Gretchen Trout
Head North America Policy &
FDA Liaison

Novartis Pharmaceuticals Corporation
1700 Rockville Pike
Suite 510
Rockville, MD 20852

Draft Guidance for Industry: Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification
Docket Number: FDA–2014–D–0609

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm.1061
Rockville, MD 20852

August 6, 2014

Dear Sir/Madam:

Novartis appreciates the opportunity to comment on the above referenced draft guidance to help ensure the integrity and safety of the drug supply chain. We have the following comments/requests for clarifications.

1. The Draft Guidance instructs trading partners to use Form 3911 to notify the FDA of the identification of an illegitimate product. Will form 3911 be considered public information and will it be posted on the FDA website?

2. If the FDA informs the trading partner that FDA has been made aware of a potentially illegitimate product, is the trading partner still required in this case to submit Form 3911?

3. Can FDA explain why Form 3911 is necessary (in place of a standard field alert report?)

Once again, Novartis appreciates this opportunity to provide comment, and we hope you will take our requests for clarification under consideration.

Sincerely,
Gretchen Trout

Gretchen Trout
Head, North America Policy & FDA Liaison
US Regulatory and Development Policy
Drug Regulatory Affairs
Novartis Pharmaceuticals Corporation