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Affidavit for Animal and Human Derived Products
 Assurance of Sourced Animal Health
 and HIV and Hepatitis Testing

All products manufactured by R&D Systems, Inc. that contain human material use only materials that have been tested for HIV, Hepatitis and all currently required FDA tests and contain the following cautionary statement:

WARNING: POTENTIALLY BIOHAZARDOUS MATERIAL. Each human donor / unit used in preparation of this product has been tested by a FDA licensed method or test and found negative or non-reactive for the presence of HBsAg, HIV-1 Ag, and antibody to HCV and HIV-1/2. Each unit is also negative by a serological test for syphilis. Because no test method can offer complete assurance that infectious agents are absent, consider this material potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29CFR Part 1910, 1030) or other equivalent biosafety procedures.

R&D Systems also manufactures some products that contain cellular components from non-human, animal sources including bovine, porcine and avian cells. Both human and non-human cellular materials are chemically fixed with either glutaraldehyde or formaldehyde, washed extensively, and are suspended in anti-microbial solutions upon formulation into product. In other products, non-cellular materials (proteins or antibodies) are obtained from rabbits, mice, rats, goats, pigs, bovine or are recombinantly produced source materials. These non-cellular materials are subsequently highly concentrated and purified before use in the products.

In all cases, the raw materials are sourced from either USDA and/or FDA inspected establishments in the United States. The animals are apparently in good health at the time the materials are collected as judged by onsite veterinarians.

In addition, some products contain Bovine Serum Albumin (BSA). The sources for this protein certify that it is obtained from USDA inspected establishments in the USA or from establishments in countries known to be free of BSE.

R&D Systems is a registered Medical Device Establishment under the U.S. Food, Drug and Cosmetic Act; registration number 2182501. R&D Systems is routinely inspected by the FDA. Our products are manufactured under the Food and Drug Administration's Good Manufacturing Practices Regulations, they are freely marketed in the U.S. and are in compliance with all U.S. laws and regulations.

Ralph E. Hogancamp.
 Quality Assurance/Regulatory Affairs

Subscribed and sworn before me
 this _____ day of _____, 2005
