BIONICHE
PHARMA GROUP
A BIONICHE LIFE SCIENCES COMPANY

8302 '01 MAR 28 P2:20

March 26, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1 – 23, 12420 Parklawn Drive
Rockville MD USA
20857

ANDA Suitability Petition

Dear Sir or Madame:

Bioniche Pharma (Canada) Ltd. submits this ANDA suitability petition under 21 CFR section 314.93. Bioniche Pharma (Canada) Ltd. requests that the Commissioner of Food and Drugs permit us to file an ANDA for our product Ketamine Hydrochloride Injection, USP 100 mg/mL which differs from the reference listed drug, Ketalar® (Ketamine Hydrochloride Injection, USP) 100 mg/mL, Parke-Davis (Parkedale Pharmaceuticals), Application #016812, by the following:

Ketamine Hydrochloride Injection, USP 100 mg/mL

100 mg/mL of Ketamine base and not more than 0.1 mg/mL benzethonium chloride in a **10 mL vial**.

Ketalar® 100 mg/mL

100 mg/mL of Ketamine base and not more than 0.1 mg/mL Phemerol® (benzethonium chloride) in a **5 mL vial.**

The dosage directions remain the same for Ketamine Hydrochloride Injection, USP 100 mg/mL as Ketalar® 100 mg/mL, as listed in the prescribing information, enclosed.

Bioniche Pharma (Canada) Ltd. is also requesting, under 21 CFR 25.31, categorical exclusion from filing an Environmental Impact Assessment.

Bioniche Pharma (Canada) Ltd. certifies, that, to the best of our knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes all information that is known to us to be unfavorable to the petition.

Sincerely,

Rhonda Noll
Regulatory Affairs Manager
Bioniche Pharma (Canada) Ltd.

Enclosed

01P-0156

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