Certification for Export to Korea:
Medical Devices and Pharmaceuticals Containing Bovine Ingredients

This protocol is intended to only cover medical devices and pharmaceuticals for export to Korea that 1) contain bovine ingredients; 2) are completely processed/finished products; and 3) are regulated for entry into Korea by the Korean Food and Drug Administration (KFDA).

The bilaterally negotiated certification statements included in this protocol are not to be amended or revised (except as noted below for statement #3 where the actual bovine materials in the product must be listed). Statements must not be added or deleted without express permission from the Veterinary Services (VS) Animal Products Exports Staff.

It is VS understanding that KFDA is NOT requiring this certificate for product registration purposes. For certification of shipments, exporters should follow general instructions provided on the Korea page of the International Animal Product Regulations. **NOTE: Export certificates MUST be endorsed PRIOR to shipping. If the date on the shipping documents precedes the date of endorsement of the export certificate, Korea will refuse entry.**

- The commodities covered under the protocol should be exported using the fillable "Export Certificate for Animal Products" VS Form 16-4 and continuation page VS 16-4A.
- The certification statement regarding the US ruminant to ruminant feed ban must be a direct attestation by Veterinary Services (VS).
- All other certification statements are to be made on the basis of a notarized affidavit which must be provided by the manufacturer/exporter. Statements made on the basis of a notarized affidavit must be preceded by the notarized affidavit line as noted in the "Export Certification Requirements" below.
- Statement number three must include the actual bovine materials used in the manufacture of the product. These should be listed in lieu of the examples provided (hide-derived collagen, pericardium). Identification and listing of the bovine materials must be specific to verify that they are not considered specified risk materials (SRMs).
- Although statement number three will be endorsed on the basis of a notarized affidavit, the manufacturer/exporter must provide supporting documentation to verify that the materials were derived only from animals that passed both ante and post mortem inspection under official veterinary supervision at approved slaughter facilities. [Slaughter facilities under FSIS supervision are approved.]
- Additional supporting documentation may be requested by the VS Area Office prior to endorsement of export certificates. VS Area Offices may also require a facility inspection if needed to verify information provided on the notarized affidavit.

Export Certification Requirements

The following certification statements must be included in the "Additional Declaration" 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; statement #3 must list the actual bovine ingredients in the product(s) being exported).

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 prohibits the feeding of ruminants with ruminant origin meat-and-bone meal and greaves, and this prohibition is effectively enforced.

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

1. The certified products are U.S. origin and were manufactured at a facility approved by the competent authority.
2. The certified products were manufactured in accordance with U.S. laws and regulations intended to ensure that they are unlikely to transmit disease agents, including transmissible spongiform encephalopathies (TSEs).
3. The bovine materials used in the manufacture of the product [list – e.g., hide-derived collagen, pericardium] were derived from healthy cattle that received ante and post mortem inspection under official veterinary supervision at approved slaughter facilities.
4. The cattle from which the bovine materials were derived were not known to be related to any herd affected by bovine spongiform encephalopathy (BSE).
5. The bovine materials used in the manufacture of the products were not derived from nor contaminated with any specified risk materials: the skull, brain, eyes, trigeminal ganglia, spinal cord, dorsal root ganglia, 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 30 months of age or older; or the tonsils or distal ileum of cattle of all ages.
6. The certified products were manufactured using a rigorous process designed to effectively mitigate any risk of disease transmission and ensure their safety for their intended use.

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In the "Product" section of the VS Form 16-4, the type of product should be identified (medical device, pharmaceutical), and the bovine materials used in the manufacture of the product, e.g., "Medical devices containing hide-derived collagen and pericardium.