



15 November 2004

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Dr. Lonnie Luther, Staff Chief
Generic Animal Drug Team (HFV-104)
C/O: Document Control Unit (HFV-199)
FDA Center for Veterinary Medicine
7500 Standish Place
Rockville, Maryland 20855

RE: CHALLENGE OF SUITABILITY PETITION (2004P-0489)

Dear Dr. Luther:

Intervet Inc. (Intervet) was recently made aware of the suitability petition (2004P-0489) filed on 05 November 2004 by Bioniche Animal Health USA, Inc. (Bioniche) to copy P.G. 600[®] (NADA 140-856), pregnant mare serum gonadatropin (PMSG) and human chorionic gonadatropin (HCG). It is Intervet's position that this petition should be denied by the Agency on the following grounds:

- Bioniche is correct in concluding that their proposed product is not eligible for filing as an Abbreviated NADA due to the differences in packaging configuration between P.G. 600[®] and the proposed new product. These variations will result in differences in the section of the label that describes the packaging and procedures for preparing the product for administration.
- Bioniche is incorrect, however, in concluding that this lack of eligibility for Abbreviated NADA filing can be addressed by seeking approval of a suitability petition under 512(n)(3) of the Act. The proposed new product does not meet the pre-requisites for a Suitability Petition; namely, it does *not* differ from the pioneer product in active ingredients, route of administration, dosage form or strength. Accordingly, a suitability petition is simply not available to seek permission to file an Abbreviated NADA for the proposed new product.



2004P-0489

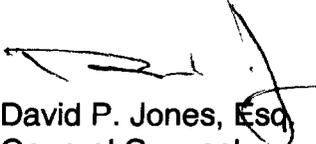
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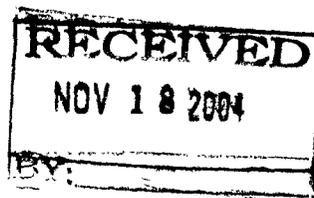
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- The difference in packaging configuration and in the procedures for preparing the proposed new product for administration may create significant issues for preparation and use of the new product. For example:
 - One could use either of the actives (PMSG, HCG) separately, which would constitute an off-label use. Safety and efficacy have not been demonstrated under this NADA for use of either of component separately.
 - Since these components would be reconstituted individually, one would be able to change the ratio of the PMSG and the HCG from what is indicated on the P. G. 600[®] label (2:1, respectively). Again, such a change in the ration could adversely affect the efficacy or the safe use of the proposed new product.
 - Because an additional mixing step is required, there is a greater potential for the introduction of contaminants into this proposed new product.

Given these information, we request that the Agency deny the suitability petition. We appreciate your consideration of this matter and would value the opportunity to discuss these issues with you in more detail at your convenience. Please do not hesitate to contact me if you have any questions.

Sincerely,


David P. Jones, Esq.
General Counsel
Intervet Inc.



Sent Fed Ex Overnight