**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Radiological Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on October 24, 2012, from 8 a.m. to 6 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

*Contact Person:* Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993, *Shanika.Craig@fda.hhs.gov,* 301–796–6639, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On October 24, 2012, the committee will discuss, make recommendations, and vote on a premarket approval application supplement to expand the indications for use of the Selenia Dimensions 3D System with C-View Software Module, sponsored by Hologic, Inc.

The Selenia Dimensions 3D System is currently approved for breast cancer screening and diagnosis. The screening exam can consist of field digital mammography (FFDM) alone or the combination of FFDM with digital breast tomosynthesis (DBT).

The new C-View Software Module can generate synthetic 2D images from the DBT data. Hologic requests to expand the indications for use to allow the combination of DBT with synthetic 2D images to be used as another exam option for breast cancer screening.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 15, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 5, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 9, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark, Conference Management Staff, at *James.Clark@fda.hhs.gov* or 301–796–5293, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 17, 2012.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2012–20608 Filed 8–21–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0001]**

### Cardiovascular and Renal Drugs Advisory Committee; Cancellation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The meeting of the Cardiovascular and Renal Drugs Advisory Committee scheduled for September 14, 2012, is cancelled. The meeting is no longer needed. This meeting was announced in the **Federal Register** of July 23, 2012 (77 FR 43093).

**FOR FURTHER INFORMATION CONTACT:** Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *CRDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information or visit our Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: August 17, 2012.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2012–20607 Filed 8–21–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0839]**

### Ranbaxy Laboratories Limited; Withdrawal of Approval of 27 Abbreviated New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**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