



**Certificate of Origin and Compliance**  
**100 Bloom Pharmaceutical Porkskin Gelatin**  
**Algon Corp.**

February 21, 2007

**GELITA NORTH AMERICA** certifies that 100 Bloom Pharmaceutical Porkskin Gelatin is made from porcine skin raw materials which are derived exclusively from healthy animals originating from federally inspected facilities. The pigs received ante- and post-mortem health inspections by veterinary service inspectors and are approved for human consumption.

Porcine gelatine is sourced from pigskins. Pigs are not affected by BSE/TSE. To date, no naturally occurring TSE infectivity has ever been detected in pigs.

Traceable records of raw materials supporting this certification for this product are maintained for external inspection.

Mark Viksten  
Manager, Regulatory Affairs



**Mallinckrodt**

February 17, 2005

Re: Magnesium Stearate NF/EP/IP (Powder) HyQual® Vegetable Source, Code 2257

To Whom It May Concern:

This letter is in response to your request for BSE/TSE information concerning manufactured lots of Mallinckrodt Magnesium Stearate NF/EP/IP (Powder) HyQual® Vegetable Source, code 2257.

Please be assured our manufactured lots of Magnesium Stearate NF/EP/IP (Powder) HyQual® Vegetable Source, code 2257, do not contain, nor are they manufactured with any raw material containing bovine or other animal related products. The fatty acid used for this product is derived from palm oil.

Mallinckrodt is dedicated to providing the highest quality products and services to our customers. If you should have any additional questions, please do not hesitate to contact your customer service representative.

Sincerely,



Robin Sladek

Quality Assurance Documentation Analyst

cc: E. Holstein  
File (S-7633)



Date: October 20, 2003

To: Ms. Helle Mikkelsen  
Chr. Hansen

From: Peg Dorn  
Quality Assurance Manager

Subject: BSE/TSE Issues and Foremost NF Lactose Monohydrate Products (Codes 310, 312, 313, 315 and 316)

The purpose of this information package is to provide you with current BSE/TSE documentation.

- We confirm that Foremost NF Lactose Monohydrate products are manufactured in compliance with CPMP Guideline "Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products", EMEA/410/01-rev.2. We confirm bovine milk used in the production of Foremost lactose is sourced from healthy animals in the same conditions as milk collected for human consumption. No other ruminant or animal materials are used during the process to obtain Foremost Farms USA NF Lactose Monohydrate products. Enzyme products used are microbially produced and are not derived from animal sources (i.e. calf rennet is not used). Therefore Foremost NF Lactose Monohydrate products are excluded from the scope of the above stated guidance.
- Thus a Certificate of Suitability from the European Directorate for the Quality of Medicines (EDQM) is not required. Foremost applied for a Certificate of Suitability with the EDQM in June 2000. The EDQM has returned our application for a Certificate of Suitability as a result of the above stated exclusion. The EDQM has informed us that "The applicants/holders of marketing applications should mention that the milk derivative is "derived from milk sourced from healthy animals in the same conditions as milk collected for human consumption. In these circumstances, no additional documentation needs to be submitted in related to TSE for these materials neither directly to the licensing authorities nor via the Certification procedure." This information package includes a copy of the EDQM response to Foremost.
- Bovines used in the production of Foremost lactose originate in the United States of America. Foremost NF lactose is derived from bovine milk supplied directly to Foremost Farms USA from US dairy farmers. This information package includes a letter from the United States Department of Agriculture (Animal and Plant Health Inspection Service) about the BSE free status of the United States. Bovines used in milk production are over 30 months of age.
- All Foremost brands of NF lactose are produced at our plant located at Rothschild, Wisconsin, USA.

Please let me know if any additional information is desired regarding this issue.

Email: [peg.dorn@foremostfarms.com](mailto:peg.dorn@foremostfarms.com)