

Dear Member:

As an added benefit to our newsletter subscribers, Cerulean provides periodic compliance updates focused on emerging news and events with analyses and relevant recommendations.

New Guidance Agenda from FDA

The FDA's CDER has published its list of expected guidance documents and revised regulations to be issued this year (2009).

Readers of our 2009 forecast will find many items on the list familiar:

- 21 CFR Part 11
- Process Validation
- Adaptive Clinical Trial Design
- Contract manufacturing
- Various marketing, promotional and labeling guidance
- "Dear Healthcare Professional Letters" for recalls

What to Do Now

SmarterCompliance™ members should consider 3 steps to stay ahead of the competition:

Review the full list of analyses and recommendations from [SmarterCompliance December 2008](http://www.ceruleanllc.com/Members_Silver/Library_Newsletter.htm)
http://www.ceruleanllc.com/Members_Silver/Library_Newsletter.htm (you need to be a full subscriber and provide your email and passcode to login)

Read the CDER Agenda (enclosed)

And for those of you who have yet to set a strategy for the revised Part 11, obtain my recorded teleseminar and resource kit, [Understanding and Implementing the Revised FDA Part 11 and EU Annex 11](http://www.ceruleanllc.com/Seminars/eSeminar203131.htm). This seminar generated a lot of positive feedback from FDA colleagues – including those involved in Part 11's rewrite; not having this is simply handicapping yourself.

<http://www.ceruleanllc.com/Seminars/eSeminar203131.htm>

If you have any questions or have a specific area you would like me to keep a special eye on, please email me directly.

Sincerely,



John Avellanet
Managing Director and Principal
Cerulean Associates LLC
Publisher, *SmarterCompliance*™

P.S. Need help trimming costs this year? Join my interactive webinar and audio-conference, *Frugal FDA Compliance*, on March 24th. Register at: <http://www.ceruleanllc.com/webinar>

Guidance Agenda: Guidances CDER is Planning to Develop During Calendar Year 2009

(See the Good Guidance Practices (GGPs) regulation on this Web page or
21 CFR 10.115 for details about the Guidance Agenda.)

CATEGORY — Advertising

- Amendment of the Brief Summary
- Presentation of Risk Information in Prescription Drug and Medical Device Promotion

CATEGORY — Chemistry

- Assay Development for Immunogenicity Testing
- Chemistry, Manufacturing, and Controls – Postmarketing Plan
- CMC Post-Approval Changes Reportable in an Annual Report
- Immunogenicity Assessment for Therapeutic Protein Products
- Incorporation of Physical-chemical Identifiers (PCID) Into Solid Oral Dosage Form Drug Products for Anticounterfeiting
- Standards Recognition

CATEGORY — Clinical/Antimicrobial

- Influenza: Developing Drugs for Treatment and/or Prophylaxis
- Microbiological Data to Support a NDA for Systemic Antibacterial DP – Development, Analysis, and Presentation

CATEGORY — Clinical/Medical

- Adaptive Trial Designs
- Myopic Progression: Developing Drugs for the Reduction of Myopic Progression
- Oncology Endpoints: Non-Small Cell Lung Cancer

CATEGORY — Clinical/Statistical

- Non-Inferiority Trials

CATEGORY — Combination Products

- Drug Diagnostic Co-Development

CATEGORY — Compliance

- Contract Manufacturing
- Dosage Delivery Devices for OTC Liquid Drug Products
- Medical Gas
- Non-Penicillin Beta-Lactam Contamination

- Part 11, Electronic Records; Electronic Signatures - Scope and Application
- PET CGMPs
- Pharmaceutical Component Quality Control
- Pharmaceutical Components At-Risk for Melamine Contamination
- Pharmaceutical Manufacturing Statistics
- Pre-Launch Activities Importation Request (PLAIR)
- Process Validation: General Principles and Practices

CATEGORY — Drug Safety Information

- Best Practices for Conducting Pharmacovigilance Studies Using Electronic Healthcare Data
- Dear Healthcare Professional Letters
- Good Naming, Labeling, and Packaging of Drugs & Biologics to Reduce Medication Errors

CATEGORY — Electronic Submissions

- Providing Regulatory Submissions in Electronic Format – Analysis Datasets and Documentation

CATEGORY — Generics

- Submission of Summary Bioequivalence Data for ANDAs

CATEGORY — IND

- Consumer Product Safety Commission – Tamper Resistant Packaging for INDs
- Determining Whether Human Research Studies Can Be Conducted Without An IND
- IND Safety Reporting

CATEGORY — Labeling

- Content and Format of the Clinical Pharmacology Section
- Drug Names and Dosage Forms
- Labeling Dietary Supplements for Women Who Are or Could Be Pregnant

CATEGORY — OTC

- Label Comprehension Studies for Nonprescription Drug Products

CATEGORY — Procedural

- Animal Models - Essential Elements to Address Efficacy Under the Animal Rule
- Assessment of Abuse Potential of Drugs
- Determining Whether Human Research with a Radioactive Drug Can Be Conducted Under a Radioactive Drug Research Committee (RDRC)
- Investigational NDAs prepared and submitted by Clinical Investigators

Note: Agenda items reflect guidances under development as of the date of this posting.