

• 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include the Docket No. FDA-2017-D-5912 for “Pediatric Gastroesophageal Reflux Disease: Developing Drugs for Treatment; Draft Guidance for Industry; Availability.” 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 <http://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:

Stacy Barley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 2642, Silver Spring, MD 20993-0002, 301-796-2137.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Pediatric Gastroesophageal Reflux Disease: Developing Drugs for Treatment.” The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of GERD in the pediatric patient population, including guidance on clinical presentation by age and disease, study populations, endpoints, and pharmacometric issues affecting dosing.

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 the development of drugs for the treatment of GERD in the pediatric patient population. 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. The Paperwork Reduction Act of 1995

This 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 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either 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

Dated: October 23, 2017.

**Anna K. Abram,**

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

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-5896]

#### Patient-Focused Drug Development: Guidance 1—Collecting Comprehensive and Representative Input; Public Workshop; Request for Comments

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

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop to convene a discussion on methodological approaches that a person seeking to collect patient experience data for submission to FDA to inform regulatory decision making may use. The methods and approaches would be considered relevant and objective, and ensure that collected data are accurate and representative of the intended population, including methods to collect meaningful patient input throughout the drug development process and methodological considerations for data collection, reporting, management, and analysis. This workshop will inform development of patient-focused drug development

guidance as required by the 21st Century Cures Act (Cures Act), and as part of commitments made by FDA under the sixth reauthorization of the Prescription Drug User Fee Act (PDUFA VI). FDA will publish a discussion document approximately 1 month before the workshop date. FDA is interested in seeking information and comments on the approaches proposed in the discussion document. FDA is also interested in input on examples where the approaches proposed in the discussion document have been successfully applied that could be illustrated in the draft guidance.

**DATES:** The public workshop will be held on December 18, 2017, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by February 16, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. Workshop updates, agenda, and discussion document will be made available at: <https://www.fda.gov/Drugs/NewsEvents/ucm574725.htm> prior to the workshop.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 16, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of February 16, 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.

#### 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-2017-N-5896 for "Patient-Focused Drug Development: Guidance 1—Collecting Comprehensive and Representative Input; Public Workshop; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

**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).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

This public workshop is intended to support FDA implementation of requirements for guidance development under section 3002 of the Cures Act and to meet a performance goal included in the sixth reauthorization of PDUFA VI. This reauthorization, part of the FDA Reauthorization Act of 2017 (FDARA) signed by the President on August 18, 2017, includes a number of performance goals and procedures that are documented in the PDUFA VI Commitment Letter, which is available at <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>.

Section 3002 of Title III, Subtitle A of the Cures Act directs FDA to develop patient-focused drug development guidance to address a number of areas including under section 3002(c)(1): Methodological approaches, which are relevant and objective and ensure that such data are accurate and representative of the intended population, that a person seeking to

collect patient experience data to inform regulatory decision making may use.

In addition, FDA committed to meet certain performance goals under PDUFA VI. These goal commitments were developed in consultation with patient and consumer advocates, health care 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," (<https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>) 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 utilize robust and meaningful patient and caregiver input that can more consistently inform drug development, and, as appropriate, regulatory decision making.

Prior to the issuance of each guidance, as part of the development, FDA will conduct a public workshop to gather input from the wider community of patients, patient advocates, academic researchers, expert practitioners, drug developers, and other stakeholders.

## II. Purpose and Scope of Meeting

FDA is announcing a public workshop to convene a discussion on topics related to approaches to collecting comprehensive and representative patient and caregiver input on burden of disease and current therapy. The purpose of this public workshop is to obtain feedback from stakeholders on considerations for: (1) Standardized nomenclature and terminologies for patient-focused drug development, (2) methods to collect meaningful patient input throughout the drug development process, and (3) methodological considerations for data collection, reporting, management, and analysis of patient input. FDA is seeking information and comments from a broad range of stakeholders, including patients, patient advocates, academic and medical researchers, expert practitioners, drug developers, and other interested persons. FDA will publish a discussion document outlining the topic areas that will be addressed in the draft guidance. This document will be published approximately 1 month before the workshop date on the Web site at: <https://www.fda.gov/Drugs/NewsEvents/ucm574725.htm>. FDA is interested in seeking information and comments on the approaches and considerations proposed in the discussion document,

as well as the examples provided. FDA is also interested in seeking information and comments on additional examples where the approaches proposed in the discussion document have been successfully applied that could be included in guidance. After this public workshop, FDA will take into consideration the stakeholder input from the workshop and the public docket, and publish a draft guidance by the end of the third quarter of fiscal year 2018.

**Registration:** Interested parties are encouraged to register early. To register electronically, please visit: <https://pfdd.eventbrite.com>. Persons without access to the internet can call 240-402-6525 to register. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability.

If you need special accommodations because of a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

**Request for Oral Presentations:** There will be time allotted during the workshop for open public comment. Sign-up for this session will be on a first-come, first-serve basis on the day of the workshop. Individuals and organizations with common interests are urged to consolidate or coordinate, and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

**Transcripts:** As soon as a transcript is available, FDA will post it at <https://www.fda.gov/Drugs/NewsEvents/ucm574725.htm>.

Dated: October 23, 2017.

**Anna K. Abram,**

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

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-P-2660]

#### Determination That CARDENE SR (Nifedipine HCl) Extended-Release Capsules, 30 Milligrams, 45 Milligrams, and 60 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that CARDENE SR (nifedipine HCl) extended-release capsules, 30 milligrams (mg), 45 mg, and 60 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for nifedipine HCl extended-release capsules, 30 mg, 45 mg, and 60 mg, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:**

Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993-0002, 301-796-6650.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the listed drug, which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is known generally as the Orange Book. Under FDA regulations, drugs are removed from the list if the Agency