

“Gel Bone” Bovine-Bone Origin Gel Bone intended for “Pharmaceutical” Purposes

The government of Japan has verified that the following attestations are required on a VS Form 16-4 for bovine origin gel bone (rendered bone chips) imported for “pharmaceutical” purposes

Only the following attestations may appear on the VS Form 16-4 [The “This is to certify that rinderpest, foot-and-mouth disease, classical swine fever, swine vesicular disease, African swine fever, and contagious bovine pleuropneumonia do not exist in the United States of America” sentence should only appear once on the VS Form 16-4 (it was pre-printed on versions preceding the JUL 2022 version). If the JUL 2022 version of the VS Form 16-4 is utilized, it should be the first sentence in the ADDITIONAL DECLARATION area.]:

This is to certify that rinderpest, foot-and-mouth disease, classical swine fever, swine vesicular disease, African swine fever, and contagious bovine pleuropneumonia do not exist in the United States of America.

This office has on file a notarized affidavit from [insert name of company here] verifying the accuracy of the statements below. I, the endorsing official listed below, have read the notarized affidavit referenced above, and to the best of my knowledge and belief these statements are true.

The products described below do not contain bovine skulls or vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), from cattle. The products described below are U.S. origin and contain only those animal origin ingredients derived from animals that passed ante-mortem government inspection at slaughter.

Prior to endorsement, the Veterinary Services field office must have on file the following notarized affidavits signed annually:

- An affidavit from the gel bone producer (renderer) verifying not only that the products exported to Japan meet the above criteria (second paragraph in blue), but also listing the FSIS slaughter or processing plants supplying the rendering plant with the raw materials.
- An affidavit from each supplier listed on the above referenced affidavit verifying that the materials supplied to the renderer for Japan:
 - Do not contain bovine skulls or vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), from cattle of any age; and
 - Contain only those animal origin ingredients derived from animals that passed ante-mortem government inspection at slaughter.