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**Bioniche Pharma  
 (Canada) Ltd.**

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# Fax

<b>To:</b> Martin Shimer, FDA	<b>From:</b> Rhonda Noll, Manager Regulatory Affairs
<b>Fax:</b> 1-301-594-1174	<b>Date:</b> May 8, 2001
<b>Phone:</b>	<b>Pages:</b> 2
<b>Re:</b> Ketamine HCl - Suitability Petition Docket # 01P-0156/CP 1	<b>CC:</b>

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Dear Martin:

Further to your telephone request this morning please find below Bioniche Pharma's Statement of Grounds for the above Suitability Petition:

*Bioniche Pharma would like to have the 100mg/mL strength as part of their Ketamine Hydrochloride line due to the variance in Dosage and Administration and the variance in weight of patients requiring Ketamine Hydrochloride Injection.*

*The average adult dosage administered intravenously is 2 mg/kg (1mg/lb), if the patient weighs between 150 and 200 lbs, which the majority of the population does, than the initial dosage would be 150 or 200 mg, so instead of administering 3 - 4 mL of the 50 mg/mL Ketamine one could administer less product by giving 1.5 - 2 mL of the 100 mg/mL. The same rationale can be used for intramuscular administration; less of the product can be given if one can use the higher strength. Since the product is in a larger vial and has a preservative in it, it can be reused during surgery for maintenance of anesthesia for longer surgeries, without having to open another vial.*

*Another added benefit for having the 100 mg/mL strength, 10 mL vial is that for intravenous administration the product needs to be diluted and administered slowly, therefore the product can be added to a I.V. bag and administered at the proper rate and then closed off and if needed it can be reopened during the surgery to further maintain the anesthesia, without having to prepare another solution.*

*In addition, since some patients fluids need to be restricted one could use the higher dosage product with less added fluid and still obtain the same affect.*

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*In addition, since some patients fluids need to be restricted one could use the higher dosage product with less added fluid and still obtain the same affect.*

*The final benefit for having the 100 mg/mL strength, 10 mL vial is that it can be more cost effective for physicians and hospitals.*

If you require further information please let me know.

Kindest Regards,

*Rhonda Noll*