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July 12, 2004

Dr. Lonnie Luther, Staff Chief (HFV-102)
c/o Dockets Management Branch (HFA-305)
Room 1061
5630 Fishers Lane
Food and Drug Administration
Rockville, MD 20852

Re: Docket No. 2004P-0175
Suitability Petition
Intravaginal Progesterone Insert

Dear Dr. Luther:

Intervet Inc. submitted on April 12, 2004, a suitability petition under §512(n)(3) of the Federal Food, Drug and Cosmetic Act ("the Act") requesting permission to file an abbreviated new animal drug application ("ANADA") for an intravaginal progesterone insert containing a different strength of progesterone from the reference approved new animal drug. Pharmacia & Upjohn, a division of Pfizer Inc., submitted comments on the suitability petition objecting to the filing of an ANADA. The Pfizer comments misconstrue the statutory criteria for approval of a suitability petition and provide no legal basis for turning down the petition. Accordingly, the suitability petition should be approved as originally requested by Intervet.

As pertinent to the subject petition, the Act authorizes the filing of an ANADA based on a showing that the proposed new animal drug has the same active ingredients, route of administration, dosage form, and strength as the approved reference drug. Section 512(n)(1)(B), (D) of the Act. Alternatively, if the proposed drug differs from the reference drug in one or more of these four "sameness" elements, the ANADA may be filed pursuant to approval of a suitability petition. *Id.* In this case, the active ingredient (progesterone), the route of administration (intravaginal), and the dosage form (intravaginal insert) of the proposed drug are the same as the reference drug. Among the four statutory "sameness" elements only the strength differs between the proposed and reference drugs (1.0 gram progesterone/insert in the proposed drug, 1.38 grams progesterone/insert in the reference drug). Section 512(n)(3) of the Act requires approval of a suitability petition ("the Secretary shall approve") unless the agency finds that "investigations must be conducted to show the safety and effectiveness, in animals to be treated with the drug, of [the statutory "sameness" element] which differ[s] from the approved new animal drug." (emphasis added.) Because the only statutory "sameness" element which differs is strength, and because the safety and effectiveness of the proposed strength can be completely established through bioequivalence studies submitted in an ANADA, the Act requires

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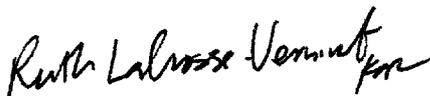
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approval of the petition, i.e., there can be no valid finding that clinical investigations must be conducted to support the difference in strength.

Any other differences between the products that are not among the four statutory "sameness" elements (e.g., size, shape, color, inactive ingredients, and any number of other potential differences) do not provide any legal basis for denying the suitability petition or refusing to allow an ANADA to be filed. Any questions raised by such matters must be dealt with in the ANADA review and approval process. This is confirmed by considering a hypothetical situation in which active ingredients, route of administration, dosage form, and strength are all the same in the proposed drug as in the reference drug. In such a case, there clearly would be no legal basis for refusing to accept an ANADA even though there may be differences in size, shape, color, inactive ingredients and so forth between the proposed and reference drugs. These matters and their significance are handled during ANADA review and approval, not by blocking the filing of an ANADA in the first instance.

In conclusion, Intervet Inc. requests approval of its suitability petition as submitted.

Sincerely,



Ruth LaCrosse-Vernimb
Manager, Regulatory Compliance and
QA -- Pharmaceuticals
Intervet Inc.