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. 2016–08689 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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 14, 2016.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

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,

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.

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 Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry. 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 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'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** on January 28, 2016 (81 FR 4913). This notice announces draft product-specific recommendations, either new or revised, that are posted on FDA's Web site.

II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available

FDA is announcing the availability of a new draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

Albendazole
Amlodipine besylate; perindopril arginine
Betamethasone dipropionate
Chlorpheniramine polistirex; codeine polistirex
Clobetasol propionate (multiple reference listed drugs)
Cobicistat; darunavir ethanolate
Daclatasvir dihydrochloride
Deferasirox
Doxycycline hyclate
Eluxadoline
Empagliflozin; linagliptin
Erythromycin ethylsuccinate
Ferric Carboxymaltose
Fluticasone furoate
Fluticasone furoate; Vilanterol trifenatate
Gefitinib
Glatiramer Acetate
Halobetasol propionate (multiple reference listed drugs)
Indacaterol Maleate
Isavuconazonium sulfate
Ivabradine hydrochloride
Ivacaftor
Ivacaftor; lumacaftor
Lenvatinib mesylate
Mometasone furoate (multiple reference listed drugs)
Oxaprozin
Oxybutynin chloride
Palbociclib
Sacubitril; valsartan
Sonidegib phosphate
Tazarotene
Triamcinolone acetonide (multiple reference listed drugs)

III. Drug Products for Which Revised Draft Product-Specific BE Recommendations Are Available

FDA is announcing the availability of a revised draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

Ciprofloxacin; Dexamethasone
Cyclosporine (multiple reference listed drugs)
Testosterone
Ticagrelor
Valganciclovir hydrochloride

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, go to *http://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when

finalized, will represent the current thinking of FDA on the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Electronic Access

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

Dated: April 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08682 Filed 4–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Request for nominations.

SUMMARY: The Health Resources and Services Administration (HRSA) is seeking nominations of qualified candidates to be considered for appointment as members of the Advisory Committee on Heritable Disorders in Newborns and Children (Committee). The Committee provides advice, recommendations, and technical information about aspects of heritable disorders and newborn and childhood screening to the Secretary of Health and Human Services. HRSA is seeking nominations of qualified candidates to fill three positions on the Committee.

Authority: Section 1111 of the Public Health Service (PHS) Act, Title XI, § 1111(g)(1) (42 U.S.C. 300b–10(g)(1)), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014. The Committee is governed by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), and 41 CFR part 102–3 and 41 CFR part 102–3, which set forth standards for the formation and use of advisory committees.

DATES: Written nominations for membership on the Committee must be received on or before May 16, 2016.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to Alaina Harris, Genetic Services Branch, Maternal and Child Health Bureau, Health Resources and Services Administration, *aharris@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Genetic Services Branch, Maternal and Child Health Bureau, HRSA, at *aharris@hrsa.gov* or (301) 443–0721. A copy of the Committee Charter and list of the current membership can be obtained by accessing the Advisory Committee Web site at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

SUPPLEMENTARY INFORMATION: The Committee is chartered under section 1111 of the Public Health Service (PHS) Act, 42 U.S.C. 300b–10, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2015 (Act). The Committee was established in 2003 to advise the Secretary of the U.S. Department of Health and Human Services regarding newborn screening tests, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. In addition, the Committee provides advice and recommendations to the Secretary concerning the grants and projects authorized under section 1109 of the PHS Act and technical information to develop policies and priorities for grants, including those that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling and health care services for newborns, and children having or at risk for heritable disorders.

The Committee is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App. 2), and 41 CFR part 102–3, which set forth standards for the formation and use of advisory committees. The Committee reviews and reports regularly on newborn and childhood screening practices for heritable disorders, recommends improvements in the national newborn and childhood heritable screening programs, and recommends conditions for inclusion in the Recommended Uniform Screening Panel (RUSP). The Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the RUSP and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13, non-grandfathered health plans and group and individual health insurance issuers are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (*i.e.,* in the individual market, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Nominations: HRSA is requesting nominations to fill three (3) positions for voting members to serve on the Committee. Nominations of potential candidates for consideration are being sought for individuals who are medical, technical, or scientific professionals with special expertise in the field of heritable disorders or in providing screening, counseling, testing, or specialty services for newborns and children at risk for heritable disorders; who have expertise in ethics (*i.e.,* bioethics) and infectious diseases and who have worked and published material in the area of newborn screening; members of the public having special expertise about or concern with heritable disorders; or representatives from such federal agencies, public health constituencies, and medical professional societies as determined to be necessary by the Secretary to fulfill the duties of the Advisory Committee established under subsection (b) of section 1111 of the Public Health Service (PHS) Act, 42 U.S.C. 300b–10, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2015 (Act). Interested applicants may self-nominate or be nominated by another individual and/or organization.

Individuals selected for appointment to the Committee will be invited to serve for up to 4 years. Members who are not federal officers or permanent federal employees are appointed as special government employees and receive a stipend and reimbursement for per diem and any travel expenses incurred for attending Committee meetings and/or conducting other business on behalf of the Committee, as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service. Members who are officers or employees of the United States Government shall not receive additional compensation for service on the Committee, but receive per diem and travel expenses incurred for attending Committee meetings and/or conducting other business on behalf of the Committee. Nominees will be invited to serve during calendar year 2017.

The following information must be included in the package of materials