attribute this adjustment to an increase in the number of entities submitting tobacco user fee information to FDA.

Dated: September 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19664 Filed 9–10–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3262]

Determination That CEFZIL (Cefprozil) Tablets, 250 Milligrams and 500 Milligrams, and for Oral Suspension, 125 Milligrams/5 Milliliters and 250 Milligrams/5 Milliliters, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 CEFZIL (cefprozil) tablets, 250 milligrams (mg) and 500 mg and CEFZIL (cefprozil) for oral suspension, 125 mg/5 milliliters (mL) and 250 mg/5 mL were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to continue to approve abbreviated new drug applications (ANDAs) that refer to these drugs as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Diana J. Pomeranz, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6288, Silver Spring, MD 20993–0002, 240–402–4654.

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 (FD&C 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.

Under § 314.161(a)(2), the Agency must also determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness if ANDAs that referred to the listed drug have already been approved prior to its market withdrawal. If the Agency determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, and there are approved ANDAs that reference that listed drug, FDA will initiate a proceeding to determine whether the suspension of the ANDAs is also required (21 CFR 314.153(b)).

CEFZIL (cefprozil) tablets, 250 mg and 500 mg, are the subject of NDA 050664 held by Corden Pharma Latina S.p.A., and initially approved on December 23, 1991. CEFZIL (cefprozil) for oral suspension, 125 mg/5 mL and 250 mg/5 mL, is the subject of NDA 050665 held by Corden Pharma Latina S.p.A., and initially approved on December 23, 1991. CEFZIL is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below:

- Upper respiratory tract: Pharyngitis/tonsillitis caused by *Streptococcus pyogenes;* otitis media caused by *Streptococcus pneumoniae, Haemophilus influenzae* (including β-lactamase-producing strains), and *Moraxella (Branhamella) catarrhalis* (including β-lactamase-producing strains); and acute sinusitis caused by *Streptococcus pneumoniae, Haemophilus influenzae* (including β-lactamase-producing strains), and *Moraxella (Branhamella) catarrhalis* (including β-lactamase-producing strains);
- Lower respiratory tract: Acute bacterial exacerbation of chronic bronchitis caused by *Streptococcus pneumoniae, Haemophilus influenzae* (including β-lactamase-producing strains), and *Moraxella (Branhamella) catarrhalis* (including β-lactamase-producing strains); and
- Skin and skin structure: Uncomplicated skin and skin-structure infections caused by *Staphylococcus aureus* (including penicillinase-producing strains) and *Streptococcus pyogenes.* Abscesses usually require surgical drainage.

In a letter dated September 7, 2010, Bristol-Myers Squibb [1] notified FDA that CEFZIL (cefprozil) tablets, 250 mg and 500 mg and CEFZIL (cefprozil) for oral suspension, 125 mg/5 mL and 250 mg/5 mL, were discontinued from sale, and FDA moved the drug products to the ''Discontinued Drug Product List'' section of the Orange Book. Later, Corden Pharma Latina S.p.A. notified the Agency in writing that these drug products were no longer marketed and requested that the approval of the applications be withdrawn. In the **Federal Register** of June 21, 2017 (82 FR 28322 at 28326), the Agency issued a notice withdrawing approval of the applications, effective July 21, 2017.

After reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CEFZIL (cefprozil) tablets, 250 mg and 500 mg, and CEFZIL (cefprozil) for oral suspension, 125 mg/5 mL and 250 mg/5 mL, were not withdrawn from sale for reasons of safety or effectiveness.

We note that CEFZIL (cefprozil) tablets, 250 mg and 500 mg, and CEFZIL (cefprozil) for oral suspension, 125 mg/5 mL and 250 mg/5 mL, previously were approved with an indication for secondary bacterial infection of acute bronchitis (SBIAB). On October 3, 2016, FDA sent Corden Pharma Latina S.p.A. a Prior Approval Supplement Request letter seeking removal of the SBIAB indication from the labeling of these drug products. In response, on October 28, 2016, Corden Pharma Latina S.p.A. submitted supplements proposing to remove the indication. On November 22, 2016, FDA approved these supplements and the indication was

[1] On May 26, 2011, Bristol-Myers Squibb transferred ownership of NDA 050664 and NDA 050665 to Corden Pharma Latina S.p.A.

removed. The ANDA applicants referencing these NDAs subsequently followed suit and submitted supplements proposing to remove the SBIAB indication from their labeling. The Agency approved these supplements.

Further, based on a review of relevant information, FDA concluded that the SBIAB indication is not appropriate because most cases of SBIAB are considered to be viral or non-infectious. As an antibacterial drug, CEFZIL (cefprozil) is not considered to be effective to treat SBIAB. Such use of CEFZIL (cefprozil) would likely result in inappropriate antibacterial drug use. Accordingly, the risk benefit balance for the treatment of SBIAB with CEFZIL (cefprozil) is unfavorable and does not support approval of these products (or ANDAs referencing them) for this indication.

The Agency will continue to list CEFZIL (cefprozil) tablets, 250 mg and 500 mg, and CEFZIL (cefprozil) for oral suspension, 125 mg/5 mL and 250 mg/5 mL, in the ''Discontinued Drug Product List'' section of the Orange Book. FDA will continue to accept and, where appropriate, approve ANDAs that refer to these drug products, but does not intend to do so if they propose to include the SBIAB indication (see, *e.g.,* section 505(j)(2)(A)(v) and (j)(4)G) of the FD&C Act and 21 CFR 314.94(a)(8)(iv) and 314.127(a)(7)). If FDA determines that labeling for this drug product should be revised, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19663 Filed 9–10–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3276]

Anesthetic and Analgesic Drug Products 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. The general function of the committee 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 October 11, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–3276. The docket will close on October 10, 2018. Submit either electronic or written comments on this public meeting by October 10, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 10, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 10, 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 October 3, 2018, will be provided to the committee. 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–3276 for ''Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; 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.'' 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