

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 021381 .....	XYLOCAINE DENTAL WITH EPINEPHRINE.	Epinephrine; Lidocaine Hydrochloride.	0.01 mg/mL/2%; 0.02 mg/mL/2%.	Injectable; Injection .....	DENTSPLY Pharmaceutical, Inc.
NDA 021511 .....	COPEGUS .....	Ribavirin .....	200 mg; 400 mg .....	Tablet; Oral .....	Hoffmann La-Roche, Inc.
NDA 022325 .....	NEXTERONE .....	Amiodarone Hydrochloride	50 mg/mL .....	Injectable; Injection .....	Baxter Healthcare, Corp.
NDA 050605 .....	CEFTIN .....	Cefuroxime Axetil .....	EQ 125 mg Base; EQ 250 mg Base; EQ 500 mg Base.	Tablet; Oral .....	GlaxoSmithKline.
NDA 050730 .....	ZITHROMAX .....	Azithromycin .....	EQ 600 mg Base .....	Tablet; Oral .....	Pfizer, Inc.
NDA 050746 .....	BACTROBAN .....	Mupirocin Calcium .....	EQ 2% Base .....	Cream; Topical .....	GlaxoSmithKline.
NDA 205103 .....	YOSPRALA .....	Aspirin; Omeprazole .....	81 mg/40 mg; 325 mg/40 mg.	Delayed-Release Tablet; Oral.	Genus Lifesciences, Inc.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 24, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-21201 Filed 9-30-19; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-D-4247]

#### Patient-Focused Drug Development: Methods To Identify What Is Important to Patients; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability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, FDA staff, and other stakeholders entitled “Patient-Focused Drug Development: Methods

To Identify What Is Important to Patients.” This guidance (Guidance 2) is the second in a series of four methodological guidance documents that FDA committed to develop to describe how to collect and submit information from patients and caregivers to be used for medical product development and regulatory decision-making.

**DATES:** Submit either electronic or written comments on the draft guidance by December 30, 2019 to ensure that the Agency considers your comment on this 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-2019-D-4247 for “Patient-Focused Drug Development: Methods To Identify What Is Important to Patients.” 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 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 this 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, or to 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. 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:** Meghana Chalasani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993-0002, 240-402-6525, Fax: 301-847-8443, [Meghana.Chalasani@fda.hhs.gov](mailto:Meghana.Chalasani@fda.hhs.gov); or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

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

FDA is announcing the availability of a draft guidance for industry, FDA staff, and other stakeholders entitled "Patient-Focused Drug Development: Methods To Identify What Is Important to Patients." This guidance (Guidance 2) is the second in a series of four methodological patient-focused drug development guidance documents that FDA committed to develop to describe how stakeholders (patients, researchers, medical product developers, and others) can collect and submit information from patients and caregivers to be used for medical product development and

regulatory decision-making. This series of guidance documents is intended to facilitate the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can more consistently inform medical product development and regulatory decision-making. The purpose of Guidance 2 is to present a range of methods and established best research practices to identify what is important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient's disease. The methods and best practices presented can help elicit relevant information from patients and other stakeholders, such as how their disease affects their daily lives; what they find most troublesome; and the challenges, problems, and burdens of the treatment for the disease.

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 "Patient-Focused Drug Development: Methods To Identify What Is Important to Patients." 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. Additional Information**

Section 3002 of Title III, Subtitle A of the 21st Century Cures Act (Pub. L. 114-255), directs FDA to develop patient-focused drug development guidance to address a number of areas, including under section 3002(c)(2) (methodological approaches that may be used to develop and identify what is important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient's disease).

In addition, FDA committed to meet certain performance goals under the sixth authorization of the Prescription Drug User Fee Act. These goal commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders, as part of negotiations with regulated industry. Section J.1 of the commitment letter, "Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making" (available at <https://www.fda.gov/media/99140/download>), outlines work, including the development of a series of guidance documents and associated public workshops to facilitate the advancement

and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can more consistently inform drug development, and, as appropriate, regulatory decision-making.

##### **III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: September 25, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; RNCP-Wide Dosimetry Guidance & Monitoring of Sources and Irradiation Protocols (Clinical Trial Not Allowed).

*Date:* October 22, 2019.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892.

*Contact Person:* Louis A. Rosenthal, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Rm 3G42B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9834, Bethesda, MD 20892-9834, (240) 669-5070, [rosenthalla@niaid.nih.gov](mailto:rosenthalla@niaid.nih.gov).