



MONTHLY UPDATE - JANUARY / FEBRUARY 2022 IN REVIEW

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US: • Califf/Woodcock Commissioner Roles • Senate Manufacturing Bill • House User Fee Hearings • User Fee Program Performance • BsUFA II First-cycle Reviews • NDA 2021 Report • OPQ 2021 Report • CDER 2022 Guidance Agenda • CBER 2022 Guidance Agenda • DSCSA Rx Drug Rule • GAO on Foreign Inspection Program • Annual Report Submissions in NextGen Portal • OGD 2021 Report • SBIA Generics Research and BE Meetings • CDER ANDA Correspondence MAPP • ANDA Guidances on Submissions, Labeling, and Review • ANDA Product-Specific Guidances • Premarket Review of Combination Products • FDA/Sponsor OTC Monograph Meetings • FDA/State MOU on Compounding Limits • 503B Outsourcer Bulks List • USP Compounding Chapters • USP mRNA Testing Draft • USP Cannabidiol Monographs

EUROPE: • Heads of Medicines CMDh Activity • EMA GMP/GDP Reflection Paper • EMA Nitrosamine Q&A • EMA 2021 Regulatory Activity • EMA ICH Q13 Comments • EMA IMP Drug Substance Guidelines • EC on Northern Ireland • EC Research/Innovation Toolkit • EU Annex on Import GMPs • EFPIA on EU Regulatory Framework • EC Unique Identifier Q&A • EDQM on CEP Improvement Consultation • EDQM on CEP Application Communications • EDQM on CEP/MAH Relationship • EDQM Reference Standard Activities • EDQM Q&A on Monograph Elaboration • Ph. Eur. Draft Monographs and Reference Standards • Ph. Eur. Pediatric Formulary Monographs

INTERNATIONAL: • Revised PIC/S GMP Guide • FDA and EMA on Drug Shortages • China Guidelines on Drug-Device Combination Products • India's CDSCO on API Labeling

FDA WARNING LETTERS AND RECALLS, EMA NON-COMPLIANCE REPORTS POSTED IN JANUARY AND FEBRUARY..... [p. 104](#)