

management of acute pain. The product has been formulated with the intent to provide abuse-deterrent properties. Benzhydrocodone is a hydrocodone prodrug which, according to the applicant, is rapidly converted into hydrocodone by enzymes in the gastrointestinal tract. The active drugs in this fixed-dose combination are hydrocodone and acetaminophen. The applicant has submitted data to support abuse-deterrent properties for this product. The committees will be asked to discuss whether the applicant has demonstrated abuse-deterrent properties for their product that would support labeling, and whether the nasal route of abuse is relevant for combination products made up of hydrocodone and acetaminophen.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: On May 5, 2016, from 9:15 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 21, 2016. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 13, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 14, 2016.

Closed Presentation of Data: On May 5, 2016, from 8 a.m. to 9:15 a.m., the

meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). During this session, the committees will discuss the drug development program of an investigational abuse-deterrent opioid product.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Stephanie L. Begansky at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 9, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0819]

Determination That KENALOG (Triamcinolone Acetonide) Lotion and Other Drug Products 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 the drug products listed in this document were 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 these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they

meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT:

Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6207, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

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 approved 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 generally known as the "Orange Book." Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug Name	Active Ingredient(s)	Strength(s)	Dosage Form/Route	Applicant
NDA 011602	KENALOG	Triamcinolone Acetonide.	0.025%; 0.1%	Lotion; Topical	Delcor Asset Corp.
NDA 016059	INDOCIN	Indomethacin	25 milligrams (mg); 50 mg	Capsule; Oral	Iroko Pharmaceuticals, LLC.
NDA 017560	BACTRIM and BACTRIM PEDI-ATRIC.	Sulfamethoxazole; Trimethoprim.	200 mg/5 milliliters (mL); 40 mg/5 mL	Suspension; Oral	Mutual Pharmaceutical Company, Inc.
NDA 017598	SEPTRA and SEPTRA GRAPE.	Sulfamethoxazole; Trimethoprim.	200 mg/5 mL; 40 mg/5 mL	Suspension; Oral	Monarch Pharmaceuticals, Inc.
NDA 018185	INDOCIN SR	Indomethacin	75 mg	Extended-Release Capsule; Oral.	Iroko Pharmaceuticals, LLC.
NDA 018450	NITROPRESS	Sodium Nitroprusside.	50 mg/vial	Injectable; Injection.	AbbVie Inc.
NDA 019834	PLENDIL	Felodipine	2.5 mg; 5 mg; 10 mg	Extended-Release Tablet; Oral.	AstraZeneca.
NDA 021475	METHYLIN	Methylphenidate Hydrochloride.	2.5 mg; 5 mg; 10 mg	Chewable Tablet; Oral.	Mallinckrodt Pharmaceuticals.
NDA 050320	UNIPEN	Nafcillin Sodium	Equal to (EQ) 500 mg base/vial; EQ 1 g (gram) base/vial; EQ 2 g base/vial; EQ 4 g base/vial; EQ 10 g base/vial; EQ 20 g base/vial.	Injectable; Injection.	Wyeth Ayerst Pharmaceuticals.
NDA 050406	KEFLEX	Cephalexin	EQ 125 mg base/5 mL; EQ 250 mg base/5 mL; EQ 100 mg base/mL.	For Suspension; Oral.	Shionogi Inc.
ANDA 060576	MYCOLOG-II	Nystatin; Triamcinolone Acetonide.	100,000 units/g; 0.1%	Cream; Topical	Delcor Asset Corp.
ANDA 062117	CEPHALEXIN	Cephalexin	EQ 125 mg base/5 mL; EQ 250 mg base/5 mL; EQ 100 mg base/mL.	For suspension; Oral.	Facta Farmaceutici S.p.A.
ANDA 062606	MYCOLOG-II	Nystatin; Triamcinolone Acetonide.	100,000 units/g; 0.1%	Cream; Topical	Delcor Asset Corp.
ANDA 062717	UNIPEN	Nafcillin Sodium	EQ 500 mg base/vial; EQ 1 g base/vial; EQ 2 g base/vial.	Injectable; Injection.	Wyeth Ayerst Pharmaceuticals.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document 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 in this document 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: March 9, 2016.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1814]

Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services To Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry; 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 document entitled “Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion;

Draft Guidance for Industry.” The draft guidance document provides blood collection establishments and transfusion services with recommendations to control the risk of bacterial contamination of room temperature stored platelets intended for transfusion through the implementation of pathogen reduction technology (PRT) or bacterial testing. The draft guidance also provides recommendations for the use of secondary testing of platelets as the basis to extend the dating period of platelets, when appropriately labeled bacterial detection devices and storage containers are used. The draft guidance replaces the draft guidance entitled “Bacterial Detection Testing by Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion,” dated December 2014. The draft guidance, when finalized, is intended to supersede the recommendation in section VII.A.2, in regard to bacterial contamination testing in the document entitled “Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods” dated December 2007.