

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.

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

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 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 seconds.*