Reckitt Benckiser Pharmaceuticals Inc.

Memo

To: Division of Dockets Management, FDA
5630 Fishers Lane, Room 1061 (4FA-305)
Rockville, MD 20852

From: Tim Baxter, Global Medical Director

Date: 11/27/2012

Re: Correction to Reckitt Benckiser Pharmaceuticals – Response to Anmeal Comment
(Doc ID: FDA-2012-P-1028-0005)

An incorrect date was listed in the above-referenced document in the second paragraph on page 2. The paragraph should read as follows:

"As explained in the citizen petition, the film product was developed in part as a response to RBP's expectation that child-resistant unit-dose packaging would reduce the risk of children being exposed to harmful doses of buprenorphine. That FDA, at the time of initial approval of the film product, did not find the then-theoretical benefits of unit-dose packaging sufficient to include them in the risk evaluation and mitigation strategy (REMS) is irrelevant to RBP's decision to discontinue marketing the tablet and also irrelevant to FDA's view of the newly-submitted data that support what had once been just a theory. As RBP noted in the citizen petition, the first pediatric death associated with a buprenorphine tablet product occurred in June 2010 and was not reported to RBP until October ***2010***, which was after the film product was approved. Before September of this year, RBP (and perhaps even FDA) strongly suspected that a child-resistant individually wrapped film product could be safer than multiple tablets in containers with child-resistant closures. As RBP gained experience with both products, its belief in the inherent safety advantage of the film product became stronger and it sought to obtain empirical data that would determine whether, in fact, its theoretically and anecdotally driven concerns were warranted. The very first summary analysis of these data was then submitted to FDA without delay. That same information led RBP to discontinue marketing buprenorphine/naloxone tablets."

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