



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

FILE COPY

August 22, 2002

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

Dear Ms. Lee:

Your petition, on behalf of Banner Pharmacaps, Inc., requesting the Food and Drug Administration to permit the filing of an Abbreviated New Drug Application (ANDA) for Loperamide Hydrochloride 2mg soft gelatin capsules, was received by this office on 08/22/02. It was assigned docket number 02P-0380/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.0380

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