DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

I-011389-P-0020-NV

NRSP-7 Minor Species Program
Attention: Margaret Oeller, D.V.M.
FDA Liaison to the MUADP
FDA/CVM (HFV-50)
7500 Standish Place
Rockville, MD 20855

Re: Impact technical section complete for progesterone-impregnated controlled intravaginal drug release (CIDR) device in goats

Dear Dr. Oeller:

Based upon the information you submitted on September 19, 2011, we consider the Environmental Impact technical section to be complete for the use of for progesterone-impregnated controlled intravaginal drug release (CIDR) device in goats. The product is for use for synchronization of fertile estrus in meat and dairy goats during the breeding season and will be administered with a dose of 0.3 g of progesterone per implant for a period of nineteen days.

In your submission you claimed a categorical exclusion under 21 CFR 25.33(d)(4) for the approval of progesterone-impregnated controlled intravaginal drug release (CIDR) device for the intended uses listed above. Furthermore, you stated that to your knowledge, no extraordinary circumstances exist that may significantly affect the human environment. We agree that the proposed uses of this drug as described above fall within the claimed categorical exclusion and we are not aware of any extraordinary circumstances. Therefore, neither an environmental assessment nor an environmental impact statement is required.

When you submit your administrative new animal drug application (NADA), your signature on the FORM FDA 356v re-certifies that the conditions of the categorical exclusion are still applicable at the time of your NADA submission.

Include a copy of this technical section complete letter when you submit your NADA. Please contact us if there are changes in the product development plan (e.g., indication, dosage, duration of use) or you become aware of any issues that may impact the status of this technical section or your application. We will make a final decision on whether we can approve your application after we have reviewed all of the data for all applicable technical sections and any other information available to us, as a whole, and determined whether the requirements for approval described in the Federal Food, Drug, and Cosmetic Act have been met.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact me at 240-276-8169. You may also contact Charles Eirkson, Leader, Environmental Safety Team, at 240-276-8173.

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Sincerely,

{see appended electronic signature page}
Veronica N. Taylor, Ph.D.
Acting Director, Division of Scientific Support
Office of New Animal Drug Evaluation
Center for Veterinary Medicine