

Target Animal Safety Evaluation for Veterinary Monoclonal Antibody Products; Draft Guidance for Industry; Availability

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Target Animal Safety Evaluation for Veterinary Monoclonal Antibody Products; Draft Guidance for Industry; Availability

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #298 (VICH GL62) titled "Target Animal Safety Evaluation for Veterinary Monoclonal Antibody Products." This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance contributes to the international harmonization of methods used for the target animal safety (TAS) evaluation of veterinary monoclonal antibody products (VMAPs) and aids in preparing and conducting VMAP TAS studies under laboratory and field conditions. A harmonized standard is intended to aid in development of mutually acceptable VMAP TAS programs.

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