

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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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.

**FOR FURTHER INFORMATION CONTACT:**

Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993-0002, 301-796-5290, [Evella.Washington@fda.hhs.gov](mailto:Evella.Washington@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.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** On June 2 and 3, 2016, the committee will discuss recent reports and epidemiologic investigations of nontuberculous mycobacteria (NTM) infections associated with the use of heater-cooler devices during cardiac surgical procedures. FDA is convening this committee to seek expert scientific and clinical opinion related to contamination of heater-cooler devices, associated patient infections, and mitigation strategies based on available scientific information. The committee will make recommendations on: (1) The effectiveness of cleaning and disinfection methods for heater-cooler devices; (2) the amount and type of premarket data and information needed to demonstrate validation of cleaning and disinfection of heater-cooler devices in support of labeling claims and technical instructions; (3) appropriate risk mitigations to be implemented by manufacturers of heater-cooler devices

and/or hospital facilities to ensure patient safety during surgical procedures where these devices are used; and (4) appropriate guidelines and/or criteria based on a risk stratification schema for notifying patients who may have already been exposed to NTM during prior cardiac surgeries. Recommendations on these issues will assist FDA in minimizing patient exposure to infections that may result from contaminated heater-cooler devices.

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 May 19, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on June 2, 2016, and between approximately 9 a.m. and 10 a.m. on June 3, 2016. 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 May 11, 2016. 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 May 12, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA is establishing a docket for public comment on this document. The docket number is FDA-2016-N-1126. The docket will close on June 16, 2016. Comments received on or before May

19, 2016, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams, at [AnnMarie.Williams@fda.hhs.gov](mailto:AnnMarie.Williams@fda.hhs.gov), or 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: April 12, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2016-08737 Filed 4-14-16; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-D-1113]

**Data Integrity and Compliance With Current Good Manufacturing Practice; Draft Guidance for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Data Integrity and Compliance With CGMP." The purpose of the draft guidance is to clarify the role of data integrity in current good manufacturing practice (CGMP) for drugs. The draft guidance is in response to an increase in CGMP violations involving data integrity observed in recent CGMP inspections. When finalized, the draft guidance is intended to provide the Agency's current thinking on the creation and handling of data in accordance with CGMP requirements.

**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 June 14, 2016.

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

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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-2016-D-1113 for "Data Integrity and Compliance With CGMP." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://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 <http://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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Bldg, 4th Floor, Silver Spring, MD 20993-0002; the 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; or the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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:** Karen Takahashi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 4244, Silver Spring, MD 20993-0002, 301-796-3191; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 240-402-7911; or Jonathan Bray, Center for Veterinary Medicine (HFV-232), Food and Drug Administration, 7519 Standish Pl., Rm. 130, Rockville, MD 20855, 240-402-5623.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Data Integrity and Compliance With CGMP." Increased CGMP violations involving data integrity observed in recent CGMP inspections have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees. The purpose of this draft guidance is to clarify the role of data integrity in CGMP for drugs, as required in 21 CFR parts 210, 211, and 212.

The draft guidance addresses specific questions about how data integrity relates to compliance with CGMP for drugs, as well as more general data integrity concepts, in question and answer format. Parts of this draft guidance have been previously published on the FDA Web site in *Questions and Answers on Current Good Manufacturing Practices, Good Guidance Practices, Level 2 Guidance—Records and Reports (Q&A Level 2 guidance)*. When finalized, this draft guidance will replace the Q&A Level 2 guidance on data integrity in CGMP.

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 current thinking of FDA on data integrity and compliance with CGMP. 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. The Paperwork Reduction Act of 1995**

This draft 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 210 and 211 (CGMPs), 212 (PET CGMPs), and 21 CFR part 11 (electronic records and signatures) have been approved under OMB control numbers 0910–0139, 0910–0667, and 0910–0303, respectively.

### III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, or <http://www.regulations.gov>.

Dated: April 11, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–08683 Filed 4–14–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–N–0198]

#### **Xanodyne Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 8 New Drug Applications and 46 Abbreviated New Drug Applications for Propoxyphene Products; Correction**

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of March 10, 2014 (79 FR 13308). The document withdrew

approval of 8 new drug applications (NDAs) and 46 abbreviated new drug applications (ANDAs) for prescription pain medications containing propoxyphene from multiple applicants. The document failed to withdraw approval of NDA 017507, held by Xanodyne Pharmaceuticals, Inc. (Xanodyne). Xanodyne wrote to FDA asking the Agency to withdraw approval of NDA 017507 and waiving its opportunity for a hearing. FDA confirms the withdrawal of approval of NDA 017507.

#### **FOR FURTHER INFORMATION CONTACT:**

David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6254, Silver Spring, MD 20993–0002, 301–796–3601.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Monday, March 10, 2014, FR Doc. 2014–05063, on page 13308, the following correction is made:

On page 13308, in table 1, the following entry is added in numerical order by Application No.:

Application No.	Drug	Applicant or holder
NDA 017507 .....	Darvocet-N 100 (propoxyphene napsylate and acetaminophen) Suspension, 100 milligrams (mg)/650 mg/15 milliliters.	Xanodyne Pharmaceuticals, Inc., One Riverfront Pl., Newport, KY 41071.

Dated: April 11, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–08689 Filed 4–14–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2007–D–0369]

#### **Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA

announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

**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 June 14, 2016.

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

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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*

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- 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,