Recommended Wording to Replace USDA and EU Approved

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NOTHING WORKS LIKE SERUM

INTERNATIONAL SERUM INDUSTRY ASSOCIATION
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For many years, the International Serum Industry Association (ISIA) has encouraged transparent description of origin on labeling and documentation. Stating the country of collection (*where the blood is collected*), more commonly referred to as origin, on these materials allows end users to know the country from where their products were collected.

WHAT IS "USDA APPROVED" / "EU APPROVED" SERUM AND WHAT DOES IT MEAN?

Serum companies have used terms such as "USDA Approved", "USDA Origin", and "USDA Grade" to refer to products from countries considered safe for entry by the United States Department of Agriculture (USDA). Historically, the term "approved" refers to material being sourced from locations USDA has deemed of an acceptable risk level for importation into the US (Mexico, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama, Chile, and Australia) and following a negative test on USDA-required viral screening, are released (approved) for distribution into the general market within the United States. Likewise, "EU Approved" or "EU Grade" refers to products from countries that the European Union considers safe for entry. Terms such as these infer approval by the regulatory agency and do not provide a clear country of origin.

WHY ARE THESE TERMS PROBLEMATIC?

While it is generally understood within the industry what these terms do and do not mean, many outside the industry may be confused by them. This may lead to a belief that a government or competent authority has certified the serum. The inadvertent misconception that USDA or EU is in some way providing legitimacy to a product by a company's use of these terms is problematic for the USDA and EU, as they do not endorse any one company's product over another. The USDA and EU do not 'approve' serum products but do confirm eligibility for importation under required and controlled conditions for the importing country. For fetal bovine serum (FBS) imported into the United States, products will undergo testing at **National Veterinary Services Laboratories (**NVSL)**. FBS imported into the US from** Mexico, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama, and Chile **is tested for** Bluetongue Virus (BTV). FBS imported into the US from Australia is tested for both Bluetongue Virus (BTV) and Akabane Virus. Material must be found free of active viral agents that are concerning to USDA and livestock industries. The USDA does not provide any kind of approval or certification for serum regarding its safety, efficacy, or suitability for any specific purpose. The USDA will provide a final report stating that the material is negative for Bluetongue Virus (BTV) and or Akabane Virus and therefore eligible for distribution.

Note: The "USDA testing" noted above is not required for import into any other country globally.

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WHAT IS THE FUTURE FOR "USDA APPROVED" and "EU APPROVED" SERUM?

The USDA strongly encourages that the ISIA, member companies, and the serum industry move away from terms such as "USDA Approved", "USDA Origin", "USDA Grade" and replace them with terms that do not inadvertently apply meaning where there is none. The ISIA and its member companies believe that an acceptable replacement term is **"USDA Safety Tested"** and that terms such as "USDA Approved", "USDA Origin", "USDA Grade" are no longer used**.** We recommend that since there is currently limited use of "EU Approved" this would be eliminated and no longer used. This could simply be replaced with the country of origin where the blood was collected. The recommended effective date for implementation of both changes is January 2025. Material manufactured after this date should use the updated terminology.

In addition, "tested for applicable animal infectious disease agents as a condition of import as per the USDA" can be added to the Certificates of Analysis (COA) and which specific viruses were tested as "USDA Safety Tested Bluetongue Virus" and or "USDA Safety Tested Akabane Virus" based on sourced/imported material. All associated product documentation such as the product label, COA, Certificates of Origin (COO), and marketing information should also state the county of collection/origin (*where the blood is collected*). The ISIA requires all Traceability Certified members to state the country of collection, also referred to as "Origin" on their product labels and other associated documentation, such as COA and COO[1].

What this means for the end users who currently purchase these products is simple and straight forward; the quality, efficacy, and suitability for the application will remain unchanged, but eliminating outdated terms and using "USDA Safety Tested" along with country of collection allows for more transparency and clarity of serum products.

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[1] https://www.serumindustry.org/traceability/traceability-overview/