

Guidance for Industry

Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial Resistance VICH GL27

DRAFT GUIDANCE

This document is being distributed for comment purposes only

This draft guidance document is an initial step in developing harmonized technical guidance for approval of therapeutic antimicrobial veterinary medicinal products intended for use in food-producing animals with regard to characterization of antimicrobial resistance selection in bacteria of human health concern in the European Union, Japan, and the United States. This information should help to characterize the potential for the use of the product to select for antimicrobial-resistant bacteria of human health concern.

Comments and suggestions regarding this document should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the Docket No.

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