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:.

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. 1502), 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 docket, 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
obtained public comment on the

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 months 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/ucm529043.htm.


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 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 months to develop the list of disease areas. FDA obtained public comment on the
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), 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 the files for records concerning the withdrawal of prescription FLONASE (fluticasone propionate) Nasal Spray, 0.05 mg, from


Leslie Kux, Associate Commissioner for Policy.

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BILLING CODE 4164–01–P