Qualicaps, Inc.
6505 Franz Warner Parkway
Whitsett, NC 27377 USA

July 7, 2016

BSE/TSE STATEMENT FOR QUALICAPS, INC
EMPTY TWO-PIECE HARD GELATIN CAPSULES

Qualicaps, Inc. is providing you with information with respect to the sourcing and processing of gelatin intended for use in foods, drugs, dietary supplements, cosmetics, and other FDA (Food & Drug Administration) regulated products. The Drug Master File for the Food and Drug Administration is 11165 and the Health Protection Branch is 1998-113.

The gelatin utilized in products manufactured from our facility is from FDA compliant sourced bones. The raw materials utilized in the gelatin employed at Qualicaps, Inc. are sourced exclusively from USDA inspected facilities that have been approved by the USDA – APHIS. We have the capability of utilizing validated, certified vendors for our products based on production demands. These vendors have been audited for compliance and are recognized as certified vendors by Qualicaps, Inc. These vendors comply with the United States regulatory guidelines and procedures for the secure production of pharmaceutical grade gelatin, as well as, the European community regulations and OIE (World Organization for Animal Health). During our audits, records are reviewed for traceability, which would include the following:

- USDA – APHIS Certificates
- Shipping Documents
- Bill of Ladings
- Import/Export documents to support country of origin, if applicable
- Compliance records

In order to maintain our current position in regards to providing customers with the most recent vendor information, we are in frequent contact with the Quality Assurance, Regulatory/Compliance personnel at these vendor sites.

If you have any additional questions, please do not hesitate to contact us at 1-800-CAPSULE.

QUALICAPS, INC.

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