74

Guidance for Industry

STABILITY TESTING OF NEW VETERINARY DOSAGE FORMS

VICH GL4

FINAL GUIDANCE

This guidance is an annex to the VICH parent guidance entitled "Stability Testing of New Veterinary Drug Substances and Medicinal Products" (VICH GL3). It addresses the recommendations on what should be submitted regarding stability of new dosage forms by the new animal drug applicant, after the original submission of stability information has been made in a new animal drug application.

This guidance represents current thinking and does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use alternative methods as long as they satisfy the requirements of the applicable statute and regulation.

Comments and suggestions regarding the document should be submitted to Carol Haley, Policy & Regulations Team, Center for Veterinary Medicine, (HFV-6), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855.

For questions regarding this guidance document, contact William G. Marnane, Center for Veterinary Medicine, (HFV-140), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-6966, E-mail: wmarnane@cvm.fda.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
September 1999

STABILITY TESTING FOR NEW VETERINARY DOSAGE FORMS

Recommended for Implementation
at Step 7 of the VICH Process
on 20 May 1999
by the VICH Steering Committee

THIS GUIDANCE HAS BEEN DEVELOPED BY THE APPROPRIATE VICH EXPERT WORKING GROUP ON THE BASIS OF THE ICH GUIDANCES ON THE SAME SUBJECT AND HAS BEEN SUBJECT TO CONSULTATION BY THE PARTIES, IN ACCORDANCE WITH THE VICH PROCESS. AT STEP 7 OF THE PROCESS THE FINAL DRAFT IS RECOMMENDED FOR ADOPTION TO THE REGULATORY BODIES OF THE EUROPEAN UNION, JAPAN AND USA.

STABILITY TESTING FOR NEW VETERINARY DOSAGE FORMS

Recommended for Implementation at Step 7 of the VICH Process
on 20 May 1999 by the VICH Steering Committee

GENERAL

This document is an annex to the VICH parent stability guidance, Stability Testing of New Veterinary Drug Substances and Medicinal Products (VICH GL3) and addresses the recommendations on what should be submitted regarding stability of new dosage forms by the owner of the original application, after the original submission for new drug substances and products.

NEW DOSAGE FORMS

A new dosage form is defined as a drug product which is a different pharmaceutical product type, but contains the same active substance as included in the existing drug product approved by the pertinent regulatory authority.

Such pharmaceutical product types include products of different administration route (e.g., oral to parenteral), new specific functionality/delivery systems (e.g., immediate release tablet to modified release tablet) and different dosage forms of the same administration route (e.g. capsule to tablet, solution to suspension).

Stability protocols for new dosage forms should follow the guidance in the parent stability guidance in principle. However, a reduced stability database at submission time may be acceptable in certain justified cases.