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August 11, 2014

Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 50852

RE: MatchRX Comments on Draft Guidance for Industry, Drug Supply chain Security Act Implementation: Identification of Suspect Product and Notification (FDA-2014-D-0609)

To Whom it May Concern:

MatchRX would like to thank the Food and Drug Administration (FDA) for the opportunity to comment on the recently published Draft Guidance for Industry, "Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification."[1] As a provider of track and trace compliance for dispenser-to-dispenser transactions with over 3,200 independent dispenser members, MatchRX applauds the Agency's efforts. We have a brief comment on the process FDA proposes for notifications of suspect products.

We note FDA's acknowledgment that this draft guidance "does not address all provisions of the DSCSA related to suspect and illegitimate products." [2] Guidance from FDA on criteria for making and terminating illegitimate product notifications would be very helpful for all trading partners. It would likely alleviate the concerns that have led FDA to propose playing a gatekeeper role over terminations and eliminate any need for an open-ended review time. Ultimately, we believe that trading partners will be fully capable of determining when to *terminate* a notification, given that they will be responsible for making the notifications in the first instance.[3]

Again, we thank you for the opportunity to comment on this Draft Guidance. Should you have any questions, please do not hesitate to contact:

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Sincerely

John Kello
CEO

[1] Draft Guidance for Industry, *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification* (June 2014), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf (hereinafter Draft Guidance).
[2] Draft Guidance at 1.
[3] The Draft Guidance indicates that the DSCSA "gives FDA authority to issue binding guidance on the process for terminating notifications of illegitimate products." Draft Guidance at 2 n.4. As such, it would be relatively easy for FDA to revise the same guidance if experience shows that the agency needs to play a more significant role in reviewing proposed terminations beyond what MatchRX proposes in these comments.