DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 29, 2001

Rhonda Noll
Regulatory Affairs Manager
Bioniche Pharma (Canada) Ltd.
151 Dundas Street, #507
London, ON N6A 5R7

Dear Ms. Noll:

Your petition requesting the Food and Drug Administration to approve an ANDA suitability petition for Ketamine Hydrochloride Injection, USP 100 mg/mL was received by this office on 03/28/01. It was assigned docket number 01P-0156/CP 1 and it was filed on 03/29/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D Jaffe
Dockets Management Branch

01P-0156

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