DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3137]

Advisory Committee; Nonprescription Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Nonprescription Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Nonprescription Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until August 27, 2019.

DATES: Authority for the Nonprescription Drugs Advisory Committee will expire on August 27, 2017, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Moon Hee Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *NDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Nonprescription Drugs Advisory Committee (Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner either on the issuance of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of Agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

The Committee shall consist of a core of 10 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/default.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: September 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–19670 Filed 9–14–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4758]

Determination That CORTONE (Cortisone Acetate) Tablets 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 007750	CORTONE	Cortisone Acetate	25 milligrams (mg)	Tablet; Oral	Merck & Co., Inc.
NDA 008662	NYDRAZID	Isoniazid	100 mg/milliliter (mL)	Injectable; Injection	Sandoz Canada Inc.
NDA 010571	COMPAZINE	Prochlorperazine Maleate.	Equivalent to (EQ) 5 mg Base; EQ 10 mg Base; EQ 25 mg Base.	Tablet; Oral	SmithKline Beecham Corporation d/b/a GlaxoSmithKline.
NDA 010670	ORINASE	Tolbutamide	250 mg; 500 mg	Tablet; Oral	Pharmacia and Upjohn Co.
NDA 011127	COMPAZINE	Prochlorperazine	2.5 mg; 5 mg; 25 mg	Suppository; Rectal	SmithKline Beecham Corporation d/b/a GlaxoSmithKline.
NDA 011808	MELLARIL	Thioridazine Hydrochloride (HCl).	30 mg/mL; 100 mg/mL	Concentrate; Oral	Novartis Pharmaceuticals Corp.
NDA 012145	PROLIXIN	Fluphenazine HCl	2.5 mg/5 mL	Elixir; Oral	Apothecon Inc., Division of Bristol Myers Squibb.
NDA 014713	ETRAFON 2–10; ETRAFON 2–25; ETRAFON–A; ETRAFON–FORTE.	Perphenazine; Amitriptyline HCl.	2 mg/10 mg; 2 mg/25 mg; 4 mg/10 mg; 4 mg/25 mg.	Tablet; Oral	Schering Corp.
NDA 014715	TRIAVIL 2–10; TRIAVIL 2–25; TRIAVIL 4–10; TRIAVIL 4–25; TRIAVIL 4–50.	Perphenazine; Amitriptyline HCl.	2 mg/10 mg; 2 mg/25 mg; 4 mg/10 mg; 4 mg/25 mg; 4 mg/50 mg.	Tablet; Oral	New River Pharmaceuticals Inc.
NDA 015539	SERAX	Oxazepam	10 mg; 15 mg; 30 mg; 15 mg.	Capsule; Oral Tablet; Oral	Alpharma U.S. Pharmaceuticals Division.
NDA 015922	HALDOL	Haloperidol Lactate	EQ 2 mg Base/mL	Concentrate; Oral	Ortho-McNeil Pharmaceutical.
NDA 016584	NAVANE	Thiothixene	1 mg; 2 mg; 5 mg; 10 mg; 20 mg.	Capsule; Oral	Pfizer Inc.
NDA 016721	DALMANE	Flurazepam HCl	15 mg; 30 mg	Capsule; Oral	Valeant Pharmaceuticals International.
NDA 017923	MELLARIL–S	Thioridazine	EQ 25 mg HCl/5 mL; EQ 100 mg HCl/5mL.	Suspension; Oral	Novartis Pharmaceuticals Corp.
NDA 018374	BACTRIM	Sulfamethoxazole; Trimethoprim.	80 mg/mL; 16 mg/mL	Injectable; Injection	Sun Pharmaceutical Industries, Inc.
NDA 018485	ISOPTIN	Verapamil HCl	2.5 mg/mL	Injectable; Injection	Mt. Adams Technologies LLC.
NDA 018596	INTAL	Cromolyn Sodium	10 mg/mL	Solution; Inhalation	King Pharmaceuticals LLC.
NDA 018644	WELLBUTRIN	Bupropion HCl	50 mg; 75 mg; 100 mg	Tablet; Oral	GlaxoSmithKline LLC.
NDA 019287	DIZAC	Diazepam	5 mg/mL	Injectable; Injection	Pharmacia and Upjohn Co.
NDA 019982	ZEBETA	Bisoprolol Fumarate	5 mg; 10 mg	Tablet; Oral	Teva Branded Pharmaceutical Products R&D, Inc.
NDA 020007	ZOFRAN; ZOFRAN PRESERVATIVE FREE.	Ondansetron HCl	EQ 2 mg Base/mL	Injectable; Injection	Novartis Pharmaceuticals Corp.
NDA 020205	PSORCON	Diflorasone Diacetate	0.05%	Cream; Topical	Taro Pharmaceuticals North America Inc.
NDA 020947	PENNSAID	Diclofenac Sodium	1.5%	Solution; Topical	Nuvo Pharmaceuticals Inc.
NDA 021575	FOSAMAX	Alendronate Sodium	EQ 70 mg Base/75 mL	Solution; Oral	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
NDA 050542	AMOXIL	Amoxicillin	125 mg; 250 mg	Chewable Tablet; Oral	Dr. Reddy's Laboratories, Inc.
NDA 050564	AUGMENTIN '250'; AUGMENTIN '500'.	Amoxicillin; Clavulanate Potassium.	250 mg/EQ 125 mg Base; 500 mg/EQ 125 mg Base.	Tablet; Oral	Do.
NDA 050581	MEFOXIN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER; MEFOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER.	Cefoxitin Sodium	EQ 20 mg Base/mL; EQ 40 mg Base/mL; EQ 20 mg Base/mL; EQ 40 mg Base/mL.	Injectable; Injection	Merck & Co., Inc.
NDA 050591	BACTROBAN	Mupirocin	2%	Ointment; Topical	SmithKline Beecham (Cork) Ltd., Ireland.
NDA 050594	ERYCETTE	Erythromycin	2%	Swab; Topical	Johnson & Johnson Consumer Inc.
NDA 050754	AMOXIL	Amoxicillin	500 mg; 875 mg	Tablet; Oral	Dr. Reddy's Laboratories, Inc.
NDA 050760	AMOXIL	Amoxicillin	200 mg/5 mL; 400 mg/5 mL	For Suspension; Oral	Do.

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 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–19611 Filed 9–14–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–4886]

Utilizing Animal Studies To Evaluate Organ Preservation Devices; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled ''Utilizing Animal Studies to Evaluate Organ Preservation Devices.'' The intent of this draft guidance is to provide recommendations regarding best practices for utilizing animal studies for the evaluation of organ preservation devices. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 14, 2017 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–2017–D–4886 for ''Utilizing Animal Studies to Evaluate Organ Preservation Devices.'' 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 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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Utilizing Animal Studies to Evaluate Organ Preservation Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Elizabeth Kunkoski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1504, Silver Spring, MD 20993–0002, 301–796–6439.

SUPPLEMENTARY INFORMATION: