disability, please contact AnnMarie Williams, at *AnnMarie.Williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://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: September 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21248 Filed 9–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4329]

Determination That KENALOG (Triamcinolone Acetonide) Ointment, 0.025% and 0.1%, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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. 6236, 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 are no longer being marketed.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 011600	KENALOG	Triamcinolone Acetonide	0.025%; 0.1%	Ointment; Topical	Mylan Pharmaceuticals, Inc.
NDA 012827	ROBINUL	Glycopyrrolate	1 milligram (mg)	Tablet; Oral	Casper Pharma LLC.
	ROBINUL FORTE	Glycopyrrolate	2 mg	Tablet; Oral.	
NDA 018029	RITALIN–SR	Methylphenidate Hydrochloride.	20 mg	Extended-Release Tablet; Oral.	Novartis Pharmaceuticals, Corp.
NDA 018164	ANAPROX	Naproxen Sodium	Equivalent to (EQ) 250 mg Base.	Tablet; Oral	ATNAHS Pharma U.S., Ltd.
NDA 018405	AYGESTIN	Norethindrone Acetate	5 mg	Tablet; Oral	Teva Branded Pharmaceutical Products R&D, Inc.
NDA 018452	SEPTRA	Sulfamethoxazole; Trimethoprim.	16 mg/milliliter (mL); 80 mg/mL.	Injectable; Injection	Monarch Pharmaceuticals, Inc.
NDA 018703	ZANTAC 150	Ranitidine Hydrochloride	EQ 150 mg Base	Tablet; Oral	GlaxoSmithKline.
	ZANTAC 300	Ranitidine Hydrochloride	EQ 300 mg Base	Tablet; Oral.	
NDA 019111	TUSSIONEX PENNKINETIC.	Chlorpheniramine Polistirex; Hydrocodone Polistirex.	EQ 8 mg Chlorpheniramine Maleate/5 mL; EQ 10 mg Hydrocodone Bitartrate/5 mL.	Extended-Release Suspension; Oral.	UCB, Inc.
NDA 019507	KERLONE	Betaxolol Hydrochloride	10 mg; 20 mg	Tablets; Oral	Sanofi-Aventis U.S. LLC.
NDA 019537	CIPRO	Ciprofloxacin Hydrochloride.	EQ 100 mg Base; EQ 750 mg Base.	Tablet; Oral	Bayer Healthcare Pharmaceuticals, Inc.
NDA 019937	ADENOCARD	Adenosine	3 mg/mL	Injectable; Injection	Astellas Pharma U.S., Inc.
NDA 020415	REMERON	Mirtazapine	45 mg	Tablet; Oral	Organon USA, Inc.
NDA 020528	MAVIK	Trandolapril	1 mg; 2 mg; 4 mg	Tablet; Oral	AbbVie, Inc.
NDA 020864	MAXALT	Rizatriptan Benzoate	EQ 5 mg Base	Tablet; Oral	Merck Sharp & Dohme Corp.
NDA 020865	MAXALT–MLT	Rizatriptan Benzoate	EQ 5 mg Base	Orally Disintegrating Tablet; Oral.	Do.
NDA 020945	NORVIR	Ritonavir	100 mg	Capsule; Oral	AbbVie, Inc.
NDA 021131	ZYVOX	Linezolid	400 mg/200 mL (2 mg/mL)	Injectable; Injection	Pharmacia & Upjohn Co.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 021381	XYLOCAINE DENTAL WITH EPINEPHRINE.	Epinephrine; Lidocaine Hydrochloride.	0.01 mg/mL/2%; 0.02 mg/mL/2%.	Injectable; Injection	DENTSPLY Pharmaceutical, Inc.
NDA 021511	COPEGUS	Ribavirin	200 mg; 400 mg	Tablet; Oral	Hoffmann La-Roche, Inc.
NDA 022325	NEXTERONE	Amiodarone Hydrochloride	50 mg/mL	Injectable; Injection	Baxter Healthcare, Corp.
NDA 050605	CEFTIN	Cefuroxime Axetil	EQ 125 mg Base; EQ 250 mg Base; EQ 500 mg Base.	Tablet; Oral	GlaxoSmithKline.
NDA 050730	ZITHROMAX	Azithromycin	EQ 600 mg Base	Tablet; Oral	Pfizer, Inc.
NDA 050746	BACTROBAN	Mupirocin Calcium	EQ 2% Base	Cream; Topical	GlaxoSmithKline.
NDA 205103	YOSPRALA	Aspirin; Omeprazole	81 mg/40 mg; 325 mg/40 mg.	Delayed-Release Tablet; Oral.	Genus Lifesciences, Inc.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products 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 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: September 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21201 Filed 9–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4247]

Patient-Focused Drug Development: Methods To Identify What Is Important to Patients; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; 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 guidance for industry, FDA staff, and other stakeholders entitled ''Patient-Focused Drug Development: Methods To Identify What Is Important to Patients.'' This guidance (Guidance 2) is the second in a series of four methodological guidance documents that FDA committed to develop to describe how to collect and submit information from patients and caregivers to be used for medical product development and regulatory decision-making.

DATES: Submit either electronic or written comments on the draft guidance by December 30, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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–2019–D–4247 for ''Patient-Focused Drug Development: Methods To Identify What Is Important to Patients.'' 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 *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