DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

I-011389-P-0018-HF August 12, 2011

National Research Support Project No.7
Attention: Margaret Oeller, D.V.M.
FDA Liaison to the NRSP-7
FDA/CVM
7500 Standish Place
Rockville, MD 20855

Re: Human food safety technical section complete for the use of CIDR-G in goats

Dear Dr. Oeller:

Based on the information you submitted on November 18, 2010, and amended on June 14, 2011 (T-0019) and the information contained in the Investigational New Animal Drug (INAD) file 011389, we consider the human food safety technical section to be complete. The human food safety technical section is complete for the use of CIDR-G (Progesterone Impregnated Controlled Intravaginal Drug Release Insert) in goats.

The human food safety requirements for the use of CIDR-G in goats have been satisfied for toxicology, residue chemistry, and microbial food safety.

The following human food safety parameters describe this product:

- Progesterone is regulated based on allowable incremental increase limits for residues above baselines. Using the revised daily consumption values, the updated allowable incremental increase limits for residues of progesterone in edible tissues are 5 ppb for muscle, 15 ppb for liver, and 30 ppb for kidney and fat.
- It is not necessary to establish allowable incremental increase limits for progesterone in milk.
- Withdrawal Period: Zero
- Milk Discard Time: Zero
- Regulatory methods for progesterone are not required.
- Because progesterone has not been reported to adversely affect bacteria of public health concern through antimicrobial resistance pressure, and residues of progesterone in edible tissues of goats are not expected to impact the intestinal flora of human consumers, microbial food safety information is not needed for this proposed use of progesterone.

Include a copy of this technical section complete letter when you submit your new animal drug application. 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 240-276-8225. You may also contact Dr. Lynn G. Friedlander, Leader, Residue Chemistry Team, at 240-276-8226.

Sincerely,

Karen B. Ekelman, PhD
Director, Division of Human Food Safety
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Enclosure: FOI Summary Language for Human Food Safety