DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FDA-2013-P-0426/CP1

AUG 1 2013

Shotwell & Carr, Inc.
Attention: Paul W. Carr. P.E., R.A.C.
President
1415 Halsey Way, Suite 304
Carrollton, TX 75007

Re: Suitability Petition Request

Dear Mr. Carr:

We approve the suitability petition (FDA-2013-P-0426) you filed on April 22, 2013. In the petition, you requested permission to submit an abbreviated new animal drug application (ANADA) for a proposed generic new animal drug that differs in dosage from the reference listed new animal drug (RLNAD). The RLNAD is ATOPICA (cyclosporine) Gelatin Capsules, sponsored by Novartis Animal Health US, Inc. under NADA 141-218. ATOPICA is indicated for the control of atopic dermatitis in dogs weighing at least 4 pounds body weight. The proposed generic new animal drug is an un-encapsulated, non-aqueous solution of cyclosporine with the indications and dosage schedule approved for the RLNAD, which is a gelatin encapsulated, non-aqueous solution of cyclosporine.

Your proposed change from the RLNAD is a permissible change that can be considered through a suitability petition, as defined under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act. We are approving the petition because we find that the proposed change in dosage form does not require you to conduct investigations to show the safety and effectiveness of the generic new animal drug for its proposed intended uses.

Approval of this suitability petition does not guarantee approval of the ANADA for your proposed generic new animal drug. We will make that determination after you have submitted your ANADA for our review.

The correct regulation to cite for a categorical exclusion from the requirement to file an environmental assessment for this agency requested action is 21 CFR 25.15. In future you may use the following language:

> In accordance with 21 CFR 25.15, <**Sponsor name**> claims that the agency requested action in this suitability petition qualifies for categorical exclusion from the requirement to prepare an environmental assessment as set forth in 21 CFR 25.30(h). We confirm that to our knowledge no extraordinary circumstances exist that may significantly affect the quality of the human environment as described in 21 CFR 25.21.

When you submit your ANADA, you must identify the RLNAD referred to in this suitability petition, and include a copy of this letter. We strongly recommend that you

request a pre-submission conference according to 21 CFR 514.5 to discuss the requirements and potential pathways for approval of the application.

A copy of this letter approving your petition will be placed on public display at www.regulations.gov with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. If you have any questions, please contact Dr. John K. Harshman, Director, Division of Generic Animal Drugs, at (240) 276-8197.

Sincerely,

for Elizabeth Rettie

Steven D. Vaughn, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine