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

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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).

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