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September 20, 2005

Elizabeth H. Dickinson, Esq.
Kim E. Dettelbach, Esq.
Food and Drug Administration
Office of the Chief Counsel
5600 Fishers Lane
Room 671
Rockville, MD 20857

Re: NDA No. 21-863 (Ibuprofen Liquid Filled Gelatin Capsules 200 mg)

Dear Ms. Dickinson and Ms. Dettelbach:

We write to confirm our conversation with you regarding the patent certifications required to be contained in Ranbaxy Pharmaceuticals, Inc.'s ("Ranbaxy") NDA No. 21-863, for Ibuprofen Liquid Filled Gelatin Capsules, which was submitted pursuant to Section 505(b)(2) of the Food, Drug and Cosmetic Act on November 2, 2004. The proposed therapeutic indication for Ranbaxy's drug product is migraine relief, which is the indication approved for Wyeth's Advil ® Migraine Liqui-gels (ibuprofen liquid filled gelatin capsules 200 mg). Ranbaxy's application relied in part on the investigations conducted for Advil Liqui-Gels. The Orange Book lists no patents for Advil Migraine Liqui-gels. Ranbaxy's application does not rely on any other investigations that either were not conducted by Ranbaxy or for which Ranbaxy has not obtained a right of reference.

Earlier this year, the Division of Over-the-Counter Drug Products informed Ranbaxy that its application must contain a patent certification(s) to Banner Pharmacap Inc.'s ("Banner") ibuprofen capsules 200 mg. In response, Ranbaxy submitted an amendment to NDA No. 21-863 containing a paragraph IV certification to U.S. Patent No. 6,251,426 ("the '426 patent"), the patent listed in the Orange Book as claiming Banner's ibuprofen capsules 200 mg. Subsequently, on May 10, 2005, Ranbaxy sent a letter to FDA asserting its objections to FDA's requirement that its NDA contain a certification to the Banner drug product, and withdrawing the paragraph IV certification to the '426 patent. Since then, you have confirmed that FDA does not and will not require that Ranbaxy's NDA No. 21-863 contain a certification to any patent listed

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in the Orange Book as claiming Banner's ibuprofen gel capsule 200 mg, and therefore to the '426 patent, because, among other things, Ranbaxy's 505(b)(2) application does not rely upon any investigations conducted for Banner's ibuprofen gel capsules 200 mg.

Sincerely,

Kate C. Beardsley
Carmen M. Shepard

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