TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 089420	Azdone Tablets (hydrocodone bitartrate 5 mg and aspirin 500 mg).	Schwarz Pharma, Inc., c/o UCB, Inc., 1950 Lake Park Dr., Smyrna, GA 30080.
ANDA 090183	Cetirizine HCl Syrup, 5 mg/5mL	Ranbaxy Laboratories Limited, c/o Ranbaxy Inc.
ANDA 090196	Letrozole Tablets USP, 2.5 mg	Synthon Pharmaceuticals, Inc.
ANDA 090464	Mycophenolate Mofetil Tablets, 500 mg	Dr. Reddy's Laboratories Limited, c/o Dr. Reddy's Laboratories, Inc., 200 Somerset Corporate Blvd., 7th Floor, Bridgewater, NJ 08807.
ANDA 090567	Polyethylene Glycol 3350 Powder for Oral Solution	Paddock Laboratories, LLC, a Perrigo Co., 3940 Quebec Ave. North, Minneapolis, MN 55427.
ANDA 090712	Polyethylene Glycol 3350 and Electrolytes for Oral Solution.	Do.
ANDA 090769	Clenz-Lyte (polyethylene glyol 3350 and electrolytes for oral solution).	Do.
ANDA 091315	Mycophenolalte Mofetil Capsules USP, 250 mg	Dr. Reddy's Laboratories Limited, c/o Dr. Reddy's Laboratories, Inc.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective July 21, 2014. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: June 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14288 Filed 6–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0640]

Draft Guidance for Industry on Uncomplicated Gonorrhea: Developing Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Uncomplicated Gonorrhea: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in the development of new antibacterial drugs for the treatment of uncomplicated gonorrhea.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 17, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Uncomplicated Gonorrhea: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in the development of new antibacterial drugs for the treatment of uncomplicated gonorrhea.

This draft guidance describes approaches for trial designs for the evaluation of new drugs for the treatment of uncomplicated gonorrhea. The draft guidance focuses on the noninferiority trial design and describes an efficacy endpoint for which there is a well-defined treatment effect. The draft guidance also provides the justification for the noninferiority margin. In addition, this guidance reflects recent developments in scientific information that pertain to drugs being developed for the treatment of uncomplicated gonorrhea.

Issuance of this draft guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144) that requires FDA to ''. . . review and, as appropriate, revise not fewer than 3 guidance documents per year . . . for the conduct of clinical trials with respect to antibacterial and antifungal drugs. . . .'' In 1998, FDA published a draft guidance entitled ''Uncomplicated Gonorrhea: Developing Drugs for Treatment'' (1998 draft guidance). In a **Federal Register** notice dated August 7, 2013 (78 FR 48175), FDA announced an initiative in the Center for Drug Evaluation and Research involving the review of draft guidance documents issued before 2010 to determine their status and to decide whether those guidances should be withdrawn, revised, or finalized with only minor changes. In the August 7, 2013, **Federal Register** notice, FDA announced that the 1998 draft guidance, as well as other draft guidances, was being withdrawn (78 FR 48175). FDA is now issuing a new draft guidance that revises the recommendations in the 1998 draft

guidance. Issuance of the new draft guidance constitutes a revision of a previously published draft guidance and fulfills a portion of the requirements of Public Law 112–144.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing drugs for the treatment of uncomplicated gonorrhea. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that 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 parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

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

Dated: June 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14303 Filed 6–18–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biological Data Management and Analysis.

Date: June 25, 2014.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mark Caprara, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7844, Bethesda, MD 20892, 301–435–1042, *capraramg@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Single Cell Analysis.

Date: July 1–2, 2014.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Amy L. Rubinstein, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7844, Bethesda, MD 20892, 301–408–9754, *rubinsteinal@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group; AIDS-associated Opportunistic Infections and Cancer Study Section.

Date: July 11, 2014.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The St. Regis Washington DC, 923 16th Street NW., Washington, DC 20006.

Contact Person: Eduardo A. Montalvo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435–1168, *montalve@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Omnibus Solicitation of the NIH for Small Business.

Date: July 11, 2014.

Time: 10 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Rebecca Henry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, 301–435–1717, *henryrr@mail.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group; HIV/AIDS Vaccines Study Section.

Date: July 15, 2014.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Row Hotel, 2015 Massachusetts Avenue NW., Washington, DC 20036.

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, *walkermc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Oncology.

Date: July 16–17, 2014.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Michael L. Bloom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7804, Bethesda, MD 20892, 301–451–0132, *bloomm2@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Nutrition, Obesity and Diabetes.

Date: July 16, 2014.

Time: 10 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Nancy Sheard, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046–E, MSC 7892, Bethesda, MD 20892, 301–408–9901, *sheardn@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Shared Instrumentation: Flow Cytometry.

Date: July 16, 2014.

Time: 11 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).