



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

File: 2004/009839

Mrs Aleksandra Harasemcuk
40 Harcourt Avenue
Kealba VIC 3021

Dear Mrs Harasemcuk

Re: NSC-631570 (Ukraine) – Orphan Drug Application

I refer to your letter of 30 April 2004 seeking orphan drug designation for NSC-631570 (Ukraine), for the treatment of pancreatic cancer.

Consideration of your application (**Application No. 03-1456-4**) has been completed.

I have decided, pursuant to subregulation 16J(2) of the *Therapeutic Goods Regulations 1990* to designate NSC-631570 (Ukraine) as an orphan drug. The indication is for the treatment of pancreatic cancer.

The Therapeutic Goods Administration (TGA) would appreciate advice on when you plan to submit an application to register the designated medicine. **It is strongly recommended that you meet with staff of the TGA prior to submitting such an application, to discuss data requirements.** If the indication in your application to register the medicine differs from that in your application for orphan drug designation, additional data may be required to demonstrate that orphan designation still applies.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'L. Hunt', written over a horizontal line.

Dr Leonie Hunt
Director
Drug Safety and Evaluation Branch
Delegate of the Secretary

Dated this 8th day of June 2004