

TITLE/TOPIC OF GUIDANCE	CONTACT
National Drug Code Number and Drug Product Labels	Do
Describing How Positron Emission Tomography Drug Products May Comply With New Current Good Manufacturing Process Requirements—Revised	Do
Sterile Drug Products Produced by Aseptic Processing	Do
CATEGORY—ELECTRONIC SUBMISSIONS	
Providing Electronic Submissions to the Division of Drug Marketing, Advertising, and Communications	Do
Providing Electronic Submissions in Electronic Format: Marketing Applications and Related Submissions	
Providing Regulatory Submissions in Electronic Format—Annual Reports for Approved New Drug Applications	Do
Providing Regulatory Submissions in Electronic Format—General Considerations	Do
Providing Regulatory Submissions in Electronic Format: Postmarketing Periodic Adverse Drug Experience Report	Do
Scope and Implementation of 21 CFR Part 11: Archiving	Do
Scope and Implementation of 21 CFR Part 11: Audit Trails	Do
Standards for Clinical Data Submissions	Do
CATEGORY—GENERICIS	
Bioequivalence Studies With Clinical Endpoints for Vaginal Antifungal Drug Products	Do
Chemistry, Manufacturing, and Controls Documentation Unique to Radiopharmaceuticals Submitted in Abbreviated New Drug Applications	Do
Generic Drug Labeling When Pediatric Labeling Information Has Been Added to the Innovator Labeling	Do
CATEGORY—GOOD REVIEW PRACTICES	
General Clinical Review Template	Do
CATEGORY—INVESTIGATIONAL NEW DRUG APPLICATIONS	
Consumer Product Safety Commission—Tamper Resistant Packaging for Investigational New Drug Applications	Do
Pediatric Safety and Efficacy Data in Investigational New Drug Applications	Do
CATEGORY—LABELING	
Drug Names and Dosage Forms	Do
Pregnancy Labeling Revisions	Do
Submitting Proprietary Names for Evaluation	Do
CATEGORY—OVER-THE-COUNTER	
Actual Use Trials	Do
Labeling Comprehension Studies for Over-the-Counter Drug Products	Do
Labeling for Over-the-Counter Human Drug Products	Do
Labeling Over-the-Counter Human Drug Products; Questions and Answers	Do
Time and Extent Applications	Do