

2140 '03 APR 23 A9:14

April 22, 2003

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

Rendle Mell

Withdrawal of Docket Number 02P-0419/CP 1

Dear Sir or Madame:

Bioniche Pharma (Canada) Ltd. would like to withdraw our Suitability Petition of an 18 mL vial for Amiodarone Hydrochloride Injection, based on the Gensia Sicor approval of their petition. The Docket number assigned to the petition was 02P-0419/CP 1.

Sincerely,

Rhonda Noll

Regulatory Affairs Manager Bioniche Pharma Group

Fax: Martin Shimer, FDA

1-301-594-1174

02P-0419

WDLI