Department of Community Services and Health

Form TS6

File Number 90/15764 (S1)

PERMIT TO IMPORT

Number 19399 LT

THERAPEUTIC SUBSTANCE(S) UNDER REGULATION 5A OF THE CUSTOMS (PROHIBITED IMPORTS) REGULATIONS

This permit is to be presented to the Collector of Customs at the port of entry

Importer's Name and Address

E. Merck Pty Ltd
[redacted]
207 Colchester Rd
Officer Commanding
KILSYTH VIC 3137
Randwick Supply Company
Avoca St, RANDWICK NSW 2031

Permission is granted to the above named to import into Australia the following therapeutic substance(s) under the above stated Regulations (where applicable, the application to import has been subjected to quarantine scrutiny):

Fourteen (14) kilos Ondoxime Chloride (Toxogonin) raw material manufactured by E. Merck, Frankfurter Strasse 250, Postfach 4119, 6100 Darmstadt 1, Federal Republic of Germany.

LIMITED AUTHORITY

THIS PERMISSION IS SUBJECT TO THE FOLLOWING REQUIREMENTS OR PROHIBITIONS:

1. This permit is a LIMITED AUTHORITY for the importation of the above stated quantity (ies) ONLY.
2. The importer is required to keep records with respect to the custody, use, disposal or distribution of the above therapeutic substance(s) for a period of three years from the date of importation.
3. For use in the local manufacture of ondoxime chloride ampoules for use inOmbat zone only. Not for use/distribution in Australia. As this Dept has not evaluated any data for this product, no guarantees of quality, safety or efficacy are given or implied

THIS PERMISSION IS ALSO SUBJECT TO THE PROHIBITIONS OR REQUIREMENTS SPECIFIED WITH AN 'X' BELOW:

- ☐ for invitro (diagnostic) use **ONLY.**
- ☐ to be labelled **'CAUTION MAY BE INFECTIOUS'.**
- ☐ Australian Radiation Laboratory approval to import also required.
- ☐ for personal use **ONLY – NOT** to be distributed for use by other persons or in animals.
- ☐ for delivery into store **ONLY** – distribution may **NOT** take place without permission of the Secretary.
- ☐ for supply to approved users **ONLY.**
- ☐ for laboratory animal use **ONLY.**
- ☐ for veterinary use **ONLY.**
- ☐ **NOT** to be used in animals.

Signature of Authorised Officer for the Secretary

[redacted]

Date 17.9.90

Further applications to import this/these or any other Therapeutic substance(s) should be made in writing to: The Drug Evaluation Branch, Therapeutic Goods Administration, P.O. Box 100, WODEN ACT 2606, AUSTRALIA

TGA Therapeutic Goods Administration

PO Box 100, Woden, ACT 2606, Australia
☐ Woden Telephone: (06) 289 1555. Fax: (06) 289 8709
☐ Mawson Telephone: (06) 286 0222. Fax: (06) 286 1386

DEPARTMENT OF COMMUNITY SERVICES AND HEALTH

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90/15764

Surgeon General Australian Defence Force
Headquarters Australian Defence Force
Department of Defence
Russell Offices
CANBERRA ACT 2600

Attention: [redacted]

Dear Sir

I refer to your facsimile letter of 9 January 1991, about a request for approval in principle for the Australian manufacture of nerve gas antidote, obidoxime chloride injections.

A permit from this Administration has already been issued to enable importation of 14 kilos of obidoxime chloride raw material to be effected (copy attached). The proposed use, ie. making into a pharmaceutical for use outside Australia, falls within the terms of the permit for this material. This Branch, therefore, has no jurisdiction in this matter.

The Good Manufacturing Practice Audit and Licensing Section of this Administration have advised that all the manufacturers named in your facsimile letter follow good manufacturing practice.

You should contact this office again if it is proposed to use the finished product within Australia.

Yours sincerely

[redacted]

Director
Evaluation Unit 1
Drug Evaluation Branch
9 January 1991

[redacted] has advised that [redacted] is analysing ~~batch~~ obtained for them. D o D will eventually use as standard [redacted]