

Certification Requirements: Inedible Bovine Livers – For Pharmaceutical Use

The following certification statements, as applicable, should be provided on a VS Form 16-4 for the exportation of inedible bovine livers to Canada for pharmaceutical use. These statements are to be made on the basis of a notarized affidavit from the exporter. Although these statements are to be made on the basis of a notarized affidavit, the endorsing APHIS Veterinary Services (VS) Area Office may require additional documentation or a facility inspection, 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 livers”). ***The name and establishment number(s) of the FSIS facilities from which the product was obtained must also be included in this section.***

Certification:

“This office has on file a notarized affidavit from [company name] verifying the accuracy of the statements below.

1. The certified inedible bovine livers:
 - 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; and
 - d. Are intended for pharmaceutical use only.
2. *The certified inedible bovine livers meet all requirements of EC Regulation 1774/2002, as amended, for inclusion in pharmaceutical products.”

* Statement #2 must be included for inedible bovine livers 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.