

2015 Issue 1



CDRH



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NEWSLETTER

December 2014 List of FDA Guidances and Drafts

The TOTAL - 15 new documents were issued by FDA



CDRH:

1. 12/2/14: [Infusion Pumps Total Product Life Cycle - Guidance for Industry and FDA Staff](#)
2. 12/2/14: [Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex - Guidance for Industry and Food and Drug Administration Staff](#)
3. 12/11/14: [Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance \(MR\) Environment - Guidance for Industry and Food and Drug Administration Staff](#)
4. 12/17/14: [Providing Submissions in Electronic Format -- Standardized Study Data](#)
5. 12/22/14: [Transfer of a Premarket Notification \(510\(k\)\) Clearance – Questions and Answers Draft Guidance for Industry and Food and Drug Administration Staff](#)
6. 12/19/14: [Minimizing Risk for Children's Toy Laser Products - Guidance for Industry and Food and Drug Administration Staff](#)
7. 12/30/14: [Radiation Biodosimetry Devices - Draft Guidance for Industry and Food and Drug Administration Staff](#)

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8. 12/1/14: [SUPAC: Manufacturing Equipment Addendum](#)
9. 12/3/14: [Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products-Content and Format](#)

- 10.12/4/14: [How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD](#)
- 11.12/8/14: [General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products](#)
- 12.12/8/14: [DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers](#)
- 13.12/9/14: [Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products — Content and Format](#)
- 14.12/23/14: [DSCSA Implementation: Product Tracing Requirements — Compliance Policy](#)

Veterinary:

- 15.12/10/14: [VICH GL35 - Pharmacovigilance of Veterinary Medicinal Products Electronic Standards for Transfer of Data](#)

We will continue watching out for new guidances issued by FDA and regulators world-wide in 2015!!!



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