoming GTAC meeting is scheduled for September 23, 2014 and will begin at 9:00 a.m. Eastern Standard Time and end no later than 4:00 p.m. Eastern Standard Time.

FOR FURTHER INFORMATION CONTACT: Ms. Marcerto Barr, Designated Federal Officer (DFO), Government-wide Travel Advisory Committee (GTAC), Office of Government-wide Policy, General Services Administration, 1800 F Street NW., Washington, DC 20405, 202–208–7654 or by email to: *gtac@gsa.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the GTAC is to conduct public meetings, submit reports and to make recommendations to existing travel policies, processes and procedures, including the per diem methodology to assure that official travel is conducted in a responsible manner with the need to minimize costs.

Authority: The GSA Office of Asset and Transportation Management, Travel and Relocation Division, establishes policy that governs travel by Federal civilian employees and others authorized to travel at Government expense on temporary duty travel through the Federal Travel Regulation (FTR).

Agenda: The meeting will cover Common Carrier, City Pair, and Standard Temporary Duty Travel (en-route) and a follow-up of previous meeting topics.

Meeting Access: The meeting is open to the public via teleconference and webinar. Members of the public wishing to listen in on the GTAC discussion are recommended to visit the GTAC Web site at *www.gsa.gov/gtac* for the meeting details. However, members of the public wishing to comment on the discussion or topics outlined in the agenda should follow the steps detailed in Procedures for Providing Public Comments.

Availability Of Materials For The Meeting: Please see the GTAC Web site *www.gsa.gov/gtac* for any available materials and detailed meeting notes after the meeting.

Procedures For Providing Public Comments: In general, public comments will be posted to *www.gsa.gov/gtac.* Non-electronic documents will be made available for public inspection and copying at GSA, 1800 F Street NW., Washington, DC 20405, on official business days between the hours of 10:00 a.m. Eastern Standard Time and 4:00 p.m. Eastern Standard Time. The public can make an appointment to inspect comments by telephoning the DFO at 202–208–7654. All comments, including attachments and other supporting materials received, are part of the public record and subject to public disclosure. Any comments submitted in connection with the GTAC meeting will be made available to the public under the provisions of the Federal Advisory Committee Act.

The public is invited to submit written comments within seven business days after each meeting by either of the following methods and cite Meeting Notice-GTAC–2014–03.

Electronic or Paper Comments: (1) Submit electronic comments to *gtac@gsa.gov;* or (2) submit paper comments to the attention of Ms. Marcerto Barr at GSA, 1800 F Street NW., Washington, DC 20405.

Dated: July 31, 2014.

Carolyn Austin-Diggs,

Acting Deputy Associate Administrator, Office of Asset and Transportation Management, Office of Government-wide Policy.

[FR Doc. 2014–18556 Filed 8–5–14; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0968]

Draft Guidance for Industry on Upper Facial Lines: Developing Botulinum Toxin Drug Products; 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 ''Upper Facial Lines: Developing Botulinum Toxin Drug Products.'' The purpose of this draft guidance is to assist sponsors with their clinical trial designs using botulinum toxin drug products intended for the treatment of upper facial lines. This draft guidance clarifies FDA's thinking on endpoint development and clinical trial design considerations for botulinum toxin drug products that present unique safety concerns.

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 this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 4, 2014.

ADDRESSES: Submit written requests for single copies of the draft 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. 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 document.

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: Cristina Attinello, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5181, Silver Spring, MD 20993–0002, 301–796–3986.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Upper Facial Lines: Developing Botulinum Toxin Drug Products.'' The purpose of this draft guidance is to assist sponsors with their clinical trial designs using botulinum toxin drug products intended for the treatment of upper facial lines. This draft guidance clarifies FDA's thinking on endpoint development and clinical trial design considerations for botulinum toxin drug products that present unique safety concerns related to the potential for local and distant spread of toxin effect.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing botulinum toxin drug products for upper facial lines. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document 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 the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18564 Filed 8–5–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0215]

In Vitro Companion Diagnostic Devices; Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''In Vitro Companion Diagnostic Devices.'' This guidance is intended to assist sponsors who are planning to develop a therapeutic product for which the use of an in vitro companion diagnostic device is essential for the therapeutic product's safe and effective use as well as sponsors planning to develop an in vitro companion diagnostic device that is intended to be used with a corresponding therapeutic product.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''In Vitro Companion Diagnostic Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. Alternatively, you may submit written requests for single copies of the 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 Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to the office that you are ordering from to assist in processing your request.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Mansfield, Center for Devices and Radiologic Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5676, Silver Spring, MD 20993–0002, 301–796–4664; or Christopher Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 22, Rm. 6462, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0017; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry and FDA staff entitled ''In Vitro Companion Diagnostic Devices.'' This guidance is intended to assist: (1) Sponsors who are planning to develop a therapeutic product (either a novel product or an existing product with a new indication) for which the use of an in vitro companion diagnostic device (or test) is essential for the therapeutic product's safe and effective use and (2) sponsors planning to develop an in vitro companion diagnostic device that is intended to be used with a corresponding therapeutic product. The guidance defines ''in vitro companion diagnostic device'' (also referred to as ''IVD companion diagnostic device'') and clarifies that in most circumstances, an IVD companion diagnostic device and its corresponding therapeutic product should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling.

Diagnostic tests have been used for many years to enhance the use of therapeutic products. Tests are also used during therapeutic product development to obtain the data FDA uses to make regulatory determinations. After a therapeutic product is commercially available for use, health care professionals may use a relevant diagnostic test, for example, to select the appropriate therapy for a particular patient or to optimize a dosing regimen. Recently, the development of therapeutic products for which the use of a diagnostic test is essential for the products to meet their labeled safety and effectiveness claims has become more common. For example, such a test can identify appropriate subpopulations for treatment or identify populations who should not receive a particular treatment because of an increased risk of a serious side effect. These new technologies are making it increasingly possible to individualize, or personalize, medical therapy by identifying patients who are most likely to respond, or who are at varying degrees of risk for a particular side effect.

FDA believes that use of an IVD companion diagnostic device with a therapeutic product raises important concerns about the safety and effectiveness of both the device and the therapeutic product. An erroneous test result could lead to withholding appropriate therapy or to administering inappropriate therapy. Health care professionals must be able to rely on information from IVD companion diagnostic devices to help make critical treatment decisions. FDA oversight of IVD companion diagnostic devices will help protect patients from treatment risks that could arise from IVD