

**Gelatin or Collagen**  
**(for purposes other than human consumption)**  
**Derived from Cattle**

Government certification is not required for gelatin or collagen derived from bovine materials exported to Japan for human consumption (for food). The Japanese importer is required to provide certain documentation to Japanese government officials. Exporters with questions should contact the U.S. Food and Drug Administration (FDA) or their Japanese importers. FDA should be consulted for the requirements for gelatin/collagen for the production of pharmaceuticals for human consumption.

[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.]

**For gelatin or collagen derived from only hides or skins not intended for human consumption:**

*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.*

*[Insert “Gelatin” or “Collagen” as appropriate] is prepared exclusively from hides and skins.*

**For gelatin or collagen derived from bones not intended for human consumption:**

*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.*

*[Insert “Gelatin” or “Collagen” as appropriate] is prepared in accordance with the following procedures.*

- (1) Skulls and vertebrae (excluding tail vertebrae) have been excluded;*
- (2) The bones have been subjected to a process which includes all the following steps:*
  - (a) pressure washing (degreasing),*
  - (b) acid demineralization,*
  - (c) prolonged alkaline treatment,*
  - (d) filtration,*
  - (e) sterilization at 138°C for a minimum of 4 second*