



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FILE COPY

August 10, 2001

Jenaay M. Brown DVM
Smart Drug Systems, Inc.
7 Masons Island Road
Mystic, CT 06355

Dear Ms. Brown:

Your petition requesting the Food and Drug Administration to permit the filing of an ANADA for a sterile injectable compressed rod containing between 35-60% ivermectin, was received by this office on 08/10/01. It was assigned docket number 01P-0349/CP 1 and it was filed on 08/10/01. 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,

Gloria Ortega
Dockets Management Branch

01P-0349

ACK 1