on the collection of information by May 5, 2017.''

Under the **ADDRESSES** section, page 11471, column two, correct the notice to read: ''Submit electronic comments on the collection of information to: *cilpprcomments@acl.hhs.gov*''.

Under the heading ''New Requirements'', the first paragraph, page 11472, column one, replace the first paragraph with the following paragraph below:

''The Workforce Innovation and Opportunity Act (WIOA), enacted on July 22, 2014, added a new core service to the list of ''independent living core services'' that ACL funded Centers for Independent Living (CILs) are required to provide. Prior to WIOA, CILs were required to provide the following core services: (1) Information and referral services; (2) independent living skills training; (3) peer counseling, including cross-disability peer counseling; (4) and individual and systems advocacy. WIOA added additional ''transition and diversion'' core services comprised of three components. It requires CILs to:''.

Dated: February 24, 2017.

Daniel P. Berger,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2017–04169 Filed 3–3–17; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0136]

Public Meeting on Patient-Focused Drug Development for Autism; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for autism. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of autism on daily life as well as patient views on treatment approaches for autism.

DATES: The public meeting will be held on May 4, 2017, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by April 24, 2017 (see **SUPPLEMENTARY INFORMATION** for instructions). Submit either electronic or written comments on the public meeting by July 5, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 5, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 5, 2016. 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. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

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):* 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–2017–N–0136 for ''Public Meeting on Patient-Focused Drug Development for Autism.'' Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://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 *https://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: *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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FDA will post the agenda approximately 5 days before the meeting at: *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm529043.htm.*

FOR FURTHER INFORMATION CONTACT: Shanon Woodward, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1141, Silver Spring, MD 20993–0002, 240–402–6167, FAX: 301–847–8443, *shanon.woodward@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected autism as the focus of a public meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patient perspectives on the severity of a disease and the available therapies for that condition. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments that are part of the reauthorization of the PDUFA under Title I of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144). The full set of performance commitments is available at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA committed to obtain the patient perspective on at least 20 disease areas during the course of PDUFA V. For each disease area, the Agency is conducting a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On April 11, 2013, FDA published a notice in the **Federal Register** (78 FR 08441) announcing the disease areas for meetings in fiscal years (FYs) 2013–2015, the first 3 years of the 5-year PDUFA V time frame. The Agency used several criteria outlined in that notice to develop the list of disease areas. FDA obtained public comment on the Agency's proposed criteria and potential disease areas through a public docket and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. FDA initiated a second public process for determining the disease areas for FY 2016–2017, and published a notice in the **Federal Register** on July 2, 2015, announcing the selection of eight disease areas. More information, including the list of disease areas and a general schedule of meetings, is posted at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm347317.htm.*

II. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will obtain input of patients and patient representatives on the symptoms of autism that matter most to patients and on current approaches to treating autism. Autism is a neurodevelopmental disorder characterized in varying degrees by difficulties with social interaction, verbal and non-verbal communication challenges, and repetitive behavior patterns. FDA has approved products for irritability related to autism including risperidone and aripiprazole. In addition to pharmacological treatments, behavioral and educational interventions are also common treatment options. FDA is interested in the perspectives of patients with autism and caregivers on (1) symptoms and the daily impacts of their condition, (2) current approaches to treatment, and (3) decision factors taken into account when selecting a treatment.

The questions that will be asked of patients and patient representatives at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient/caregiver panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient representative participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see **ADDRESSES**).

Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

(1) Of all the symptoms that you/your child experiences because of the condition, which 1–3 symptoms have the most significant impact on your/your child's life? (Examples may include behavioral symptoms, difficulty with motor coordination, difficulty sleeping, difficulty concentrating, seizures, etc.)

(2) Are there specific activities that are important to you/your child but that you/your child cannot do at all or as fully as you would like because of these symptoms? (Examples of activities may include sleeping through the night, daily hygiene, eating, dressing, participation in sports or social activities, etc.)

(a) How do these symptoms and their negative impacts affect daily life on the best days? On the worst days?

(3) How has your/your child's condition and its symptoms changed over time?

(4) What worries you/your child most about your/your child's condition?

Topic 2: Patients' Perspectives on Current Approaches to Treating

(1) What are you/your child currently doing to help treat the condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies such as behavioral interventions)

(a) How has your/your child's treatment regimen changed over time, and why?

(2) How well does your/your child's current treatment regimen treat the most significant symptoms of the condition?

(a) How well do your/your child's treatments address specific activities that are important to you/your child's daily life?

(b) How well have these treatments worked for you/your child as the condition has changed over time? Which symptoms are not addressed as well?

(3) What are the most significant downsides to your/your child's current treatments, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, interacts with other medications, time devoted to treatment, etc.)

(4) What specific things would you look for in an ideal treatment for your/your child's condition?

(a) What would you consider to be a meaningful improvement (for example symptom improvements or functional improvements) in your/your child's condition that a treatment could provide?

(5) What factors do you/your child take into account when making decisions about selecting a course of treatment?

(a) What information on potential benefits of these treatments factors most into your/your child's decision?

(b) How do you/your child weigh the potential benefits of these treatments versus the common side effects of the treatments? (Common side effects could include headache, nausea, fatigue, weight gain)

(c) How do you/your child weigh potential benefits of these treatments versus the less common but serious risks associated with the treatments? (Examples of less common but serious risks are infections, organ damage or failure, suicidal thoughts)

III. Meeting Attendance and Participation

If you wish to attend this meeting, visit *https://autismpfdd.eventbrite.com*. Persons interested in attending this public meeting must register by April 24, 2017. 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. Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. 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 Shanon Woodward (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients and patient representatives who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients and patient representatives also must send to *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by April 17, 2017. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient representatives who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *https://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A link to the transcript will also be available on the Internet at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm529043.htm*.

Dated February 28, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–04229 Filed 3–3–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–P–1725]

Determination That FLONASE (Fluticasone Propionate) Nasal Spray, 0.05 Milligram, Was 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 prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 milligram (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and this determination will allow FDA to continue to approve ANDAs for fluticasone propionate nasal spray, 0.05 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David Faranda, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 301–796–8767.

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 withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, is the subject of NDA 020121, held by GlaxoSmithKline, and initially approved on October 19, 1994. FLONASE is indicated for the management of the nasal symptoms of perennial nonallergic rhinitis in adult and pediatric patients aged 4 years and older.

In a letter dated May 25, 2016, GlaxoSmithKline notified FDA that prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated June 20, 2016 (Docket No. FDA–2016–P–1725), under 21 CFR 10.30, requesting that the Agency determine whether prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, from