

burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by May 29, 2018.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

**CMS-10148 HIPAA Administrative Simplification (Non-Privacy/Security) Complaint Form**

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* Revision of the currently approved collection.; *Title of Information Collection:* HIPAA Administrative Simplification (Non-Privacy/Security) Complaint Form; *Use:* The authority for administering and enforcing compliance with the non-privacy/security Health Insurance Portability and Accountability Act (HIPAA) rules has been delegated to the Centers for Medicare & Medicaid Services (CMS). At present, CMS' compliance and enforcement activities are primarily complaint-based. Although our enforcement efforts are focused on investigating complaints, they may also include conducting compliance reviews to determine if a covered entity is in compliance. Potential violations can come through a complaint form or a compliance review.

This standard form collects identifying and contact information of the complainant, as well as, the identifying and contact information of the filed against entity (FAE). This information enables CMS to respond to the complainant and gather more information if necessary, and to contact the FAE to discuss the complaint and CMS' findings.

In addition to the identifying and contact information, the standard form collects a summary which outlines the nature of the complaint. This summary is used to determine the validity of the complaint, and to categorize the complaint as related to transactions, standards, code sets, unique identifiers, and/or operating rules. This ensures the

appropriate direction of the complaint process and enables CMS to produce accurate reports regarding complaint activity.

The revision form associated with this submission adds an option for filing complaints under Unique Identifier and Operating Rules. It also requests an email address for filed against entities, if available. *Form Number:* CMS-10148 (OMB Control number: 0938-0948); *Frequency:* Occasionally; *Affected Public:* Individuals; *Number of Respondents:* 125; *Total Annual Responses:* 125; *Total Annual Hours:* 125. (For policy questions regarding this collections contact Kevin Steward at 410-786-6149.)

Dated: March 26, 2018.

**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2018-06312 Filed 3-28-18; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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

**Product-Specific Guidance for Doxycycline Hyclate; Revised 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 revised draft guidance for industry on generic doxycycline hyclate oral delayed-release tablets, entitled "Product-Specific Guidance for Doxycycline Hyclate." The revised 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 doxycycline hyclate oral delayed-release tablets.

**DATES:** Submit either electronic or written comments on the draft guidance by May 29, 2018 to ensure that the Agency considers your comments on the draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time 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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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 "Product-Specific Guidance for Doxycycline Hyclate; Revised Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," will be publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 Dockets Management Staff. 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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 (HFD-600), 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 "Guidance for Industry on Bioequivalence Recommendations for Specific Products" that explained the process that would be used to make product-specific guidances available to

the public on FDA's website at <https://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/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 revised draft guidance for generic doxycycline hyclate oral delayed-release tablets.

FDA initially approved new drug application (NDA) 050795 for DORYX (doxycycline hyclate oral delayed-release tablets) in May 2005. In May 2009, FDA issued a draft guidance for industry on generic doxycycline hyclate oral delayed-release tablets and most recently revised that guidance in June 2015. On May 20, 2016, FDA approved a supplement to NDA 050795 for a new formulation of doxycycline hyclate delayed-release tablets in equivalent to (EQ) 60 milligram (mg) and EQ 120 mg strengths under the trade name Doryx MPC. We are now issuing another revised draft guidance for industry on doxycycline hyclate oral delayed-release tablets to include recommendations for demonstrating bioequivalence to these strengths.

In November 2016, Mayne Pharma International Pty Ltd submitted a citizen petition requesting that FDA require certain in vitro dissolution criteria as part of the BE demonstration for any ANDA referencing DORYX MPC. FDA has reviewed the issues raised in this citizen petition and is responding to the citizen petition separately in the docket for that citizen petition (Docket No. FDA-2016-P-4047, available at <https://www.regulations.gov>).

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on the design of BE studies to support ANDAs for doxycycline hyclate oral delayed-release tablets. 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. This guidance is not subject to Executive Order 12866.

##### II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: March 20, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-06253 Filed 3-28-18; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-0875]

#### Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on May 22, 2018, from 8 a.m. to 4:30 p.m.

**ADDRESSES:** College Park Marriott Hotel and Conference Center, General Vessey Ballroom, 3501 University Blvd., Hyattsville, MD 20783. The conference center's telephone number is 301-985-7300. Answers to commonly asked questions about FDA Advisory Committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>. Information about the College Park Marriott Hotel and Conference Center can be accessed at: <https://www.marriott.com/hotels/travel/wasum-college-park-marriott-hotel-and-conference-center/>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2018-N-0875. The docket will close on May 21, 2018. Submit either electronic or written comments on this public meeting by May 21, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 21, 2018. The <https://www.regulations.gov>

electronic filing system will accept comments until midnight Eastern Time at the end of May 21, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before May 8, 2018, will be provided to the committees. Comments received after that date will be taken into consideration by FDA.

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):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2018-N-0875 for "Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug

Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received comments, those filed in a timely manner (see the **ADDRESSES** section), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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." FDA 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 Dockets Management Staff. If you do not wish your name and contact information 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 the 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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Moon Hee V. Choi, 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