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–2016–D–3750 for ''Revised Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products Who Have Received Human-Derived Clotting Factor Concentrates; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://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 *http://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 dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Revised Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products Who Have Received Human-Derived Clotting Factor Concentrates; Guidance for Industry.'' The guidance document provides establishments that make DE determinations for donors of HCT/Ps with information on infectious disease risks related to receipt of HDCFCs. The guidance explains that FDA no longer considers FDA licensed HDCFCs as a risk factor for HIV, HBV, or HCV. As such, receipt of FDA licensed HDCFCs, or sex with a person who has received FDA licensed HDCFCs, should not be considered a risk factor when determining eligibility of a donor of HCT/Ps. The recommendations in the guidance supersede the recommendations contained in section IV.E.3. of the guidance entitled ''Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Guidance for Industry'' dated August 2007.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2) without initially seeking prior comment because the Agency has determined that prior public participation is not appropriate. This guidance recommends a less burdensome policy that is consistent with the public health. The guidance represents the current thinking of FDA on ''Revised Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products Who Have Received Human-Derived Clotting Factor Concentrates.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 1271.47 have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: November 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27768 Filed 11–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3680]

Determination That BENEMID (Probenecid) Tablet 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 007898	BENEMID	Probenecid	500 milligrams (mg)	Tablet; Oral	Merck and Co., Inc.
NDA 008048	XYLOCAINE	Lidocaine	5%	Ointment; Topical	AstraZeneca Pharmaceuticals LP.
NDA 011111	VISTARIL	Hydroxyzine Hydrochloride (HCl).	25 mg/milliliter (mL); 50 mg/mL.	Injectable; Injection	Pfizer Inc.
NDA 012209	FLUOROURACIL	Fluorouracil	500 mg/10 mL (50 mg/mL)	Injectable; Injection	Spectrum Pharmaceuticals, Inc.
NDA 013220	PERIACTIN	Cyproheptadine HCl	2 mg/5 mL	Syrup; Oral	Merck and Co., Inc.
NDA 017534	FIORINAL	Aspirin; Butalbital; Caffeine.	325 mg; 50 mg; 40 mg	Tablet; Oral	Allergan Sales, LLC.
NDA 017577	DITROPAN	Oxybutynin Chloride	5 mg	Tablet; Oral	Ortho-McNeil-Janssen Pharmaceuticals, Inc.
NDA 017781	DIPROSONE	Betamethasone Dipropionate.	Equivalent to (EQ) 0.05% Base.	Lotion; Topical	Schering Corp.
NDA 018211	DITROPAN	Oxybutynin Chloride	5 mg/5 mL	Syrup; Oral	Ortho-McNeil-Janssen Pharmaceuticals, Inc.
NDA 018586	TOPICORT	Desoximetasone	0.05%	Gel; Topical	Taro Pharmaceuticals U.S.A., Inc.
NDA 018631	TRENTAL	Pentoxifylline	400 mg	Extended-Release Tablet; Oral.	U.S. Pharmaceutical Holdings II, LLC.
NDA 019155	LAC–HYDRIN	Ammonium Lactate	EQ 12% Base	Lotion; Topical	Ranbaxy Laboratories Inc.
NDA 019323	TEMOVATE	Clobetasol Propionate	0.05%	Ointment; Topical	Fougera Pharmaceuticals Inc.
NDA 019778	PRINZIDE	Hydrochlorothiazide; Lisinopril.	12.5 mg/10 mg; 12.5mg/20mg.	Tablet; Oral	Merck Sharp & Dohme Corp., Subsidiary of Merck & Co., Inc.
NDA 019842	MOTRIN	Ibuprofen	100 mg/5 mL	Suspension; Oral	McNeil Consumer Healthcare Division of McNEIL–PPC, Inc.
NDA 019915	MONOPRIL	Fosinopril Sodium	10 mg; 20 mg; 40 mg	Tablet; Oral	Bristol-Myers Squibb Co.
NDA 020343	PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER.	Milrinone Lactate	EQ 10 mg Base/100 mL; EQ 15 mg Base/100 mL; EQ 20 mg Base/100 mL; EQ 40 mg Base/200 mL.	Injectable; Injection	Sanofi-Aventis U.S. LLC.
NDA 020508	LAC–HYDRIN	Ammonium Lactate	EQ 12% Base	Cream; Topical	Ranbaxy Laboratories, Inc.
NDA 020635	LEVAQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER.	Levofloxacin	EQ 250 mg/50 mL (EQ 5 mg/mL); EQ 500 mg/100 mL (EQ 5 mg/mL); EQ 750 mg/150 mL (EQ 5 mg/mL).	Injectable; Injection	Janssen Pharmaceuticals, Inc.
NDA 020863	PLETAL	Cilostazol	50 mg; 100 mg	Tablet; Oral	Otsuka Pharmaceutical Co., Ltd.
NDA 20950	DUONEB	Albuterol Sulfate; Ipratropium Bromide.	EQ 0.083% Base; 0.017%	Solution; Inhalation	Mylan Specialty, L.P.
NDA 21460	METAGLIP	Glipizide; Metformin HCl	2.5 mg/250 mg; 2.5 mg/500 mg; 5 mg/500 mg.	Tablet; Oral	Bristol-Myers Squibb Co.
NDA 021759	ELOXATIN	Oxaliplatin	200 mg/40 mL (5 mg/mL)	Injectable; Intravenous (Infusion).	Sanofi-Aventis U.S. LLC.
NDA 050442	VIBRAMYCIN	Doxycycline Hyclate	EQ 100 mg Base/Vial; EQ 200 mg Base/Vial.	Injectable; Injection	Pfizer Inc.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 050624	ROCEPHIN W/DEXTROSE IN PLASTIC CONTAINER.	Ceftriaxone Sodium	EQ 10 mg Base/mL; EQ 20 mg Base/mL; EQ 40 mg Base/mL.	Injectable; Injection	Hoffmann-La Roche, Inc.
NDA 050739	OMNICEF	Cefdinir	300 mg	Capsule; Oral	AbbVie Inc.
NDA 050749	OMNICEF	Cefdinir	125 mg/5 mL; 250 mg/5 mL	For Suspension; Oral	AbbVie Inc.
ANDA 060003	V–CILLIN K	Penicillin V Potassium	EQ 125 mg Base; EQ 250 mg Base; EQ 500 mg Base.	Tablet; Oral	Eli Lilly and Company.
ANDA 060463	GARAMYCIN	Gentamicin Sulfate	EQ 0.1% Base	Ointment; Topical	Schering-Plough Corp.
ANDA 086833	CYPROHEPTADINE HYDROCHLORIDE.	Cyproheptadine HCl	2 mg/5mL	Syrup; Oral	Actavis Mid Atlantic LLC.
ANDA 088877	BENZTROPINE MESYLATE.	Benztropine Mesylate	0.5 mg	Tablet; Oral	Lannett Holdings, Inc.
ANDA 088894	BENZTROPINE MESYLATE.	Benztropine Mesylate	1 mg	Tablet; Oral	Lannett Holdings, Inc.
ANDA 088895	BENZTROPINE MESYLATE.	Benztropine Mesylate	2 mg	Tablet; Oral	Lannett Holdings, Inc.

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: November 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27855 Filed 11–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–M–3249, FDA–2015–M–3251, FDA–2015–M–3253, FDA–2015–M–4130, FDA 2015–M–3254, FDA–2016–M–2210, FDA–2014–M–0740, FDA–2016–M–1072, FDA–2014–M–2304, FDA–2014–M–2305, FDA–2015–M–2100, FDA–2015–M–3255, FDA–2015–M–4981]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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 Nos. FDA–2015–M–3249, FDA–2015–M–3251, FDA–2015–M–3253, FDA–2015–M–4130, 2015–M–3254, FDA–2016–M–2210, FDA–2014–M–0740, FDA–2016–M–1072, FDA–2014–M–2304, FDA–2014–M–2305, FDA–2015–M–2100, FDA–2015–M–3255, FDA–2015–M–4981 for ''Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets