

RANBAXY

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May 10, 2005

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Over-the-Counter Drug Products
Attn: Document Control Room (HFD-560)
5600 Fishers Lane
Rockville, MD 20855

UPS

PATENT AMENDMENT

RE: NDA 21-863
Ibuprofen Liquid Filled Gelatin Capsules 200 mg

Dear Sir/Madam,

Ranbaxy Laboratories Limited submitted a New Drug Application (NDA) for Ibuprofen Liquid Filled Gelatin Capsules 200 mg pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act on November 5, 2004. This NDA referred to the listed drug, Advil® Migraine Liqui-Gels (Ibuprofen Liquid Filled Capsules) 200 mg, which is manufactured by Wyeth Cons, the holder of the approved application, NDA 20-402, and which is listed in the 2004 Approved Drug Products with Therapeutic Equivalence Evaluations, 24th Edition. Ranbaxy submitted a Paragraph I certification to NDA 20-402, as there are no patents listed in the Orange Book for this drug product.

The proposed therapeutic indication for Ibuprofen Liquid Filled Gelatin Capsules 200 mg is migraine relief, which is the indication approved for Advil® Migraine Liqui-Gels (Ibuprofen Liquid Filled Gelatin Capsules 200 mg). Ranbaxy's Ibuprofen Liquid Filled Capsules incorporate ibuprofen base at the same strength as those of Advil® Migraine Liqui-Gels, i.e., ibuprofen base equivalent of 200 mg. Advil® Migraine Liqui-Gels, 200 mg contain solubilized ibuprofen equal to 200 mg ibuprofen as free base and potassium salt. Ranbaxy's Ibuprofen Liquid Filled Capsules constitute a switch from the approved ibuprofen base and potassium salt to the base form, i.e., active moiety, ibuprofen.

A WHOLLY OWNED SUBSIDIARY OF RANBAXY LABORATORIES LIMITED, INDIA

CONFIDENTIAL-COUNSEL AND EXPERTS ONLY

Exhibit 3 Page 1 of 4

R0010387

May 10, 2005
New Drug Application No. 21-463
Ibuprofen Liquid Filled Gelatin Capsules 200 mg

Ranbaxy's application relied on the non-clinical pharmacology and toxicology data and clinical safety and efficacy data approved under Advil Migraine Liqui-gels' NDA 20-402. Irrespective of whether the base or the potassium salt of ibuprofen is administered to animals or man, the pharmacologically active moiety, ibuprofen base, is the moiety found in the blood stream and measured in toxicokinetic and pharmacokinetic studies. Ranbaxy's New Drug Application contained data from three pharmacokinetic studies in healthy volunteers. These studies show that Ibuprofen Liquid Filled Gelatin Capsules 200 mg are bioequivalent to the reference product, Advil[®] Migraine Liqui-Gels, when the product is administered under fasted and fed conditions.

On February 18, 2005, Ms. Lea Christa from FDA left a voice message stating that Ranbaxy needs to certify to Banner Pharmacap's NDA 21-472, which is also a liquid gelatin capsule for ibuprofen capsules. Based on a telephone contact of March 1, 2005, the Agency stated that Ranbaxy needed to certify to NDA 21-472 because Banner's capsule product also is a free acid form and Ranbaxy's product is pharmaceutically equivalent to Banner's product.

On March 4, 2005, in response to the FDA's requirement, Ranbaxy submitted patent amendment containing a Paragraph IV patent certification to Banner's Ibuprofen Capsules. The holder of the approved drug application, Banner Pharmacaps, was notified of Ranbaxy's NDA 21-863 for Ibuprofen Liquid Filled Gelatin Capsules, 200 mg via certified mail sent on March 4, 2005. On March 14, 2005, Ranbaxy submitted notice of certification to the FDA. On April 18 2005, Banner sued Ranbaxy for patent infringement.

At this time Ranbaxy withdraws the Patent certification referencing NDA 21-472 sent to the Agency on March 4, 2005. As described in further detail below, because section 505(b) of the Food, Drug and Cosmetic Act does not require certification of

May 10, 2005
New Drug Application No. 21-863
Ibuprofen Liquid Filled Gelatin Capsules 200 mg

patents listed for pharmaceutical equivalents unless that is the drug whose safety and effectiveness information is being relied upon by the current 505(b)(2) NDA applicant, FDA should not have required Ranbaxy to file a paragraph IV certification as to Banner's drug product.

The Food, Drug, and Cosmetic Act provides that an application submitted for a drug for which any of the investigations of safety and effectiveness relied upon by the applicant for approval were not conducted for the applicant and for which the applicant has not obtained a right of reference or use, must include a certification with respect to each patent which claims the drug for which such investigations were conducted, or which claims a use for such drug. Food, Drug, and Cosmetic Act, Section 505(b)(2)(A); 21 U.S.C. § 355(b)(2)(A). FDA's regulations similarly require patent certifications with respect to each patent that claims a drug, whether the drug product or drug substance, "on which investigations that are relied upon by the applicant for approval of its application were conducted or that claims an approved use for such drug. . . ." 21 C.F.R. § 314.50(i)(A). The only investigations on which Ranbaxy relies in its NDA 21-863 are the non-clinical pharmacology and toxicology data and the clinical safety and efficacy data for Advil Migraine Liqui-gels (Ibuprofen Liquid-Filled Capsules) 200 mg. Thus, the "drug for which investigations were conducted" for purposes of the statute and the regulations, is Advil Migraine Liqui-gels. These are no patents listed in the Orange Book for Advil Migraine Liqui-gels. Accordingly, Ranbaxy's 505(b)(2) application, which was submitted with a Paragraph I certification, complies with the applicable statutory and regulatory requirements.

Ranbaxy's NDA 21-863 does not rely on any investigations conducted for Banner Pharmacap's NDA 21-472. Accordingly, under the clear language of the statute and

May 10, 2005
New Drug Application No. 21-863
Ibuprofen Liquid Filled Gelatin Capsules 200 mg

regulations, Ranbaxy's NDA need not include a certification for any patents listed as claiming Banner's drug product.

Ranbaxy recognizes that FDA has determined that a 505(b)(2) application must contain patent certifications for any listed drug that is the pharmaceutical equivalent of the drug referenced in the 505(b)(2) application. See, e.g., Abbott Response, Draft guidance. This determination, however, is contrary to the applicable Hatch-Waxman statutory and regulatory criteria. Ranbaxy therefore (1) objects to FDA's decision to require Ranbaxy to file a certification as to Banner's drug product; (2) withdraws its paragraph IV certification, leaving the original Paragraph I certification as the only certification required by and contained in the 505(b)(2) application; and (3) believes no thirty month stay was triggered by Banner's filing of a patent infringement suit.

All correspondence with regard to this New Drug Application should be directed to my attention, at the following address:

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Please contact me at 609-720-5666 if you have any questions regarding this submission.

Sincerely,



Abha Pant
US Agent for Ranbaxy Laboratories Limited