DIA Combination Products Conference

October 29-30 | Bethesda, MD

FDA Guidances Related to Combination Products

Postmarketing Safety Reporting for Combination Products *Guidance for Industry and FDA Staff*	This guidance addresses certain ways to comply with the final rule on postmarketing safety reporting (PMSR) requirements for combination products that FDA issued on December 20, 2016 (81 FR 92603) and that is codified in 21 CFR Part 4, Subpart B.	**Released: July 2019**
Instructions for Use – Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products – Content and Format	This guidance provides recommendations for developing the content and format of an 18 Instructions for Use (IFU) document for human prescription drug and biological products and 19 drug-device or biologic-device combination products submitted under a new drug application (NDA) or a biologics license application (BLA).	**Draft Guidance Released: July 2019**
Compliance Policy for Combination Product Postmarketing Safety Reporting *Immediately in Effect Guidance for Industry and FDA Staff*	This guidance document is intended to assist Combination Product Applicants who are subject to the Combination Product Postmarketing Safety Reporting Final Rule.	**Released: April 2019**
Evaluation of Devices Used with Regenerative Medicine Advanced Therapies	Provides manufacturers, applicants, and sponsors engaged in the development of RMATs, with current FDA thinking regarding evaluation of devices used in the recovery, isolation, or delivery of therapies.	**Released: February 2019**
Principles of Premarket Pathways for Combination Products *Guidance for Industry and FDA Staff*	Pursuant to Cures Act section 3038, amendments focus on enhancing clarity, predictability, efficiency, and consistency of premarket regulatory expectations for combination products, including appropriate coordination of premarket review.	**Draft Guidance Released: February 2019**
Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use	Finalizes 2015 draft guidance that provides recommendations on the selection of appropriate package type terms and selection of appropriate discard statements for relevant products.	**Released: October 2018**

Additional Updates

The abbreviated 510(k) program has been expanded to outline how sponsors can win clearance for devices after showing they meet certain performance levels, rather than through direct comparisons with predicate products.

The *Multiple Function Device Products* draft guidance describes FDA's current approach to regulating digital health tools and medical devices that include both medical device functions and non-medical device functions.

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