[redacted]

Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Merck Sharp & Dohme Australia Pty Ltd

for approval to supply

JANUVIA (sitagliptin phosphate monohydrate) 25mg tablet blister pack - export only (Cancelled)

ARTG Identifier	AUST L 133053
ARTG Start Date	16/11/2006
Product Type	Listed (Export Only) RC CHANGE Medicine
Export Names	JANUVIA (sitagliptin phosphate monohydrate) 25mg tablet blister pack XELEVIA (sitagliptin phosphate monohydrate) 25mg tablet blister pack

[redacted]

ARTG Standard Conditions

The above Medicine Listed (Export Only) RC CHANGE has been entered on the Register subject to the following conditions:

- Except where the sponsor has been contracted by an overseas partry to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the

Head, Office of Prescription Medicines Authorisation Branch, Therap [redacted] produce such evidence to this officer.

- Conditions applicable to all therapeutic goods as specified in the doc [redacted] Applying to Registered or Listed Therapeutic Goods Under Section 2 [redacted] 1989" effective 1 July 1995, other than condition No. 8 and condition
- Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11
- The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:
- The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.
- This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products Covered by This Entry

1. JANUVIA (sitagliptin phosphate monohydrate) 25mg tablet blister pack - export only (Cancelled)

Product Specific Conditions

- The sponsor must advise the regulatory authorities of the importing country that the product contains a substance, sitagliptin phosphate monohydrate, which has not been evaluated for oral internal therapeutic use in Australia.

Product Permitted Indications

[redacted]

sitagliptin phosphate monohydrate

Component:

Active Ingredients

[redacted]

sitagliptin phosphate monohydrate

sitagliptin phosphate monohydrate

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 133053
ARTG Start Date: 16/11/2006

[redacted]