Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act

FDA PUBLIC MEETING – OCTOBER 14, 2016

Pharmaceutical Distribution Security Alliance (PDSA)

Lessons Learned from 2015

◦ Collaboration

◦ Implementation of standards

◦ Regulatory flexibility and early guidance

◦ Preemption

PDSA
Pharmaceutical Distribution
Security Alliance

2017 Readiness

◦ PDSA members are working diligently to meet the 2017 electronic exchange and serialization requirements

◦ Readiness may vary depending on the supply chain participant

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2017 Challenges

◦ Guidance on grandfathering, exceptions, exemptions, and waivers

◦ Solution providers and equipment vendors

◦ Maturing software systems

◦ Contract manufacturers

◦ Changing business relationships

◦ Technical issues

◦ Aggregation

◦ Downstream impact

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2019 Saleable Return Requirements & Progress

◦ Industry collaboration

◦ Relationship to Phase II

2023 Requirements & Progress

◦ Early industry understanding

◦ Early completion of piloting

◦ Regulator/industry dialogue, feedback, and collaboration

◦ Guardrails