



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SP 00P-1519/CP 1

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

Dear Dr. Brown:

We refer to your Suitability Petition filed September 15, 2000, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a dosage form that differs from that of an approved new animal drug. The proposed pioneer product is Merial's Heartgard® Chewables (ivermectin) which is intended for use in dogs (NADA 140-886).

Your proposed product differs from the pioneer product in dosage form. The proposed generic product is a chewable compressed tablet, whereas the pioneer is a chewable formulation that is an "extruded" product that has a texture similar to a semi-moist dog food. The directions for use, the amount of active ingredient per dosage unit, and the dosage of active ingredient per pound of body weight will be the same.

Change in dosage form is one of the five variances in the pioneer product which can be considered through a Suitability Petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended. We are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed generic product. You indicated in your petition that you plan to conduct appropriate bioequivalence and palatability testing under your Investigational New Animal Drug Application. Palatability is not directly related to effectiveness. Palatability studies may be required in an ANADA with regard to the change in dosage form under section 512(n)(1)(D) of the FFDCA. We recommend that you submit protocols for our evaluation before initiating any studies.

Your Suitability Petition is approved. Approval of the Suitability Petition does not alter the requirements for approval of the ANADA, nor assure approval of the ANADA. Please include a copy of this letter in your generic application submission.

We will conduct a definitive labeling review when the ANADA for the proposed generic product is submitted to the Center. The generic labeling should be a verbatim copy of the approved labeling for the pioneer, with certain allowable differences, such as manufacturer's tradename and the changes approved in this petition.

DEC - 7 2000
11 73 00 DEC 15 AM '00

00P-1519

PAV

SP 00P-1519/CP 1

Page 2

You may contact Dr. Lonnie W. Luther, Generic Animal Drug and Quality Assurance Staff, telephone (301) 827-0209, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,

A handwritten signature in cursive script that reads "Claire M. Lathers". The signature is written in dark ink and is positioned above the printed name and title.

Claire M. Lathers, Ph.D., F.C.P.

Director

Office of New Animal Drug Evaluation

Center for Veterinary Medicine



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

2172 '00 DEC 15 AM 0:36

September 15, 2000

Ms. Jenaay M. Brown DVM
Smart Drug Systems,
Incorporated
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 generic new animal drug which differs from that of the pioneer product was received by this office on 09/15/00. It was assigned docket number 00P-1519/CP 1 and it was filed on 09/15/00. 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,

Helen K. Harris
Dockets Management Branch

00P-1519

ACK 1

MEMO

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

DATE: 12/14/00

FROM: Animal Scientist
Quality Assurance Support Staff, HFV-102

SUBJECT: Suitability Petition Response for Display.

TO: Lyle Jaffe, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD
Dockets Management Branch, 301 827-6860 (V)

2174 '00 DEC 15 AM 03:36

The attachment is the Center for Veterinary Medicine's letter related to Suitability Petition SP 00P-1519 CP 1 Smart Drug Systems, filed as a **Suitability Petition**. We are forwarding a copy for public display with the petition.

If you have any questions, please call me at 827-0211, or FAX 594-2297.

Thank you.



12-14-00

Sam Hansard, Ph.D.

Attachment

Samuel Hansard, Ph.D.
FDA/CVM/ONADE/GADQAS/HFV-102
7500 Standish Place MPN II 384
Rockville, MD 20855
(301) 827-0211
(301) 594-2297 fax
shansard@cvm.fda.gov