



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 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 strength and 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), 1 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 strength from 2 mg to 1 mg and change the dosage form from tablet to soft gelatin capsule.

02P-0424



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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 strength and 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 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. Further, for products labeled with divided-dosage regimens (i.e., ½ tablet), the Commissioner has approved ANDA suitability petitions to provide a means by which the lower strength proposed drug product could meet the conditions of use in the approved RLD labeling on which it is based.

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 and the same route of administration as that of the RLD, Imodium® A-D (Loperamide HCl, 2 mg) tablets. A copy of the most current 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 one-half strength of the RLD and appropriately labeled with the recommended dosing regimen for all intended consumers. RLD labeling is provided. (Attachment 2)

(3) The proposed drug product will be labeled with the same conditions of use as the RLD, 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 dosing regimen, 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:



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(3) Attachments