

Certification Requirements: Inedible Bovine Meat & Meat Byproducts - For Pharmaceutical Use

The following certification statements, as applicable, should be provided on a VS Form 16-4 for the exportation of inedible bovine meat and/or meat byproducts (except liver and veal) to Canada for pharmaceutical use. Please see the link on the main Canada page of the International Animal Products Regulations (IREGs) entitled “Required Language Prefacing Attestations on Export Certificates for Canada” for information regarding endorsement of animal product export certificates for Canada. As noted in that document, the endorsing APHIS Veterinary Services (VS) Area Office may require additional documentation, a facility inspection, or participation in an Agricultural Marketing Service (AMS) export verification program, as deemed necessary, to verify the accuracy of the statements.

Please note that the product description (product box on VS Form 16-4) should include the species of origin, as well as the type of product (e.g., “bovine meat, bovine kidneys”).
The name and establishment number(s) of the FSIS facilities from which the product was obtained must also be included in this section.

Certification:

“I, the undersigned official veterinarian, after due inquiry and to the best of my knowledge and belief, do hereby certify:

1. The inedible bovine meat and/or meat byproducts:
 - a. Were derived exclusively from animals which received ante-mortem and post-mortem inspection in a federally inspected establishment;
 - b. Did not show evidence of infectious pathological condition at the time of collection;
 - c. Were hygienically prepared and handled in accordance with U.S. laws and regulations;
 - d. Are intended for pharmaceutical use only;
 - e. Do not contain any of the following tissues considered to be specified risk materials (SRMs): skull, brain, eyes, tonsils, trigeminal ganglia, spinal cord, dorsal root ganglia, and vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from bovines 30 months of age or older, and the distal ileum from bovines of all ages.
2. *The certified inedible bovine meat and/or meat byproducts meet all requirements of EC Regulation 1774/2002, as amended, for inclusion in pharmaceutical products.”

* Statement #2 must be included for materials being exported to Canada for inclusion in pharmaceutical products intended for export to the European Union. The endorsing APHIS VS Area Office will verify that the FSIS establishment(s) from which the product was sourced is (are) approved by APHIS VS to export the product to the European Union under the requirements of EC Regulation 1774/2002, as amended.