

**FDA and Industry GDUFA III Implementation Quarterly Meetings – 2Qtr 2024 Meeting April 22, 2024, 2:00 PM – 4:00 PM**

**White Oak Campus and Virtual Zoom Meeting**

**Agenda**

* FDA Discussion
* DSCSA
* CR Analysis
* Industry Inquiries
* Inspections (Current and Future State)
* OGD Annual Report
* Generic Related and Public Databases

**Participants**

| FDA: | Office | Industry: | Organization |
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| Tiana Barnes | CDER | Deborah Atwood | BPTF |
| Carter Beach | CDER | Joel Carpenter | BPTF |
| Ashley Boam | CDER | David Gaugh | AAM  |
| Kennerly Chapman | CDER  | Kiran Krishnan | AAM (Apotex) |
| Jacqueline Corrigan-Curay | CDER | Scott Kuzner | AAM  |
| Alonza Cruse | ORA | Brian McCormick | AAM (Teva) |
| Kristin Davis | CDER | Giuseppe Randazzo | AAM |
| Kim Dettelbach | OCC | Gil Roth | PBOA |
| Richard Friedman | CDER | Cornell Stamoran | PBOA (Catalent) |
| Michael Kopcha | CDER |  |  |
| Iilun Murphy | CDER |  |  |
| Susan Rosencrance | CDER |  |  |
| Darby Kozak | CDER |  |  |
| Leigh Verbois | CDER |  |  |
| Geoffrey Wu | CDER |  |  |
| Menglu Yuan | CDER |  |  |

**FDA Topics**

FDA presented on topics related to the current implementation.

*Drug Supply Chain Security Act (DSCSA)*

FDA presented on the ongoing execution of the DSCSA as it enters its tenth year of enactment. FDA requested feedback from Industry regarding implementation challenges and ideas for effective solutions to address Industry needs.

*Analysis of CRL Major Deficiencies*

FDA presented on FY2023 ANDA approval dynamics and the top issues preventing a first cycle approval. FDA requested feedback from Industry on how to address common issues and improve ANDA submission quality.

**Industry Topics**

Industry posed questions to FDA related to current implementation activities.

*Inspections*

Industry inquired about the current inspection numbers and how inspections may be changing in the future. FDA outlined the current state of inspections, its risk-based model for domestic and foreign inspections, and the unannounced vs announced inspections pilot.

*OGD Annual Report*

Industry inquired about OGD’s Annual Report and if there are any areas FDA wishes to amplify. FDA gave an overview of data contained within the Annual Report, including numbers on approvals, submissions, and controls.

*Generic Related and Public Databases*

 Industry inquired on the cadence of updates for specific databases and how changes are being communicated to the public and provided some suggestions on communicating changes for FDA to consider. FDA explained how different databases are updated, the frequency of updates, and how changes are communicated.