

receipt date will be the receipt date of a complete User Fee Coversheet via eSubmission. If a User Fee Coversheet is submitted outside of normal business hours (Monday to Friday, 8 a.m. to 4:30 p.m. excluding Federal holidays or dates the Federal Government is shutdown), the User Fee Coversheet receipt date will be considered the next business day.

4. Volunteers interested in participating in the CDRH 510(k) eSubmissions Pilot should contact eSubmissions Pilot staff by email at [eSubpilot@fda.hhs.gov](mailto:eSubpilot@fda.hhs.gov). This email address should also be used to report issues and ask questions. General feedback and comments about the eSubmissions Pilot, 510(k) template, and process can be provided via <http://www.regulations.gov> or the Division of Dockets Management (see Comments).

5. Additional information on the CDRH 510(k) eSubmissions Pilot is available at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm>.

**III. Duration of the eSubmissions Pilot**

FDA intends to accept requests for participation in the eSubmissions Pilot through September 30, 2014, or as resources and eSubmissions Pilot needs allow. Modifications to the CDRH 510(k) eSubmissions Pilot will be made available at <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm> to all eSubmissions Pilot participants and stakeholders.

**IV. Comments**

Interested persons may submit electronic comments regarding the

eSubmissions Pilot for CDRH Electronic Submission of Premarket Notification Submissions to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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>.

Dated: April 25, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-09912 Filed 4-30-14; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0021]

**Actavis Totowa LLC, et al.; Withdrawal of Approval of Abbreviated New Drug Applications for Prescription Pain Medications Containing More Than 325 Milligrams of Acetaminophen; Correction**

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a

notice that appeared in the **Federal Register** of March 27, 2014 (79 FR 17163). The document withdrew approval of 108 abbreviated new drug applications (ANDAs) for prescription pain medications containing more than 325 milligrams (mg) of acetaminophen per dosage unit from multiple applicants, effective March 27, 2014. The document failed to withdraw approval of ANDAs 040825, 040822, and 040824, held by Ranbaxy Laboratories Inc. and Ranbaxy Inc., 600 College Rd. East, Princeton, NJ 08540, and ANDA 040182, held by Pharmaceutical Associates, Inc., 201 Delaware St., Greenville, SC 29605. The holders of these applications have voluntarily requested that approval of these applications be withdrawn and have waived their opportunity for a hearing. FDA confirms the withdrawal of approval of ANDAs 040825, 040824, 040822, and 040182.

**FOR FURTHER INFORMATION CONTACT:**

Rachel Turow, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-5094.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2014-06801, appearing on page 17163, in the **Federal Register** of Thursday, March 27, 2014, the following correction is made:

On page 17166, in table 1, the following entries are added in alphabetical order by Applicant:

Application No.	Drug product(s)	Applicant or holder
ANDA 040182	Acetaminophen and Hydrocodone Bitartrate Oral Solution, 7.5 mg/500 mg/15 milliliters (mL), available in 473 mL, 118 mL, 15 mL, and 10 mL.	Pharmaceutical Associates, Inc., 201 Delaware St., Greenville, SC 29605.
ANDA 040825	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg.	Ranbaxy Laboratories Inc., 600 College Rd. East, Princeton, NJ 08540.
ANDA 040822	Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg.	Do.
ANDA 040824	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/10 mg.	Ranbaxy Inc., 600 College Rd. East, Princeton, NJ 08540.

Dated: April 24, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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