August 11, 2014

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

Re: Federal Register Notice Requesting Comments on Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification
Docket No. FDA–2014–D–0609

Dear Sir/Madam:

On behalf of the Pharmaceutical Distribution Security Alliance (PDSA), I am pleased to submit these comments regarding the Food and Drug Administration's (FDA or Agency) June 11, 2014 Federal Register notice seeking comments on its Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (the Guidance).

PDSA is a multi-stakeholder coalition with membership that spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, repackagers, wholesale distributors, third-party logistics providers, and pharmacies. More than 30 companies are formal members of PDSA, while many other external stakeholders provide additional policy and technical support through industry trade associations. Our primary goal is ensuring patients have uninterrupted access to safe, authentic, FDA-approved medicine.

PDSA appreciates the opportunity to provide input on the Guidance, which will be a critical piece of information in the successful implementation of the Drug Supply Chain Security Act (DSCSA). Our comments represent the operational expertise of individuals throughout industry and reflect the knowledge of those at the front lines of implementing the DSCSA. PDSA hopes to remain engaged throughout the development and finalization of the Guidance as well as the implementation of other portions of the DSCSA. To the extent it is useful to the Agency, we offer our experience and expertise as a resource and welcome the opportunity for further discussion about this important topic.

The DSCSA establishes a national system for the traceability of certain prescription pharmaceutical products through the distribution chain. A cornerstone of that system is the identification and disposition of "illegitimate products." In order to ensure the prompt, successful, and efficient identification and disposition of illegitimate products, all sectors of the

distribution chain must be prepared to work together and coordinate their activities. This Guidance is a critical piece of information in helping trading partners to achieve such coordination. Given its importance and the impending January 1, 2015 effective date for compliance, we respectfully ask that the Agency address our comments below and promptly publish final guidance.

1. Many of the scenarios identified as specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution chain are overly broad.

While we recognize and appreciate that the DSCSA requires the Agency to identify scenarios that could significantly increase the risk of suspect product entering the supply chain, the Guidance's instruction to exercise "heightened vigilance"[1] and be "particularly diligent"[2] should not be construed as creating a legal standard. The Agency does not have the authority to establish a legal standard. Furthermore, companies throughout the supply chain have existing systems and processes for identifying and responding to suspect products. The scenarios identified in the Guidance should inform the operation of those existing systems and processes, not require the implementation of new processes. Accordingly, the Agency should clarify that the phrases "heightened vigilance" and "particularly diligent" do not impose a heightened legal standard.

Many of the scenarios identified in the Guidance as presenting a significantly increased risk of entering the supply chain are overly broad. All scenarios included in the final guidance should be narrowly tailored to prevent unnecessary concern and confusion in the distribution chain. We are particularly concerned by the sweeping breadth of the following scenarios.

- Purchasing product from a new source[3] typically should not increase the risk of a suspect product entering the distribution chain. The DSCSA establishes a new requirement that all trading partners be "authorized."[4] Compliance with that requirement will help to ensure new trading partners are legitimate. Therefore, purchasing from a new trading partner should not, alone, increase the risk of suspect product entering the supply chain.

- The fact that a trading partner has been involved in business transactions where it sold or delivered suspect product[5] does not necessarily increase the risk of suspect product entering the distribution chain. "Suspect product" has not been determined to be illegitimate and may always be cleared.[6] If the past purchase or delivery of suspect product was a rare occurrence and the product was cleared, the fact that a suspect product was purchased or delivered presents little or no increase in risk. In fact, the most diligent trading partners may be the most likely to identify suspect product, and that diligence

[1] Food & Drug Admin., *Draft Guidance for Industry Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*, (June 2014) (*hereinafter* "Draft Guidance"), at ln. 124.
[2] Draft Guidance, ln. 129.
[3] Draft Guidance, ln. 133.
[4] *See* FDCA §§ 582(b)(3), (c)(3), (d)(3), (e)(3).
[5] Draft Guidance, ln. 148–49.
[6] *See* FDCA §§ 582(b)(4)(A)(ii), (c)(4)(A)(ii), (d)(4)(A)(iii), (e)(4)(A)(ii).

should not cause such trading partners' transactions to be labeled as high-risk transactions.

- Similarly, not all products that have previously been the subject of an illegitimate product notification[7] should be deemed to increase the risk of suspect product entering the supply chain. Some limitations on this characterization should be included. For example, if a discrete quantity of a product is identified as illegitimate, all transactions involving that product should not be considered to present increased risk indefinitely. Some restrictions in time and circumstance should apply.

- Not all high-demand products[8] should be considered to present an increased risk of suspect product entering the distribution chain. While we recognize that high-demand products may, in some instances, create an incentive for bad actors to introduce illegitimate product into the distribution chain, a large number of products could be considered high-demand products. Unnecessarily identifying too broad a category of products as products that increase the risk of suspect product entering the supply chain may actually decrease the level of diligence given to those products that truly do present increased risk. Increased-risk characterization should be reserved for that small portion of products truly deserving of particular diligence and should reflect the relatively small number of products that are in fact illegitimate.

- High-volume, low-value products[9] should not necessarily be considered a scenario that could significantly increase the risk of a suspect product entering the distribution chain. While we understand that high sales volume may, in some instances, create an incentive for bad actors to introduce illegitimate product into the supply chain, many high-volume products are of such low value that such a financial incentive for bad actors is not present. In fact, Congress recognized the low risk presented by some high-volume, low-value products and expressly exempted those products from the traceability requirements of the DSCSA.[10] Furthermore, "high-volume products" is a very broad category of products—high-volume, relatively low-priced products account for over 80% of the domestic prescription drug volume.[11] Heightened vigilance should be reserved for a more narrowly defined set of scenarios, as we are concerned that broad application will lead to complacency and undermine the value of heightened vigilance.

- An incomplete transaction information, transaction history, or transaction statement[12] should not, in all circumstances, immediately be considered to increase the risk of a suspect product entering the supply chain. "Incomplete" information, for example, could be nothing more than a typographical error. Trading partners should have an opportunity—and, in fact, should be encouraged—to communicate and coordinate to correct incomplete transaction information, transaction history, and transaction

[7] Draft Guidance, ln. 180.
[8] Draft Guidance, ln. 164.
[9] Draft Guidance, ln. 169.
[10] *See, e.g.*, FDCA § 581(24)(B)(xiv)–(xvi).
[11] *See* IMS Institute for Healthcare Informatics, *Declining Medicine Use and Costs: For Better or Worse*, at 15 (May 2013).
[12] Draft Guidance, ln. 159–60.

statements to avoid unnecessary returns or misidentification of legitimate product as suspect. We also suggest that the Agency avoid the term "suspicious"[13] because the same term is used in Drug Enforcement Administration (DEA) regulations. Specifically, 21 C.F.R. § 1301.74(b) requires DEA registrants to design and operate a system to disclose "suspicious orders" of controlled substances. Rather than risk potential confusion regarding the meaning of the term "suspicious" and which agency should receive each type of report, we suggest that FDA revise the phrase "incomplete or suspicious" to merely use the term "suspect" in its place.

All of the above scenarios, as currently described in the Guidance, are likely to cause undue concern and disruption within the distribution chain. The efficient and rapid movement of product through the distribution supply chain is critical to patient care, and the addition of unnecessary activities to confirm the validity of product can significantly disrupt product movement and patient care. Defining scenarios of increased risk in an overly broad manner will also detract from attention given and resources allocated to those situations that truly do significantly increase the risk of suspect product entering the supply chain. While the impact of illegitimate product can be significant, the percentage of product in the pharmaceutical distribution chain that is in fact illegitimate is extremely small. Scenarios identified in the final guidance should be narrowly tailored to account for the relative rarity of illegitimate product.

2. Trading partners should have an opportunity to work collaboratively to resolve discrepancies before concluding a product is suspect.

We appreciate and support the opportunity for trading partners to work together to resolve discrepancies and confusion without triggering a suspect product event.[14] It is critical that trading partners have this opportunity to collaborate and determine the true status of a product without being forced to a conclusion that the product is suspect. This is especially true with regard to questions related to transaction information, transaction history, and transaction statements for product and packaging that do not appear suspect. Suspect classification requires quarantining and investigation, which, in addition to their inherent operational burden, have the potential to unnecessarily delay distribution of critical pharmaceutical products to patients.

Furthermore, we believe that all trading partners should engage and coordinate with the relevant manufacturer prior to determining that a product is suspect product. The manufacturer is best positioned to assess the authenticity and quality of the product under consideration. Coordination with the manufacturer will avoid unnecessary and incorrect determinations that a product is suspect and the related disruption such determinations cause throughout the distribution chain.

We urge the Agency to retain in the final guidance the opportunity and flexibility to work collaboratively with trading partners, and we ask that the Agency expressly encourage trading partners to coordinate with the relevant manufacturer prior to making the determination that a product is suspect product.

[13] *Id.*
[14] Draft Guidance, ln. 219–22.

3. Trading partners should be given the flexibility to use existing systems and process for, and determine on a case-by-case basis the best methods for, identifying and evaluating suspect product.

Section III.B. of the Guidance sets out numerous recommendations for how trading partners might identify suspect product. The Agency should clarify that the practices in Section III.B. are only non-binding illustrative examples of actions that could be taken. A requirement to perform the activities in Section III.B. for all product, or even very large quantities of product, would be immensely burdensome. For example, closely examining every high-demand product[15] to confirm lot numbers and expiration dates match the outer container[16] would be virtually impossible for most trading partners, some of which handle tens of thousands of products every day. Similarly, many of the activities in Section III.B. cannot be performed for product in a sealed case without opening the sealed case. While there may be circumstances in which confirmation of lot numbers and expiration dates against the outer container is appropriate, the Agency should clarify that trading partners have the flexibility to determine the specific situations in which such confirmation is appropriate.

Most companies already have systems and processes in place to identify and evaluate product that may be suspect or illegitimate. The Guidance should afford trading partners the flexibility to use those existing systems and processes, and their related experiences, to determine on a case-by-case basis the best methods for identifying and evaluating suspect product.

4. Guidance related to requests for verification should be consistent with the statute.

The Guidance states that trading partners must quarantine and investigate product "upon determining that a product in their possession or control is suspect or upon receiving a request for verification from the FDA."[17] However, the DSCSA provides that these obligations are triggered "[u]pon making a determination that a product in the possession or control of the [trading partner] is a suspect product, or upon receiving a request for verification from the Secretary *that has made a determination that a product within the possession or control of a [trading partner] is a suspect product*."[18] We ask that the Agency revise the Guidance to reflect the statutory language that limits requests for verification to those instances in which the Secretary has determined a product is suspect product.

As drafted, the Guidance could be construed as authorizing the Secretary to make a request for verification with regard to product that is not suspect product and that such request would trigger an obligation to quarantine and investigate the product. Such an interpretation would be inconsistent with the DSCSA and could lead to unnecessary quarantine of product, which would unnecessarily drain resources and disrupt product distribution.

[15] Draft Guidance, ln. 164.
[16] Draft Guidance, ln. 256.
[17] Draft Guidance, ln 105–06.
[18] FDCA §§ 582(b)(4)(A)(i), (c)(4)(A)(i), (d)(4)(A)(i), (e)(4)(A)(i).

5. The Agency should clarify the meaning of the terms "suspect product" and "illegitimate product" and what is meant by a high risk of illegitimacy.

The terms "suspect product" and "illegitimate product" are the lynchpin of the Guidance and the related systems and processes. Although both terms are defined in the DSCSA,[19] neither definition provides clear comprehensive direction for industry to understand what is meant by those terms. We are concerned that overly broad interpretation of these terms will lead to over-notification, unnecessary disruptions in distribution and, potentially, drug shortages, and other unintended consequences.

We, therefore, ask that the Agency clarify the meaning of the terms "suspect product" and "illegitimate product" in the final guidance. The phrases "subject of a fraudulent transaction" [20] and "appears otherwise unfit for distribution"[21] in the definition of those terms are particularly vague and concerning. We specifically suggest that the phrase "fraudulent transaction" be defined as "a transaction that involves the introduction into or transportation through interstate commerce of counterfeit, diverted, intentionally adulterated, or intentionally distributed expired drugs for resale." The Agency has used similar language in previous discussions of drug traceability.[22] Alternatively, we ask that the Agency provide examples of scenarios that do constitute a "fraudulent transaction."

Similarly, we ask that the Agency clarify what the phrase "appears otherwise unfit for distribution" means and provide examples of scenarios that do not rise to such level. For example, the Agency should clarify that this category does not encompass quality issues addressed through other existing regulatory schemes, such as cGMP requirements and recall processes. The return of expired product and other unsalable returned product also should not be considered "unfit for distribution" for purposes of the definitions of suspect product and illegitimate product.

In addition, the DSCSA requires a manufacturer to notify the FDA and certain trading partners if the manufacturer has reason to believe there is a "high risk" that a product is an illegitimate product.[23] We ask that the Agency provide greater clarity of what constitutes a "high risk" of illegitimacy. Such clarification should account for both the likelihood that a product has become illegitimate and the severity of consequences if a patient accessed the product in question.

6. The Agency should avoid use of the term "pedigree."

The Agency should avoid use of the term "pedigree" when referring to DSCSA requirements, including in the Guidance.[24] The term "pedigree" connotes a historical state requirement, and such requirements were different from and have been preempted by the DSCSA. The Guidance,

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[19] FDCA §§ 581(8), (21).
[20] FDCA §§ 581(8)(C), (21)(C).
[21] FDCA §§ 581(8)(D), (21)(D).
[22] Food & Drug Admin,, *Determination of System Attributes for Tracking and Tracing of Prescription Drugs*. (Feb. 15–16, 2011), *available at* http://www.fda.gov/downloads/Drugs/NewsEvents/UCM245540.pdf.
[23] FDCA § 582(b)(4)(B)(ii)(II).
[24] Draft Guidance, ln. 152, 156.

and any other related publications, should use the statutory terms "transaction information" and "transaction history" unless specifically referring to historical state requirements.

7. Companies should be allowed to use existing systems and processes to notify trading partners of illegitimate product and to terminate those notifications.

Companies throughout the distribution chain have effective systems and processes in place for notifying and communicating with trading partners about illegitimate products. Each company's systems and processes are uniquely tailored to its operations and its relationship with its trading partners. It is critical that trading partners be allowed to use their existing systems and processes to notify trading partners of illegitimate product and to terminate notifications as those systems and processes have proven to be effective, and implementation of new systems and processes would cause undue burden and confusion.

We appreciate and support the Agency's acknowledgement in the Guidance that trading partners may use existing systems and processes to terminate notifications.[25] Further, we strongly urge the Agency to clarify in the final guidance that companies may use existing systems and processes to make initial notifications to trading partners. In the notice of availability, the Agency clearly contemplates that companies may use existing systems and processes to make initial notifications to trading partners,[26] but we urge the Agency to clarify this within the final guidance document.

8. The Agency should terminate notifications as quickly as possible.

All illegitimate products must be promptly quarantined. While quarantine is critical to containing illegitimate product and protecting patient health, it can also cause severe delays in delivery of important, even life-sustaining, products. Once product has been cleared, every effort should be made to terminate notifications as quickly as possible and to promptly and safely resume distribution of that product. Through the notification process, the Agency will be provided significant visibility to the investigation of illegitimate product and the procedures to identify, correct and disposition illegitimate product. That visibility and engagement should facilitate rapid termination of notifications. Therefore, we request that the Agency commit to terminating notifications within three business days.

9. Companies should be allowed to request expedited review of a request for consultation and termination.

We appreciate and support the opportunity to request an expedited review of a request for consultation and termination of an illegitimate product notification.[27] As noted above, a notification of illegitimate product can cause severe delays in distribution and have significant consequences for patients. We urge the Agency to retain in the final guidance the ability to

[25] Draft Guidance, ln. 337–41.
[26] 79 Fed. Reg. 33,564, at 33,566 (June 11, 2014) ("Manufacturers/repackagers, wholesale distributors, and pharmacies might notify their trading partners using existing systems and processes used for similar types of communications . . . .").
[27] Draft Guidance, ln. 329–32.

request expedited review of termination requests and establish a clear process for making such requests.

10. Trading partners must coordinate with the manufacturer to determine whether a product is illegitimate.

There is wide agreement throughout the distribution chain that trading partners must coordinate with the relevant manufacturer to determine whether a product is an illegitimate product. The DSCSA itself requires such coordination,[28] as do the practical realities of making such determinations. The manufacturer of a product is best positioned to determine whether a product is illegitimate as it has the best understanding of the product, its appearance, its composition, its packaging, and its other characteristics. In addition, determining whether a product is illegitimate will often require testing of the product's chemical composition, which requires access to information on product composition available only to the manufacturer. We urge that the Agency recognize in the final guidance that trading partners must coordinate with the manufacturer to determine whether a product is illegitimate.

In addition, we request that the Agency add to Form 3911 a checkbox for trading partners to confirm that they coordinated with the manufacturer in determining the product at issue is illegitimate. This checkbox will serve as a valuable reminder to trading partners that they must coordinate with the manufacturer. It will also provide FDA assurance that the existence of illegitimate product has been communicated back to the beginning of the supply chain to support active resolution of the product concern.

11. The Agency should clarify that notification is not required to be provided to *all* trading partners.

The calculations in the notice of availability are based on an assumption that notifications will be sent to all of a given company's immediate trading partners.[29] The DSCSA only requires that notification of illegitimate product be provided to "immediate trading partners that the [company] has reason to believe may have received such illegitimate product."[30] Frequently, a company will only have reason to believe that a discrete subset of its immediate trading partners may have received the illegitimate product. We ask that the Agency clarify that not all immediate trading partners are required to be notified of illegitimate product.

12. We strongly support the clarification that a third-party logistics provider is not a "trading partner" for purposes of the Guidance.

We appreciate and support the clarification in footnote 3 of the Guidance that, for purposes of the Guidance, a third-party logistics provider is not a "trading partner." This clarification

[28] *See, e.g.*, FDCA § 582(c)(4)(B)(i) ("Upon determining, *in coordination with a manufacturer*, that a product in the possession or control of a wholesale distributor is an illegitimate product . . . .") (emphasis added).
[29] *See, e.g.*, 79 Fed. Reg. 33,564, at 33,566 (June 11, 2014) (explaining that the average wholesale distributor has 2,350 immediate trading partners and, therefore, would be required to notify 2,350 trading partners for each illegitimate product).
[30] FDCA §§ 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), (e)(4)(B)(ii).

accurately reflects the requirements of the DSCSA, and we urge the Agency to retain this express clarification in the final guidance.

13. The title of Form 3911 should be revised to be more descriptive.

The current title of Form 3911—Drug Notification—is not descriptive. Given the particular importance of the information provided through a notification, we believe the title of Form 3911 should clearly reflect its purpose. Specifically, we ask that the title reference "Illegitimate Drug Product" to avoid confusion and to avoid suggesting, inaccurately, that notification is required for suspect product.

14. The Agency should clarify which trading partners are responsible for submitting Form 3911.

The DSCSA requires trading partners to notify the FDA upon determining that a product in its possession or control is illegitimate (and, in the case of a manufacturer, if the manufacturer has reason to believe there is a high risk that a product is an illegitimate product). [31] Initial notification to the Agency upon initial determination of illegitimacy is critical to the Agency's engagement and participation in the process of identifying and preventing the further distribution of illegitimate product.

The DSCSA also requires a trading partner, upon determining in coordination with the manufacturer that a product in its possession or control is illegitimate, to make notification to "immediate trading partners that the [company] has reason to believe may have received such illegitimate product."[32] Upon receipt of such notification from a trading partner, those subsequent trading partners must identify any illegitimate product in its possession or control.[33] Identification of these additional trading partners with possession or control of the illegitimate product is also critical to preventing further distribution of illegitimate product.

For any given incident of illegitimate product, the number of trading partners with possession or control of that product can vary widely. In some instances, hundreds, if not thousands, of trading partners could have possession or control of the illegitimate product. Disparate individual notifications to the Agency from every trading partner with possession or control of the illegitimate product could lead to the reporting of redundant, confusing, and even inconsistent information. Therefore, the Agency should clearly define any notification process that must be used by trading partners who identify illegitimate product in their possession or control in response to notification from a trading partner who has already notified FDA through submission of Form 3911. Any such process should be structured in a way that minimizes the operational challenges and burdens of excessive notification and maximizes the usability and reliability of the related information. We urge the Agency to engage PDSA and other stakeholders in developing any such process.

[31] FDCA §§ 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), (e)(4)(B)(ii).
[32] FDCA §§ 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), (e)(4)(B)(ii).
[33] FDCA §§ 582(b)(4)(B)(iii)(I), (c)(4)(B)(iii), (d)(4)(B)(iii), (e)(4)(B)(iii).

To further aid in the efficiency and predictability of the notification process, we also ask that the Agency clarify the ways in which it intends to use information included in notifications it receives and the activities and processes in which the Agency will engage upon receipt of a notification of illegitimate product.

15. Form 3911 should include a clear way for manufacturers to indicate that the notification relates to a product for which there is a high risk of illegitimacy.

As the Guidance notes, the DSCSA requires a manufacturer to notify the Agency if it has reason to believe there is a high risk that a product is an illegitimate product.[34] However, Form 3911 and its instructions do not account for such "high risk of illegitimacy" notifications. We suggest that the Agency revise Form 3911 to include a clear mechanism by which a manufacturer can indicate that it is making a "high risk of illegitimacy" notification.

16. The Agency should clarify the way in which Form 3911 will interact with other FDA systems and processes.

The Agency has many systems and processes for controlling and responding to drug products that raise quality or safety concerns, such as Medwatch, Field Alert Reports, and recalls. We believe it would be useful to understand how the new reports will interact with those systems and processes. We encourage the Agency to evaluate these related processes to avoid conflicting requirements, unnecessary overlap, and inefficiencies. We also ask that FDA clearly identify any other systems or processes that are superseded or obsoleted by Form 3911, such as reporting to the Office of Criminal Investigations.

17. The Agency should clarify the way in which it will protect confidential or proprietary information included in Form 3911.

In some instances, detailed completion of Form 3911 may require inclusion of proprietary information (*e.g.*, proprietary drug formulation, description of unique distribution arrangements and business practices) or confidential information related to investigation of the event (*e.g.*, information about the event relevant to an ongoing criminal investigation). This is particularly true with regard to lines 16 (description of event/issue) and 17 (description of why notification is no longer necessary). We urge the Agency to clearly describe the ways in which proprietary or confidential information in Form 3911 will be protected. Failure to clearly define such protections may deter trading partners from including the full details of their investigations in Form 3911.

18. Lines 7 and 8 of Form 3911 and the instructions for those lines are unclear.

Line 7 of Form 3911 calls for the "Drug Use," and the instructions explain that an example[35] of a drug use is "human use." However, all products that are subject to the DSCSA, by definition, are intended for human use.[36] Similarly, line 8 of Form 3911 calls for a "Drug Description," and

[34] FDCA § 582(b)(4)(B)(ii)(II).
[35] Presumably, the parentheticals in the instructions for lines 5, 7, 8, and 9 should use the abbreviation "*e.g.,*" rather than "*i.e.,*".
[36] *See* FDCA § 581(12).

the instructions explain that an example of a drug description is "finished." All products that are subject to the DSCSA, by definition, are in finished dosage form.[37] If the Agency is asking that product be identified as human use or finished, we suggest that lines 7 and 8 be struck from Form 3911 as all products covered by the DSCSA are within those categories. If the Agency is seeking other information through lines 7 and 8, we suggest that it better clarify through the instructions the specific information it is seeking.

19. Other minor revisions and clarifications to Form 3911 are warranted.

Some additional revisions and clarifications to Form 3911 will assist in its usability and help to avoid confusion. These include:

- The instructions should clarify that Form 3911 should include either the generic name of the product (line 5) *or* the trade name of the product (line 6). Including both may cause confusion regarding the exact product that has been identified as illegitimate.
- The form should include contact information for assistance with questions related to the form.
- The instructions for line 19 should be clarified to more specifically identify the referenced company. It is not clear what it means to be "responsible" for the product, particularly with regard to illegitimate product. Further, it is not clear that the company "responsible" for the product would always be the same company as the company submitting the form.
- The Agency should provide a confirmation or reference number to the submitter upon receipt of Form 3911.

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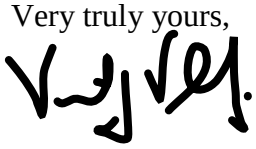
We appreciate the opportunity to provide these comments on this important topic, and we thank the Agency for its consideration of these comments. As useful to the Agency, we welcome the opportunity for further discussion on the Guidance and related topics.

Very truly yours,



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[37] *See* FDCA § 581(13).