

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 27 abbreviated new drug applications (ANDAs) held by Ranbaxy Laboratories Ltd., c/o Ranbaxy Inc. (Ranbaxy), 600 College Rd. East, Princeton, NJ 08540. The drug products are no longer marketed, and Ranbaxy has requested that the approval of the applications be withdrawn.

DATES: *Effective date:* September 21, 2012.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: The drug products listed in table 1 in this document are no longer marketed, and Ranbaxy has requested that FDA withdraw approval of the applications.

The company has also waived its opportunity for a hearing. Ranbaxy requested withdrawal of approval under a Consent Decree of Permanent Injunction (Decree) entered in *United States v. Ranbaxy Laboratories, Ltd. et al.*, JFM 12-250 (D. Md.) on January 26, 2012. The Decree specifies that Ranbaxy must never submit another application to FDA for these withdrawn drug products and must never transfer these ANDAs to a third party.

TABLE 1

| Application No. | Drug |
|-----------------|--|
| 064155 | Cefaclor for Oral Suspension USP, 375 milligrams (mg)/5 milliliters (mL). |
| 064156 | Cefaclor Capsules USP, 250 mg and 500 mg. |
| 064164 | Cefaclor for Oral Suspension USP, 250 mg/5 mL. |
| 064165 | Cefaclor for Oral Suspension USP, 187 mg/5 mL. |
| 064166 | Cefaclor for Oral Suspension USP, 125 mg/5 mL. |
| 065015 | Cefadroxil Capsules USP, 500 mg. |
| 065018 | Cefadroxil Tablets USP, 1 gram. |
| 065043 | Cefuroxime Axetil Tablets USP, 125 mg, 250 mg, and 500 mg. |
| 065080 | Dispermox (amoxicillin tablets for oral suspension USP), 200 mg and 400 mg. |
| 065092 | Raniclor (cefaclor chewable tablets USP), 125 mg, 187 mg, 250 mg, and 375 mg. |
| 065100 | Panixine Disperdose (cephalexin tablets for oral suspension USP), 125 mg and 250 mg. |
| 065159 | Dispermox (amoxicillin tablets for oral suspension USP), 600 mg. |
| 065198 | Cefprozil Tablets USP, 250 mg and 500 mg. |
| 065202 | Cefprozil for Oral Suspension USP, 125 mg/5 mL and 250 mg/5 mL. |
| 075226 | Etodolac Tablets USP, 400 mg and 500 mg. |
| 076021 | Terazosin Hydrochloride (HCl) Capsules, 1 mg, 2 mg, 5 mg, and 10 mg. |
| 076220 | Ofloxacin Tablets, 200 mg, 300 mg, and 400 mg. |
| 076386 | Fluconazole Tablets, 50 mg, 100 mg, 150 mg, and 200 mg. |
| 076413 | Metformin HCl Extended-Release Tablets USP, 500 mg. |
| 076445 | Pravastatin Sodium Tablets USP, 10 mg, 20 mg, 40 mg, and 80 mg. |
| 076457 | Ganciclovir Capsules, 250 mg and 500 mg. |
| 076580 | Fosinopril Sodium Tablets USP, 10 mg, 20 mg, and 40 mg. |
| 076875 | Glimepiride Tablets USP, 1 mg, 2 mg, 4 mg, and 8 mg. |
| 076951 | Nitrofurantoin/Nitrofurantoin Macrocrystalline Capsules, 75 mg/25 mg. |
| 077211 | Metformin HCl Extended-Release Tablets USP, 750 mg. |
| 077327 | Zidovudine Tablets USP, 300 mg. |
| 078849 | Ramipril Capsules, 5 mg and 10 mg. |

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 September 21, 2012. 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)).

Dated: August 15, 2012.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 2012-20588 Filed 8-21-12; 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; Dermatology and Rheumatology.

Date: September 19, 2012.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Aruna K Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-435-6809, beheraak@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Nanotechnology Study Section.

Date: September 20-21, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW., Washington, DC 20036.

Contact Person: James J Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge

Drive, Room 5148, MSC 7849, Bethesda, MD 20892, 301-806-8065, lijames@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Social Sciences and Population Studies A Study Section.

Date: September 20–21, 2012.

Time: 8:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Churchill Hotel, 1914 Connecticut Avenue NW., Washington, DC 20009.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435-1712, ryansj@csr.nih.gov.

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

Date: September 20, 2012.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Krish Krishnan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435-1041, krishnak@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Biological Chemistry and Macromolecular Biophysics.

Date: September 20–21, 2012.

Time: 11:00 a.m. to 10:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Donald L Schneider, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5160, MSC 7842, Bethesda, MD 20892, (301) 435-1727, schneidd@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Gastrointestinal and Hepatic Physiology/Pathophysiology.

Date: September 21, 2012.

Time: 11:00 a.m. to 1:00 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: Patricia Greenwel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301-435-1169, greenwep@csr.nih.gov.

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

Date: September 21, 2012.

Time: 1:00 p.m. to 3:00 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: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301-496-8551, ingrahamrh@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 16, 2012.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-20606 Filed 8-21-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Aging.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting 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: National Advisory Council on Aging.

Date: September 18–19, 2012.

Closed: September 18, 2012, 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 10, Bethesda, MD 20892.

Open: September 19, 2012, 8:00 a.m. to 1:15 p.m.

Agenda: Call to order and reports from the Director; discussion of future meeting dates;

consideration of minutes from the last meeting; reports from the Task Force on Minority Aging Research, the Council of Councils, the Working Group on Program; council speaker; and Program Highlights.

Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 10, Bethesda, MD 20892.

Contact Person: Robin Barr, Ph.D., Director, National Institute On Aging, Office of Extramural Activities, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20814, (301) 496-9322, barr@nia.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: www.nih.gov/nia/naca/, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 16, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-20605 Filed 8-21-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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.