Pfizer Manufacturing Belgium NV
Rijksweg 12
B-2870 Puurs
tel +32 3 890 92 11
fax +32 3 889 65 32

Pfizer Global Manufacturing

Puurs, 30 March 2006

TO WHOM IT MAY CONCERN

CAVERJECT SPO

The Pfizer Company declares that the product Caverject SPO contains the ingredients mentioned below :

- Alprostadil
- Sodium Citrate
- Lactose
- 2-Methyl-2-Propanol
- Hydrochloric Acid
- Sodium Hydroxide
- Water For Injections

All raw materials used in the product Caverject SPO, manufactured at Pfizer Manufacturing Belgium NV, have been investigated about the origin and use of animal material.

Lactose is prepared from milk originating from cows. A declaration of the supplier is attached stating the material has no infectivity risk.

All other ingredients are not of animal origin.

No material of animal origin has been used during manufacturing.

Sabine DIERICKX
Manager Site Compliance

The European Agency for the Evaluation of Medicinal Products
Pre-authorisation Evaluation of Medicines for Human Use

London, 27 February 2002
Doc. Ref: EMEA/CPMP/571/02

PUBLIC STATEMENT

LACTOSE PREPARED USING CALF RENNET: RISK ASSESSMENT IN RELATIONSHIP TO BOVINE SPONGIFORM ENCEPHALOPATHIES (BSE).

The Committee for Proprietary Medicinal Products (CPMP) and its Biotechnology Working Party (BWP) have conducted a risk assessment of lactose prepared using calf rennet. The opinions of the Scientific Steering Committee[1], together with the following relevant processing parameters or factors have been considered:

- the tissue used for the production of calf rennet (Abomasum is classified as a tissue with no detectable BSE infectivity);
- the procedure used to procure the abomasums, including the precautions taken to avoid cross-contamination with high(er) risk tissues;
- the age of animals from which the abomasum is procured, including their feed (usually the animals are less than 6 months of age and none are older than 12 months); and
- the lactose processing steps involved (and particularly dilution and partitioning).

Taking all these factors and the scientific assessment performed by the BWP into consideration, the CPMP concludes that the BSE risk in pharmaceutical grade lactose is negligible.

The same conclusions can be drawn for other products derived from whey, such as lactulose, galactose and ethanol.

[1] The Scientific Steering Committee, established by Commission Decision 97/404/EC, provides advice to the European Commission on matters concerning consumer health. For more information consult the website of DG Sanco (http://europa.eu.int/comm/food/fs/sc/index_en.html).

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.eu.int http://www.emea.eu.int

DMV INTERNATIONAL

Statement on the BSE/TSE safety of all pharmaceutical grades of lactose manufactured by DMV International.

Veghel, March 6, 2002

We hereby certify that the milk used for the manufacturing of our pharmaceutical grade lactose is sourced from healthy animals under the same conditions as milk collected for human consumption (EMEA 410/01 rev 1) and calf rennet used for production of raw material whey is in accordance with Public Statement EMEA/CPMP/571/02 of February 27 2002. The sourcing and processing of the milk is constantly, officially supervised according to the milk hygiene directive 92/46/EEC.

Sincerely yours,
DMV INTERNATIONAL

Dr. Armand M. Janssen, pharmacist
Manager Regulatory Affairs (Food & Pharma)

DMV International
division of Campina Melkunie bv
NCB-laan 80, P.O. Box 13,
5460 BA Veghel - The Netherlands
telephone +31 (0)413 377777
telefax +31 (0)413 343695

Pfizer Manufacturing Belgium NV
Rijksweg 12
B-2870 Puurs
tel +32 3 890 92 11
fax +32 3 889 65 32

Pfizer Global Manufacturing

Puurs, 24 April 2006

TO WHOM IT MAY CONCERN

BWFI – DILUENT OF CAVERJECT SPO

The Pfizer Company declares that the product Bacteriostatic Water For Injections contains the ingredients mentioned below :

- Benzyl Alcohol
- Water For Injections

All raw materials used in the product BWFI, diluent of Caverject SPO, manufactured at Pfizer Manufacturing Belgium NV, have been investigated about the origin and use of animal material.

None of these ingredients are of animal origin.

No material of animal origin has been used during manufacturing.

Sabine DIERICKX
Manager Site Compliance