

TITLE/TOPIC OF GUIDANCE	CONTACT
Guidance for Industry: Preclinical Toxicity Studies for Prophylactic Vaccines	Do
Guidance for Industry: Immunization Human Plasma Donors to Obtain Source Plasma for Preparation of Specific Immune Globulins	Do
Guidance for Industry: Content and Format of Chemistry, Manufacturing, and Controls Information and Establishment Description Information for a Vaccine or Related Product	Do
Guidance for Industry on the Content and Format of Chemistry, Manufacturing, and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test	Do
CATEGORY—OTHER	
Providing Regulatory Submission in Electronic Format—Stability	Do
Environmental Assessment/National Environmental Policy Act	Do
Requests for Engagement of Independent Consultant	Do
Eligibility Determination for Donors of Human Cells, Tissue and Cellular and Tissue-Based Products (HCT/PS)	Do
Filing and Application When the Applicant Protests a Refusal to File Action	Do
Guidance for Industry: Multi-Product Manufacturing With Spore-Forming Microorganisms	Do

## II. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

CATEGORY—PREMARKET REVIEW—PROCEDURAL	
Delegation of Investigational Device Exemption (Withdrawal)	Joanne R. Less, Center for Devices and Radiological Health (HFZ-403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190
Overdue Investigational Device Exemption Annual Progress Report Procedures (Withdrawal)	Do
Humanitarian Device Exemptions (HDE) Regulation: Questions and Answers (Revised)	Do
Guidance for the Medical Device Industry on Premarket Approval Application Shell Development and Modular Review (Revised)	Thinh Nguyen, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186
Modifications to Devices Subject to Premarket Approval Application—The Premarket Approval Application Supplement Decision Making Process (Final)	Do
Real-Time Review Program for Premarket Approval Application (PMA) Supplements (Revised)	Do
Pre-Premarket Approval Application Meetings	Do
A New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications (Revised)	Heather Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190
Frequently Asked Questions on the New 510(k) Paradigm (Revised)	Do
New Section 513(f)(2)—Evaluation of Automatic Class III Designation (Revised)	Do
Implementation of Third Party Programs Under the Food and Drug Modernization Act of 1997 (Revised)	Ronald Parr, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-6597, ext. 109
Statistical Guidance on Reporting Results From Studies Evaluating Diagnostic Tests: Draft Guidance for Industry and FDA Reviewers	Kristen Meier, Center for Devices and Radiological Health (HFZ-542), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-4369