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March 21, 2006

BY FEDERAL EXPRESS

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: **Docket No. 2005P-0436:**
NDA 21-863; Ibuprofen Liquid Filled Gelatin Capsules 200 mg; Ranbaxy Laboratories Ltd.

SECOND SUPPLEMENT TO CITIZEN PETITION

The undersigned, on behalf of Banner Pharmacaps Inc. of High Point, North Carolina, submits this Second Supplement to its above-referenced Citizen Petition.

I. Approval of Banner's Ibuprofen Drug Product for Migraine

In a very recent development, on March 13, 2006, Banner's drug product ibuprofen liquid filled gelatin capsules 200 mg was approved for the treatment of migraine (NDA 21-472/S-005). A copy of the approval letter is enclosed.

II. Banner's Product is Indisputably the RLD

Ranbaxy's proposed drug product is ibuprofen liquid filled gelatin capsules 200 mg, with ibuprofen base (ibuprofen in free acid form) as the active ingredient, indicated for treatment of migraine (Ranbaxy comments to Citizen Petition, p. 5). Banner's product includes ibuprofen base as the active ingredient, and now has an approved migraine indication.

Therefore, it is all the more certain that Banner's product is the reference listed drug (RLD), upon which Ranbaxy must rely. Ranbaxy's drug product has the same active ingredient, dosage form, strength, route of administration and labeled indication as Banner's approved drug product. Ranbaxy no longer has the excuse that its migraine indication differs from Banner's. Indeed, the Orange Book

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unequivocally states that Banner's drug product is the RLD for ibuprofen liquid filled gelatin capsules 200 mg.

From the foregoing, it further follows that the proper regulatory approval mechanism for Ranbaxy's drug product is an Abbreviated New Drug Application (ANDA). Ranbaxy should be required to convert its Section 505(b)(2) NDA to an ANDA, based on Banner's product as the RLD. Upon conversion to an ANDA, Ranbaxy should be required to conduct a study demonstrating bioequivalence to Banner's product, prior to any final approval decision on Ranbaxy's application.*

III. Ranbaxy Must Maintain A Certification To Banner's '426 Patent

Since Ranbaxy's drug product is subject to ANDA requirements, there can be no doubt that Banner must maintain a certification as to U.S. Patent No. 6,251,426, owned by Banner and listed in the Orange Book for Banner's RLD. 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12)(i)(A).**

IV. Conclusion

For the reasons set forth in Banner's original Citizen Petition, First Supplement thereto and herein, Banner's Citizen Petition should be granted in all respects.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By_____
Charles J. Raubicheck

CJR:bav
Encl.

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* Concerning safety data, on information and belief Ranbaxy did not rely on Wyeth's NDA, but was required by FDA to submit safety information from a scientific literature search. As for efficacy data, Ranbaxy can rely additionally on Wyeth's NDA, as Banner did.

** Banner advances this position without waiving the position in its Citizen Petition and First Supplement that Ranbaxy must certify to the '426 patent if Ranbaxy is permitted to maintain its Section 505(b)(2) application.

cc(w/encl.): Charles Ganley, M.D.
Director, FDA Office of Nonprescription Drug Products (HFD-560)

Andrea Leonard-Segal, M.D.
Acting Director, FDA Division of Nonprescription Clinical Evaluation (HFD-560)

Elizabeth H. Dickinson, Esq.
Kim E. Dettelbach, Esq.
FDA Office of Chief Counsel (GCF-1)

Leah A. Christl, FDA Division of
Nonprescription Drug Products (HFD-560)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-472/S-005

Banner Pharmacaps Inc.
Attention: Shelly K. Meachum, B.Sc., RAC
Director, Regulatory Affairs
4125 Premier Drive
High Point, NC 27265

Dear Ms. Meachum:

Please refer to your supplemental new drug application dated January 26, 2005, received January 27, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ibuprofen capsules, 200 mg.

We acknowledge receipt of your submissions dated November 17, 2005 and January 12, 2006.

Your submission of January 12, 2006 constituted a complete response to our November 18, 2005 action letter.

This supplemental new drug application provides for ibuprofen capsules, 200 mg, for the treatment of migraine.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container and carton labels submitted November 17, 2005), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL for **all stock keeping units** according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-472/S-005**." Approval of this submission by FDA is not required before the labeling is used.

In addition, we have the following recommended revision to your label:

> Increase the size of the arrow symbols and use a contrasting color to increase their prominence to help consumers read the label information in the correct order because of the volume of text and the number of separate panels included in the Drug Facts box on the outer carton.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for under the age of 12 years and deferring pediatric studies for ages 12 - 17 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of migraine in pediatric patients ages 12 - 17 years.

   Final Report Submission: March 13, 2009

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

In addition, we request that you submit one copy of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print to this division.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Acting Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Andrea Segal
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