

REGULATORY 101 - Field Alert Reports

By **Karen R. Zimm and Renee King-Alliego** Mar 20, 2020 7:00 am EDT



Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article. Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specification established for it in the application. The term "bacteriological" used in 21 CFR 314.81(b)(1)(ii) has been interpreted by the FDA to mean "microbiological" and encompasses any kind...

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