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has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


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.

ADDRESS: 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.”


Application No. | Drug name | Active ingredient(s) | Strength(s) | Dosage form/route | Applicant
--- | --- | --- | --- | --- | ---
NDA 050624 | ROCHEPHIN W/D| Ceftriaxone Sodium | EQ 10 mg Base/mL; EQ 20 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 | Benztrapine Mesylate | 0.5 mg | Tablet; Oral | Lannett Holdings, Inc.
ANDA 088894 | BENZTROPINE MESYLATE | Benztrapine Mesylate | 1 mg | Tablet; Oral | Lannett Holdings, Inc.
ANDA 088895 | BENZTROPINE MESYLATE | Benztrapine Mesylate | 2 mg | Tablet; Oral | Lannett Holdings, Inc.
II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/default.htm.

Dated: November 14, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–27769 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–2015–D–2148]

Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHSS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices.” This guidance provides a detailed description of the information that should be included in a premarket notification for a magnetic resonance diagnostic device (MRDD).

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

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Dated: November 14, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–27769 Filed 11–17–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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