



FILE COPY

September 27, 2002

Donna Lee, R.Ph.
Banner Pharmacaps Inc.
P.O. Box 2210
4125 Premier Drive
High Point, NC 27261-2210

Dear Dr. Lee:

Your petition requesting the Food and Drug Administration to permit the filing of an Abbreviated New Drug Application for Loperamide Hydrochloride 1 mg soft gelatin capsules was received by this office on 08/22/02. It was assigned docket number 02P-0424/CP 1 and it was filed on 08/22/02. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

02P.0424

ACK 1