

**BANNER
PHARMACAPS**

August 5, 2002

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

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 Loperamide Hydrochloride (Loperamide HCl), 2 mg 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 McNeil Consumer Healthcare's Imodium® A-D (Loperamide HCl, 2 mg) tablets;
- (3) Therefore, a request is being made to change the dosage form from tablet to soft gelatin capsule.

02P.0380

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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 the pediatric population as an OTC drug (first approved as an oral solution March 1, 1988 and as an oral tablet November 2, 1989);
- (4) It is unlikely that a soft gelatin capsule will be administered to a substantial number of children under 6 years of age.

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, Imodium® A-D (Loperamide HCl, 2 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 Reference Listed Drug (RLD) labeling includes conditions of use for children under 12 years of age. These conditions specify ½ caplet (tablet) dosing, which is not feasible for accurate delivery of the recommended dosage with the proposed "soft gelatin capsule" dosage form. Hence the proposed drug product will be labeled for consumers 12 years of age and older only. RLD labeling is provided. (Attachment 2)

- (3) 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. Labeling for the proposed drug product and the RLD will differ with respect to the manufacturer identification and contact information, and the inactive ingredients. 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) 447-1144 ext. 3312

(3) Attachments

ATTACHMENT 1

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

| Appl No | RLD | Active Ingredient | Dosage Form; Route | Strength | Proprietary Name | Applicant |
|---------|-----|---------------------------------------|------------------------|-----------|------------------|--------------------|
| 074991 | No | LOPERAMIDE HYDROCHLORIDE | Solution; Oral | 1MG/5ML | LOPERAMIDE HCL | DURAMED PHARM BARR |
| 074352 | No | LOPERAMIDE HYDROCHLORIDE | Solution; Oral | 1MG/5ML | LOPERAMIDE HCL | HI TECH PHARMA |
| 019487 | Yes | LOPERAMIDE HYDROCHLORIDE | Solution; Oral | 1MG/5ML | IMODIUM A-D | MCNEIL |
| 074730 | No | LOPERAMIDE HYDROCHLORIDE | Solution; Oral | 1MG/5ML | LOPERAMIDE HCL | MORTON GROVE |
| 073243 | No | LOPERAMIDE HYDROCHLORIDE | Solution; Oral | 1MG/5ML | LOPERAMIDE HCL | PERRIGO |
| 073079 | No | LOPERAMIDE HYDROCHLORIDE | Solution; Oral | 1MG/5ML | LOPERAMIDE HCL | ROXANE |
| 073478 | No | LOPERAMIDE HYDROCHLORIDE | Solution; Oral | 1MG/5ML | LOPERAMIDE HCL | TEVA |
| 020448 | Yes | LOPERAMIDE HYDROCHLORIDE | Tablet, Chewable; Oral | 2MG | IMODIUM A-D | MCNEIL |
| 073254 | No | LOPERAMIDE HYDROCHLORIDE | Tablet; Oral | 2MG | LOPERAMIDE HCL | LEINER |
| 019860 | Yes | LOPERAMIDE HYDROCHLORIDE | Tablet; Oral | 2MG | IMODIUM A-D | MCNEIL |
| 074091 | No | LOPERAMIDE HYDROCHLORIDE | Tablet; Oral | 2MG | LOPERAMIDE HCL | OHM LABS |
| 074194 | No | LOPERAMIDE HYDROCHLORIDE | Tablet; Oral | 2MG | LOPERAMIDE HCL | PERRIGO |
| 075232 | No | LOPERAMIDE HYDROCHLORIDE | Tablet; Oral | 2MG | LOPERAMIDE HCL | PERRIGO |
| 020606 | Yes | LOPERAMIDE HYDROCHLORIDE; SIMETHICONE | Tablet, Chewable; Oral | 2MG;125MG | IMODIUM ADVANCED | MCNEIL |
| 021140 | No | LOPERAMIDE HYDROCHLORIDE; SIMETHICONE | Tablet; Oral | 2MG;125MG | IMODIUM ADVANCED | MCNEIL CONS SPECLT |

Thank you for searching the Electronic Orange Book

[Return to Electronic Orange Book Home Page](#)

ATTACHMENT 2

IMODIUM® A-D

Active ingredient (in each caplet)

Loperamide HCl 2mg

Purpose

Anti-diarrheal

Use

Controls symptoms of diarrhea, including Traveler's Diarrhea.

Warnings

Allergy Alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl.

Do not use if you have bloody or black stool.

Ask a doctor before use if you have fever, mucus in the stool, or a history of liver disease.

Ask a doctor or pharmacist before use if you are taking antibiotics.

Stop use and ask a doctor if symptoms get worse or diarrhea lasts for more than 2 days.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Drink plenty of clear fluids to help prevent dehydration caused by diarrhea.

Find right dose on chart. If possible, use weight to dose; otherwise, use age.

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER

2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours.

CHILDREN 9-11 YEARS OLD (60-95 LBS.)

1 caplet after the first loose stool; ½ caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours.

CHILDREN 6-8 YEARS OLD (48-59 LBS.)

1 caplet after the first loose stool; ½ caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours.

CHILDREN UNDER 6 YEARS OLD (UP TO 47 LBS.)

Ask a doctor.

Other Information

Store between 20-25°C (68-77°F).

Do not use if carton or blister unit is open or torn.

See side panel for lot number and expiration date.

Inactive ingredients

Colloidal silicon dioxide, D&C Yellow #10, dibasic calcium phosphate, FD&C Blue #1, magnesium stearate, microcrystalline cellulose,.

Questions or comments?

Call 1-800-962-5357. Llamamos con preguntas: 1-888-466-8746

**McNeil Consumer Healthcare
DIVISION OF MCNEIL-PPC, INC.
Fort Washington, PA 19034 USA**

ATTACHMENT 3

LOPERAMIDE HCl

Active ingredient (in each softgel)

Loperamide HCl 2mg

Purpose

Anti-diarrheal

Use

Controls symptoms of diarrhea, including Traveler's Diarrhea.

Warnings

Allergy Alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl.

Do not use if you have bloody or black stool.

Ask a doctor before use if you have fever, mucus in the stool, or a history of liver disease.

Ask a doctor or pharmacist before use if you are taking antibiotics.

Stop use and ask a doctor if symptoms get worse or diarrhea lasts for more than 2 days.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Drink plenty of clear fluids to help prevent dehydration caused by diarrhea.

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER

2 softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than 4 softgels in 24 hours.

Other Information

Store between 15-30°C (59-86°F).

Do not use if carton or blister unit is open or torn.

See side panel for lot number and expiration date.

Inactive ingredients

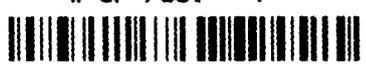
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TO: HFA-305/ RM 1061

FDA
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RM :
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Rockville, Maryland 20857

BANNER
PHARMACAPS
P O Box 2210, 4125 PREMIER DRIVE
HIGH POINT, NORTH CAROLINA 27261-2210



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MAIL



Questions or comments?

To be determined.

RM : HFA-305 / RM 1061

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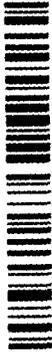
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