



**Australian Government**

**Department of Agriculture, Fisheries and Forestry**  
Australian Quarantine and Inspection Service

**Quarantine Act 1908 Section 13(2AA)**

Phone: 02 6272 4578  
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File Ref: 08/01772

**Permit to Import Quarantine Material**

Permit: **IP07023449** Valid From: **25 Feb 2008** Valid To: **25 Feb 2010** Page 1 of 3

Importer	Exporter
Mr Ross Wayne Hanna Global Medical Solution TA Radpharm Sci 59 Oatley Crt Belconnen ACT 2617	Mr Paul Ernest Lewis Bio-Mer Limited 38 Sonter Road Sockburn Canterbury 8042 New Zealand

**You are authorised to import the following material under the listed conditions**

*Note: This permit covers AQIS quarantine requirement only.*

All imports may be subject to quarantine inspection on arrival to determine compliance with the listed permit conditions and freedom from contamination. Imports not in compliance or not appropriately identified or packaged and labelled in accordance with the import conditions they represent may be subject to seizure, treatment, re-export or destruction at the importer's expense.

Additionally, all foods imported into Australia must comply with the provisions of the *Imported Food Control Act 1992*, and may be inspected and/or analysed against the requirements of the Australia New Zealand Food Standards Code.

All imports containing or derived from Genetically Modified material must comply with the *Gene Technology Act 2000*.

It is the importer's responsibility to identify, and to ensure it has complied with, all requirements of any other regulatory organisations and advisory bodies prior to and after importation including The Australian Customs Service, The Department of Health and Ageing, Therapeutic Goods Administration, Australian Pesticides and Veterinary Medicines Authority, Department of Environment and Water Resources, Food Standards Australia New Zealand and any state agencies such as Departments of Agriculture and Health and Environmental Protection authorities. Importers should note that this list is not exhaustive.

Import conditions are subject to change at the discretion of the Director of Quarantine. This permit may be revoked without notice.



Notification of the import must be provided to AQIS for all imported goods other than goods imported as accompanied baggage or goods imported via the mail and not prescribed under the *Customs Act 1901*. Notification must be consistent with *Quarantine Regulations 2000* (examples include a Quarantine Entry or a Quarantine declaration).

Commodity Name	Condition Number(s)	Country	End Use
<b>Human Therapeutic (Nexavir Porcine Liver Peptide Derivative)</b>	PC1672	New Zealand	Human Therapeutic

Condition	Condition Text
PC1672	1. All consignments must be accompanied by a valid Import Permit (or a method of identifying the Import Permit such as the Import Permit number) and all required documentation. Alternatively, necessary documentation must be presented to AQIS at the time of clearance. In order to facilitate clearance, airfreight or mail shipments should have all documentation securely attached to the outside of the package, and clearly marked 'Attention Quarantine'. Documentation may include Import Permit (or Import Permit number) and invoice. The importer must meet all costs associated with the importation of this product.

**Documentation Requirements**

**This permit is granted subject to the condition that fees determined under Section 86E are paid**

  Delegate of Director of Quarantine <b>Printed Name</b> Dennis Bittisnich	Stamp: 
<b>Date</b> 25 Feb 2008	

Condition	Condition Text
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2. Each consignment must be accompanied by official Government Certification, stating:

- a) The porcine ingredient has been sourced from New Zealand ; and
- b) During processing the product has been digested at pH 3 at 60°C for 3 hours, stored in 70% ethanol for 7 days, and heated to 100°C for 15 minutes

Government Certification must be:

- . on official government letterhead.
- . signed by a Government Officer whose name and title also appear (all alterations must be initialled or stamped by the government officer responsible for signing the certificate).
- . dated and free from erasures and uncertified alterations.
- . sealed with the stamp of the Government Department.
- . written in English and containing the correct statement/s as required above.
- . specific to the relevant commodity listed on this permit.
- . specific to the consignment by referring to at least one of the following: container number, bill of lading number, commercial invoice number, preferential tariff certificate number, packing list number, letter of credit number, batch/serial number or date of manufacture.

3. Each consignment must be clearly identified and linked to the relevant item(s) on the Import Permit. Identifying documentation must be available to the quarantine officer at the time of clearance. This documentation may include:

- a) an accompanying invoice or airway bill; or
- b) the physical labelling of the goods; or
- c) an overseas supplier's declaration describing the goods.

3. If the product description on the Import Permit varies from the identifying documentation provided for clearance, the importer is responsible for providing evidence to the quarantine officer that the Import Permit covers the products in the consignment.

#### Post Entry Requirements

4. Upon arrival in Australia all Nexavir Porcine Liver Peptide Derivative must be directed to the following quarantine approved premise (QAP):

Federal Express (Australia) Pty Ltd (#N0242)  
 215 -225 Euston Rd  
 ALEXANDRIA  
 NSW  
 2015

This premise is only permitted to distribute imported Nexavir Porcine Liver Peptide Derivative to the following manufacturing facility for processing into human therapeutics:

Radpharm Scientific  
 59 Oatley Crt  
 Belconnen ACT 2617  
 TGA Registration Number: 1192

Products may be released from the above facility once they are fully retail packaged and labelled for Human Therapeutic use only.

Condition

Condition Text

Records of receipt and distribution of all imported Nexavir Porcine Liver Peptide Derivative must be maintained by the QAP and made available to AQIS upon request.

End of Condition Text