

TITLE/TOPIC OF GUIDANCE	CONTACT
Development of Supplemental Applications for Approved New Animal Drugs (Section 403(b) of the Food and Drug Administration Modernization Act of 1997)	Marilyn Martinez, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7577
Administrative New Animal Drug Application Process	Gail Schmerfeld, Center for Veterinary Medicine (HFV-112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0205
CATEGORY—LABELING	
Manufacture and Labeling of Raw Meat Diets for Consumption by Dogs, Cats, and Captive Non-Companion Animal Carnivores and Omnivores	William Burkholder, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0179
Labeling and Professional Flexible Labeling	Douglass Oeller, Center for Veterinary Medicine (HFV-112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0131
CATEGORY—TARGET ANIMAL SAFETY	
New Drug Dosage or Dosage Range Characterization	Gail Schmerfeld, Center for Veterinary Medicine (HFV-112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0205
Use of Field Studies to Demonstrate the Effectiveness of a New Animal Drug	Steven Vaughn and Gail Schmerfeld, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7584
CATEGORY—STATUTORY REQUIREMENTS	
Dispute Resolution—Food and Drug Administration Modernization Act of 1997	Marcia Larkins, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4535
CATEGORY—INTERNATIONAL HARMONIZATION	
Guidance GL27 International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products	William Flynn, Center for Veterinary Medicine (HFV-2), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4514
VI. OFFICE OF THE COMMISSIONER, OFFICE FOR GOOD CLINICAL PRACTICE (OGCP)	
CATEGORY—GOOD CLINICAL PRACTICE; GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS AND CLINICAL INVESTIGATORS	
Cooperative Arrangements for Institutional Review Board's Review of Research	Bonnie M. Lee, Office of the Commissioner, Office for Good Clinical Practice (HF-34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3340
Institutional Review Board's Review of Research Conducted at Other Sites	Do
Continuing Review After Study Approval	Do
Dates of Continuing Review	Do
Interactions Among FDA, Sponsor, Investigator, and Institutional Review Board	Do
Acceptance of Clinical Studies Conducted Outside the United States	Do
Charging for Investigational Products	Do
Recruiting Study Subjects	Do
Payment to Research Subjects	Do
Screening Tests Prior to Study Enrollment	Do
A Guide to Informed Consent	Do
Use of Investigational Products When Subjects Enter a Second Institution	Do