

onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

For those without Internet access, please contact Scott Winiecki, (see **FOR FURTHER INFORMATION CONTACT**) to register. If you need special accommodations due to a disability, please contact Scott Winiecki no later than September 1, 2017.

*Transcripts:* A transcript of the public workshop will be accessible at <https://www.regulations.gov> approximately 30 days after the workshop. It may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: April 18, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-08178 Filed 4-21-17; 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.

**DATES:** Pharmaceutical companies may send proposed agendas to the Agency by June 23, 2017.

**FOR FURTHER INFORMATION CONTACT:** Dan Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5480, Silver Spring, MD 20993-0002, 301-796-0578, [dan.brum@fda.hhs.gov](mailto:dan.brum@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

#### I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of

the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

#### II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

#### III. Site Selection

All travel expenses associated with the Site Tours Program will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA's

Office of Regulatory Affairs District Offices in the firms' respective regions. Firms that want to learn more about this training opportunity or that are interested in offering a site tour should respond by sending a proposed agenda by email directly to Dan Brum (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: April 17, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2007-D-0369]

#### Product-Specific Guidance for Naloxone Hydrochloride; New Draft Guidance for Industry; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a new draft guidance for industry on generic naloxone hydrochloride nasal spray entitled "Draft Guidance on Naloxone Hydrochloride." The new draft guidance, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for naloxone hydrochloride nasal spray.

**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 versions of the guidance, submit either electronic or written comments on the draft guidances by June 23, 2017.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2007-D-0369 for "Draft Guidance on Naloxone Hydrochloride." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be

made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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.

#### FOR FURTHER INFORMATION CONTACT:

Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993-0002, 301-796-5850.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products," which explained the process that would be used to make product-specific guidances available to the public on FDA's Web site at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a new draft guidance for generic naloxone hydrochloride nasal spray.

FDA initially approved new drug application 208411 for NARCAN (naloxone hydrochloride) nasal spray in November 2015. We are now issuing a new draft guidance for industry on generic naloxone hydrochloride nasal spray ("Draft Guidance on Naloxone Hydrochloride").

In November 2016, Adapt Pharma Operations Limited (APOL), manufacturer of the reference listed drug NARCAN nasal spray, submitted a citizen petition requesting that FDA refrain from approving any ANDA referencing NARCAN nasal spray unless certain conditions are satisfied, including conditions related to demonstrating BE. FDA has reviewed the issues raised in the citizen petition and is responding to it separately in the docket for that citizen petition (Docket No. FDA-2016-P-4094, available at <https://www.regulations.gov>).<sup>1</sup>

The new draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The new draft guidance, when finalized, will represent the current thinking of FDA on the design of BE studies to support ANDAs for naloxone hydrochloride nasal spray. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### II. Electronic Access

Persons with access to the Internet may obtain the draft guidances at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: April 18, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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<sup>1</sup> On January 31, 2017, Mucodel Pharma LLC (Mucodel) submitted a citizen petition requesting that FDA "refrain from approving any [intranasal] naloxone drug application (whether an NDA or ANDA) for the emergency treatment of a known or suspected opioid overdose until the FDA considers whether such application adequately addresses the reliability of [intranasal] naloxone in actual field use." (Docket No. FDA-2017-P-0663). This petition remains under review and FDA's issuance of the naloxone hydrochloride nasal spray product-specific guidance and its response to the citizen petition from APOL are not intended in any way to address the merits of the Mucodel citizen petition.