Bovine Bone-Derived Gelatin: Export to Vietnam

These requirements are for certifying bovine bone-derived gelatin intended for either human or animal consumption/use for export to Vietnam. The targeted population (human or animal) and intended end use of the product (pharmaceutical or food) must be declared on the export certificate.

The Veterinary Services (VS) Animal Products Export Staff believes that the government of Vietnam, Department of Animal Health (DAH), will accept this product with the certifications as described below. However, exporters are responsible for coordinating with their Vietnamese importers to ensure that all requirements for importation are met and the product will be allowed entry.

General Instructions for Exporters

1. Use the fillable VS Form 16-4 "Export Certificate for Animal Products," which can be accessed through the home page of the International Animal Product Export Regulations (IREGs).
2. Note that the certification statement regarding the official U.S. bovine spongiform encephalopathy (BSE) status must be a direct attestation by VS. Therefore, this statement will precede the notarized affidavit line.
3. Prepare a notarized affidavit with the required certification statements listed under the notarized affidavit line in the "Export Certification Requirements" below. If assistance is needed in preparing your properly notarized affidavit, please work with the local VS Service Center that will be endorsing your export certificate(s).
4. Complete all applicable sections of the VS Form 16-4, including product description (bovine gelatin). Please see general instructions on the home page of the IREGs. If assistance is needed, please contact your local VS Service Center.

Export Certification Requirements

The following certification statements must be included in the "Additional Declarations" section of the VS Form 16-4. These statements must not be modified except as noted (the notarized affidavit line should include the actual name of the manufacturer/exporter; the pertinent section of #3 should be used, including a description of "the equivalent or better process" if (b) is used; specific intended end-use must be identified in statement #4).

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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.

The United States has been officially recognized by the World Organization for Animal Health (OIE) as a country having negligible bovine spongiform encephalopathy (BSE) risk status.

This office has on file a notarized affidavit from [*manufacturer/exporter*] verifying the accuracy of the statements below.

1. The product was derived from the bones of health cattle that were subjected to slaughter inspection in official establishments under the control of the competent authority.
2. The product was manufactured in accordance with U.S. laws and regulations, including exclusion of skulls and vertebral columns from cattle over 30 months of age from raw materials used to manufacture the product.
3. The bones from which the product was manufactured were subjected to (a) a process that includes degreasing, acid demineralization, acid or alkaline treatment, filtration, and sterilization at >138°C for a minimum of 4 seconds; or (b) an equivalent or better process in terms of infectivity reduction, such as high-pressure heating. [*Use only the pertinent section. If (b) is used, describe the equivalent or better process*]
4. The product is U.S. origin and is intended for [*insert intended end use; e.g., pharmaceutical use – human; pharmaceutical use – animal; food – human consumption; food – animal consumption*].