4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0411]

Bristol-Myers Squibb Co. et al.; Withdrawal of Approval of 70 New Drug Applications and 97 Abbreviated New Drug Applications; 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 June 8, 2011 (76 FR 33310). The document announced the withdrawal of approval of 70 new drug applications (NDAs) and 97 abbreviated new drug applications (ANDAs) from multiple applicants, effective July 8, 2011. The document indicated that FDA was withdrawing approval of the following three ANDAs after receiving a request from the ANDA holder, A.H. Robins Co., c/o Wyeth Pharmaceuticals, Inc., P.O. Box 8299, Philadelphia, PA 19101-8299: ANDA 086661, DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine (HBr)) Elixir; ANDA 086676, DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine (HBr)) Tablets; and ANDA 086677, DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine (HBr)) Capsules. Before withdrawal of these ANDAs became effective, PBM Pharmaceuticals, Inc., acquired the rights to the ANDAs and informed FDA that it did not want them withdrawn. Because the basis for withdrawal would have been a request from the ANDA holder and the request was timely withdrawn, the approval of ANDAs 086661, 086676, and 086677 is still in effect.

FOR FURTHER INFORMATION CONTACT:

Florine 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: In FR Doc. 2011-14164 appearing on page 33310, in the Federal Register of Wednesday, June 8, 2011, the following correction is made:

On page 33313, in Table 1, the entries for ANDAs 086661, 086676, and 086677 are removed.

Dated: December 16, 2011.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2011-32822 Filed 12/21/2011 at 8:45 am; Publication Date: 12/22/2011]