BANNER
PHARMACAPS

October 10, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

This Citizen's Petition is submitted by the undersigned on behalf of Banner Pharmacaps, Inc. under the authority of 21 CFR §10.30, 21 CFR §314.93, and Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act. The petitioner is requesting that the Food and Drug Administration permit the filing of an Abbreviated New Drug Application for a proposed drug product that has the same active ingredient, is of the same strength, and is expected to have the same therapeutic effect as that of a Reference Listed Drug in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, but differs in dosage form.

A. Action Requested

By this petition, the Commissioner of the Food and Drug Administration is being requested to declare that:

(1) A new drug application for Naproxen Sodium, 220 mg (equivalent to 200 mg Naproxen) soft gelatin capsules is suitable for submission as an Abbreviated New Drug Application (ANDA), pursuant to 21 CFR §314.94;

(2) The Reference Listed Drug (RLD) on which the contents of this petition is based is Bayer Corporation's Aleve® (Naproxen Sodium, 220 mg) tablets;

(3) Therefore, a request is being made to change the dosage form from tablet to soft gelatin capsule.

02P.0473 CP1

BANNER PHARMACAPS INC P O BOX 2210 4125 PREMIER DRIVE HIGH POINT, NC 27261-2210 PHONE 336 812 8700 FAX 336 812 8777
CALIFORNIA NORTH CAROLINA CANADA MEXICO NETHERLANDS INDIA

At this time, the undersigned is also requesting a waiver of the requirement to conduct pediatric studies in accordance with 21 CFR §314.55(c)(2). The basis for this request is that:

(1) The effectiveness of the proposed drug product can be extrapolated from adequate and well-controlled studies in adult and pediatric populations;

(2) The dosing and safety data for relevant age groups is well-defined;

(3) The innovator product has a long history of use in ages 12-17 as an OTC drug (first approved as an oral tablet January 11, 1994);

(4) The drug product is not labeled with dosage recommendations in children less than 12 years old.

B. Statement of Grounds

Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act allows for the submission of an Abbreviated New Drug Application for a proposed new drug product that differs in dosage form from that of the Reference Listed Drug on which it is based, provided that the Commissioner of Food and Drugs has approved a petition, filed by or on behalf of the applicant, requesting a declaration that an application to market a drug product with such change is suitable for an ANDA submission.

The Commissioner of Food and Drugs has previously approved ANDA suitability petitions of this nature, in particular, those in which the petitioners have sought to change the dosage form in order to make an alternate dosage form available for those who have difficulty swallowing tablets or simply prefer the alternative.

In support of this petition, the following information is being provided:

(1) The proposed drug product is a soft gelatin capsule with the same active ingredient, the same strength, and the same route of administration as that of the RLD, Aleve® (Naproxen Sodium, 220 mg) tablets. A copy of the most recent Orange Book listing of "Approved Drug Products with Therapeutic Equivalence Evaluations" is provided. (Attachment 1)

(2) The proposed drug product will be labeled with the same conditions of use as the RLD for consumers 12 years of age and older, and is expected to have the same therapeutic effect when used as indicated in the labeling. A copy of the RLD labeling is provided. (Attachment 2)

(3) Labeling for the proposed drug product and the RLD will differ with respect to dosage form, inactive ingredients, and manufacturer/distributor identification and contact information. A draft of the proposed drug product labeling is provided. (Attachment 3)

C. Environmental Impact

The applicant claims a categorical exclusion under 21 CFR §25.31.

D. Economic Impact

Information will be provided upon request of the Commissioner.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted by:

Donna Lee, R.Ph.
Director of Regulatory Affairs and Project Management
Phone: (800) 447-1140 ext. 3312

(3) Attachments

ATTACHMENT 1

Active Ingredient Search Results from "OTC" table for query on "naproxen."

Appl No	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
020204	Yes	NAPROXEN SODIUM	Tablet; Oral	EQ 200MG BASE	ALEVE	BAYER
075168	No	NAPROXEN SODIUM	Tablet; Oral	EQ 200MG BASE	NAPROXEN SODIUM	DR REDDYS LABS INC
074646	No	NAPROXEN SODIUM	Tablet; Oral	EQ 200MG BASE	NAPROXEN SODIUM	INVAMED
074635	No	NAPROXEN SODIUM	Tablet; Oral	EQ 200MG BASE	NAPROXEN SODIUM	LEINER
074661	No	NAPROXEN SODIUM	Tablet; Oral	EQ 200MG BASE	NAPROXEN SODIUM	PERRIGO
074789	No	NAPROXEN SODIUM	Tablet; Oral	EQ 200MG BASE	NAPROXEN SODIUM	PVT FORM
021076	Yes	NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE	Tablet, Extended Release; Oral	EQ 200MG BASE;120MG	ALEVE COLD AND SINUS	BAYER

Thank you for searching the Electronic Orange Book

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