COST OF REGISTRATION

Affiliation	Through August 6, 2013	After August 6, 2013
Member	$1,895	$2,095
Nonmember	2,144	2,344
Government/Health Authority Member	700	700
Government/Health Authority Nonmember*	800	800
Academic Member	700	700
Academic Nonmember*	800	800
Student Member	280	280
Student Nonmember*	310	310

* Applicable Nonmember rates.

Please visit PDA's Web site at *http://www.pda.org/pdafda2013* to confirm the prevailing registration fees. (FDA has verified the 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 Wanda Neal (see *Contact*), at least 7 days in advance of the conference.

Registration Instructions: To register, please submit your name, affiliation, mailing address, telephone, fax number, and email address, along with a check or money order payable to ''PDA.'' Mail your registration information along with your payment to: PDA, Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 200, Bethesda, MD 20814. To register via the Internet, go to PDA's Web site at *http://www.pda.org/pdafda2013.*

The registrar will also accept payment by major credit cards (VISA/American Express/MasterCard only). For more information on the meeting, or for questions on registration, contact PDA (see *Contact*).

Transcripts: Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The PDA/FDA Joint Regulatory Conference offers the unique opportunity for participants to join FDA representatives and industry experts in face-to-face dialogues. Each year, FDA speakers provide updates on current efforts affecting the development of global regulatory strategies, while industry professionals from some of today's leading pharmaceutical companies present case studies on how they employ global strategies in their daily processes.

Through a series of sessions and meetings, the conference will provide participants with the opportunity to hear directly from FDA experts and representatives of global regulatory authorities on best practices, including:

- Regulatory Submission and Meetings.
- Quality Risk Management Implementation.
- Manufacturing in the Future.
- Quality Systems.
- Regulatory Considerations During Development.
- Cell Therapy Innovations.
- Life Cycle Management.
- Process Validation.
- Validation FDA Guidance.
- Challenges of Contract Manufacturing Organizations.
- Contract Agreements.
- Drug Safety.
- Emerging Active Pharmaceutical Ingredients (API) Regulations.
- Investigations.
- Emerging API Regulations.
- User Fees.
- Excipient Best Practices.
- Good Manufacturing Practices Foreign Inspections Findings.
- Regulatory Process to Approval (Inspectional Readiness).
- Combination Products and Companion Diagnostics.

To help ensure the quality of FDA-regulated products, the workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by Government Agencies to small businesses.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07854 Filed 4–3–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0126]

Draft Compliance Policy Guide Sec. 100.250 Food Facility Registration—Human and Animal Food; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft Compliance Policy Guide Sec. 100.250 Food Facility Registration—Human and Animal Food (the draft CPG). The draft CPG, when finalized, will provide guidance for FDA staff on issues related to food facility registration under a section of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including the requirement that certain food facilities register with FDA, the requirement that registered facilities biennially renew their registrations with FDA, and FDA's authority to suspend a food facility's registration.

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 comments on this draft CPG before it begins work on the final version of the CPG, submit either electronic or written comments on the draft CPG by May 6, 2013.

ADDRESSES: Submit written requests for single copies of the draft CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-

addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

Submit electronic comments on the draft CPG 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: Mischelle B. Ledet, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–205–1165; or Kim R. Young, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9200.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft CPG entitled ''Compliance Policy Guide Sec. 100.250 Food Facility Registration—Human and Animal Food.'' The draft CPG is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will replace ''Compliance Policy Guide Sec. 110.300 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.''

Section 415 of the FD&C Act (21 U.S.C. 350d) requires owners, operators, or agents in charge of domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register their facilities with FDA, unless an exception applies (see 21 CFR 1.226 and 1.227). The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), enacted on January 4, 2011, amended section 415 of the FD&C Act in relevant part to require registrants for food facilities to submit additional registration information to FDA, and to require facilities required to register with FDA to renew such registrations biennially. FSMA also amended section 415 of the FD&C Act to provide FDA with authority to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that: (1) Created, caused, or was otherwise responsible for such reasonable probability; or (2) knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

The draft CPG is intended to provide guidance for FDA staff regarding enforcement of the food facility registration provisions of section 415 of the FD&C Act, including the requirement that certain food facilities register with FDA, the requirement that registered facilities biennially renew their registrations with FDA, and FDA's authority to suspend a food facility's registration. The draft CPG also contains information that may be useful for the regulated industry and to the public.

The draft CPG, when finalized, will represent the Agency's current thinking on food facility registration requirements of section 415 of the FD&C Act. 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

This draft guidance refers to previously approved collections of information found in FDA regulations and section 415 of the FD&C Act. 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 collections of information in 21 CFR 1.230 through 1.235 and section 415 of the FD&C Act have been approved under OMB Control No. 0910–0502.

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 draft CPG from FDA's Office of Regulatory Affairs history page. It may be accessed at *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm.* Guidance documents are also available at *http://www.regulations.gov.*

Dated: March 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–07809 Filed 4–3–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the joint meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the **Federal Register** of March 14, 2013 (78 FR 16271–16272). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31 rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *ACRHD@fda.hhs.gov,* or use the 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.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 14, 2013, FDA announced that a joint meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee would be held on April 18, 2013. On page 16272, in the first column, the *Agenda* portion of the document is changed to read as follows:

Agenda: The committee will discuss the efficacy and safety of new drug application (NDA) 22219, AVEED (testosterone undecanoate) intramuscular injection, submitted by Endo Pharmaceutical Solutions, Inc., for the proposed indication of replacement