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has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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

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.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, 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

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations (21 CFR 814.44(d) and 814.45(d)) provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of PMAs approved by CBER for which safety and effectiveness summaries were placed on the Internet from October 1, 2010, through September 30, 2016. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2010, THROUGH SEPTEMBER 30, 2016

PMA No., Docket No.	Applicant	Trade name	Approval date
BP090032, FDA–2015–M–3249	bioLytical Laboratories Inc	INSTI HIV–1 Antibody Test Kit	November 29, 2010.
BP100064, FDA–2015–M–3251	Bio-Rad Laboratories, Inc	GS HIV Combo Ag/Ab EIA	July 22, 2011.
BP120001, FDA–2015–M–3253	OraSure Technologies, Inc	OraQuick® In-Home HIV Test	July 3, 2012.
BP120032, FDA–2015–M–4130	Chembio Diagnostic Systems, Inc	DPP HIV ½ Assay	December 12, 2012.
BP120037, FDA–2015–M–3254	Alere Scarborough, Inc	Alere Determine™ HIV–1/2 Ag/Ab Combo	August 9, 2013.
BH110018, FDA–2016–M–2210	Miltenyi Biotec, Inc	CliniMACs CD34 Reagent System	January 23, 2014.
BP130026, FDA–2014–M–0740	BioArray Solutions, Ltd	Immucor PreciseType™ Human Erythrocyte Antigen Molecular BeadChip Test.	May 21, 2014.
BP140120, FDA–2016–M–1072	Bio-Rad Laboratories, Inc	Bio-Rad Geenius HIV ½ Supplemental Assay	October 24, 2014.
BP130076, FDA–2014–M–2304	Cerus Corporation	INTERCEPT® Blood System for Plasma	December 16, 2014.
BP140143, FDA–2014–M–2305	Cerus Corporation	INTERCEPT® Blood System for Platelets	December 18, 2014.
BP140103, FDA–2015–M–2100	Siemens Healthcare Diagnostics, Inc	ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay.	June 8, 2015.
BP140111, FDA–2015–M–3255	Bio-Rad Laboratories, Inc	BioPlex® 2200 HIV Ag-Ab	July 22, 2015.
BP150262, FDA–2015–M–4981	Roche Molecular Systems, Inc	Cobas HIV–1	December 18, 2015.

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, HHS.

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.