

TABLE 1—CERTIFICATES AND USES

Type of certificate	Use
“Supplementary Information Certificate to Foreign Government Requests”.	For the export of products legally marketed in the United States.
“Exporter’s Certification Statement Certificate to Foreign Government”.	
“Exporter’s Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)”.	
“Supplementary Information Certificate of Exportability Requests”.	For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the FD&C Act.
Exporter’s Certification Statement Certificate of Exportability”.	
“Supplementary Information Certificate of a Pharmaceutical Product”.	Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license.
“Exporter’s Certification Statement Certificate of a Pharmaceutical Product”.	
“Supplementary Information Non-Clinical Research Use Only Certificate”.	For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the FD&C Act.
“Exporter’s Certification Statement (Non-Clinical Research Use Only)”.	

FDA will continue to rely on self-certification by manufacturers for the first three types of certificates listed in table 1 of this document. Manufacturers are requested to self-certify that they are in compliance with all applicable requirements of the FD&C Act, not only at the time that they submit their request to the appropriate center, but

also at the time that they submit the certification to the foreign government. The appropriate FDA centers will review product information submitted by firms in support of their certificate and any suspected case of fraud will be referred to FDA’s Office of Criminal Investigations for follow up. Making or submitting to FDA false statements on any documents may constitute violations of 18 U.S.C. 1001, with

penalties including up to \$250,000 in fines and up to 5 years imprisonment.

In the **Federal Register** of November 14, 2014 (79 FR 68277), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

FDA center and FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research ..... FDA 3613. FDA 3613a. FDA 3613b. FDA 3613c.	2,114	1	2,114	1	2,114
Center for Devices and Radiological Health ..... FDA 3613. FDA 3613a. FDA 3613c.	10,528	1	10,528	2	21,056
Center for Veterinary Medicine ..... FDA 3613. FDA 3613a. FDA 3613b.	855	1	855	1	855
Total .....					24,025

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 30, 2015.  
**Leslie Kux**,  
*Associate Commissioner for Policy*.  
 [FR Doc. 2015–02348 Filed 2–5–15; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2014–N–1168]

**Generic Drug User Fee Amendments of 2012; September 2014 Public Hearing on Policy Development; Reopening of Docket; Request for Comments**

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

**ACTION:** Notice; reopening of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the reopening of the docket to solicit public comment on certain topics related to implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA) and the GDUFA Commitment Letter that accompanies the legislation. A public hearing in September 2014 provided an opportunity for public input on future

policy priorities. FDA is seeking additional written comments from all interested parties, including, but not limited to, regulated industry, consumers, patients, caregivers, health care professionals, and patient groups.

**DATES:** Submit electronic or written comments by March 9, 2015.

**ADDRESSES:** 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. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Giaquinto, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 75, Rm. 1670, Silver Spring, MD 20993-0002, 240-402-7930, [elizabeth.giaquinto@fda.hhs.gov](mailto:elizabeth.giaquinto@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the Hatch-Waxman Amendments) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The Hatch-Waxman Amendments created section 505(j) of the FD&C Act (21 U.S.C. 355(j)), which established the abbreviated new drug application (ANDA) approval pathway, which allows lower-priced generic versions of previously approved innovator drugs to be approved and marketed.

On July 9, 2012, GDUFA was signed into law by the President to help speed the delivery of safe and effective generic drugs to the public and to reduce costs to industry. Under GDUFA, FDA agreed to certain obligations as laid out in the GDUFA Commitment Letter that accompanies the legislation.<sup>1</sup> To support these obligations, FDA is developing numerous guidance documents. At the time of the September 2014 public hearing, FDA had developed the following draft guidances for industry:<sup>2</sup>

<sup>1</sup> See Generic Drug User Fee Act Program Performance Goals and Procedures (GDUFA Commitment Letter) for fiscal years 2013 through 2017, available at <http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf>.

<sup>2</sup> The draft guidance documents referenced in this document are available on the FDA Drugs guidance Web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

- “ANDA Submissions—Content and Format of Abbreviated New Drug Applications”
- “ANDA Submissions—Refuse to Receive for Lack of Proper Justification of Impurity Limits”
- “ANDA Submissions—Amendments and Easily Correctable Deficiencies Under GDUFA”
- “ANDA Submissions—Prior Approval Supplements Under GDUFA”
- “Controlled Correspondence Related to Generic Drug Development”

##### II. Purpose and Scope of the September 2014 Public Hearing

###### A. GDUFA Implementation: Draft Guidance Documents

The purpose of the public hearing was to: (1) Solicit public comment on the five draft guidance documents described in section I that FDA had issued to facilitate implementation of GDUFA and (2) recommend future policy priorities, including recommendations for additional guidance topics to facilitate GDUFA implementation. We continue to solicit comments from interested members of the public, including industry, consumers, patient groups, caregivers, and health care professionals, on the following topics related to GDUFA implementation guidances:

- Are there comments on the five guidances described in section I?
- Are there GDUFA implementation issues related to the five draft guidances described in section I that have not been addressed?
- What other GDUFA implementation topics need the development of guidance?
- Are there any topics or issues related to generic drug development other than those related to GDUFA implementation that need the development of guidance?

###### B. GDUFA Implementation Related to Generic Drug Exclusivity

Another purpose of the hearing was to solicit feedback on issues that may arise in FDA’s consideration of 180-day exclusivity provided for in section 505(j)(5)(B)(iv) of the FD&C Act.

Timing of ANDA approval is directly affected by an applicant’s eligibility for 180-day exclusivity, and thus FDA’s consideration of any issues related to 180-day exclusivity is a component of approval actions. FDA decisions regarding 180-day exclusivity are fact-specific, and the facts that have the potential to determine eligibility for exclusivity may shift up to the time when an ANDA that is eligible for 180-day exclusivity, or another ANDA

referencing the same listed drug, is ready for approval.

With the enactment of GDUFA, FDA will take actions on pending applications consistent with the timeframes agreed upon in the GDUFA Commitment Letter. During the hearing, we sought input on possible processes FDA might introduce under GDUFA for making determinations on 180-day exclusivity, as described in the following questions:

- Should FDA’s consideration of eligibility for 180-day exclusivity for a specific drug product be a public process, including consideration of whether a first applicant has forfeited its eligibility for exclusivity under section 505(j)(5)(D) of the FD&C Act? If a public process is advisable, would it be so in all instances, or is there a subset of circumstances in which the process should be public? Also, what administrative mechanisms would best facilitate such a process?

- Legal challenges to FDA’s decisions on 180-day exclusivity often must be resolved on an expedited basis that can be inconvenient for the parties and the court. What legal or regulatory mechanisms, if any, are available to better facilitate FDA’s determination of and orderly resolution of sponsors’ challenges to 180-day exclusivity determinations?

- Are there other topics related to 180-day exclusivity on which you would like to comment?
- Are there topics related to 180-day exclusivity that would benefit from FDA guidance?

We continue to seek comment on these topics. When submitting input on the questions provided in this notice, we encourage commenters to consider FDA’s statutory and regulatory authorities, including any restrictions on FDA’s authority to disclose certain information related to unapproved ANDAs.

###### C. GDUFA Implementation and Potential First Generics

At the public hearing, we also sought comment on meeting the goals of the GDUFA Commitment Letter with regard to the “first generics” review prioritization category. Subsequent to that hearing, the Agency opened a separate, dedicated docket, Docket No. FDA-2014-N-1741, seeking comment on “first generic” criteria, as described in the **Federal Register** notice “Proposed Criteria for ‘First Generic’ Submissions for Purposes of Abbreviated New Drug Application Review Prioritization Under the Generic Drug User Fee Amendments; Establishment of a Public Docket.” This

docket opened on November 19, 2014, and closed on December 19, 2014. We are no longer seeking comment on the "first generic" review prioritization category at this time.

### III. How To Submit 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>.

Dated: February 2, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-02401 Filed 2-5-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0824]

#### Anesthetic and Analgesic Drug Products 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:* Anesthetic and Analgesic Drug Products 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 March 18, 2015, from 8 a.m. to 5 p.m.

*Location:* Holiday Inn Gaithersburg, Grand Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301-948-8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/>

*About Advisory Committees/ucm408555.htm.*

*Contact Person:* Stephanie L. Begansky, 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, email: [AADPAC@fda.hhs.gov](mailto:AADPAC@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> 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:* The committee will discuss new drug application (NDA) 022225, sugammadex sodium injection, submitted by Organon USA Inc., for the proposed indication of reversal of moderate or deep neuromuscular blockade induced by rocuronium or vecuronium.

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 March 4, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 February

24, 2015. 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 February 25, 2015.

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 Stephanie L. Begansky 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: February 2, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015-02408 Filed 2-5-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0179]

#### Training Program for Regulatory Project Managers; Information Available to Industry

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.