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# Determination That BENEMID (Probenecid) Tablet and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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 |
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| NDA 007898 | BENEMID | Probenecid | 500 milligrams (mg) | Tablet; Oral | Merck and Co., Inc. |
| NDA 008048 | XYLOCAINE | Lidocaine | 5% | Ointment; Topical | AstraZeneca Pharmaceuticals LP |

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| 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. |

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| 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. |
| 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.

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