August 11, 2014

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

Re: Food and Drug Administration (FDA) Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (Docket No. FDA-2014-D-0609)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 or Madam:

The undersigned organizations thank the U.S. Food and Drug Administration for the opportunity to provide comments on draft guidance for the identification of suspect pharmaceutical product and the associated process to notify affected supply chain stakeholders of illegitimate product.

The Drug Supply Chain Security Act represents a landmark opportunity to protect consumers by securing the U.S. pharmaceutical supply in new and unprecedented ways, and its robust implementation is required in order to realize the full intent of the statute. The law, which requires the participation of all sectors in pharmaceutical distribution, builds toward an electronic and interoperable system between 2014 and 2023 that allows each package of medicine to be traced via its unique serial number.

The new system will make it more difficult for criminals to introduce potentially suspect or illegitimate medicines into pharmaceutical distribution. A vitally important step is the requirement for industry supply chain stakeholders to investigate any pharmaceutical product in their possession that appears to be suspect, report any product determined to be illegitimate to their trading partners and to the FDA, and remove it from the supply chain starting in 2015. This requirement may eventually encourage the practice of routinely verifying a medicine's authenticity before it reaches consumers.

The draft guidance released by the FDA will help make the law meaningful for consumers and patients, and it offers an important opportunity to ***define*** and ***reinforce*** the responsibilities of industry stakeholders when it comes to proactively identifying and removing medicines that pose a threat to the public's health from the drug supply. The draft guidance covers a wide range of risk factors, and this breadth should be maintained. However the FDA should add clarity and detail to its recommendations to ensure supply chain sectors can meaningfully operationalize them, and should also differentiate between scenarios of higher and lower risk.

In addition, the FDA should encourage industry supply chain stakeholders to consider a multi-layered approach that builds upon and integrates each feature of the future system when screening for suspect products. Stakeholders should be encouraged to take full advantage of the new tools available in the Drug

Supply Chain Security Act, including the verification of serial numbers beyond investigations, and the validation of transaction histories.

RECOMMENDATIONS

1. Maintain breadth, but differentiate scenarios by level of risk

The scenarios described in the draft guidance cover a wide range of risk factors that companies should consider when screening for suspect product, including product sourcing, market signals, and product appearance. This breadth should be maintained, but we recommend FDA provide additional clarity and specificity to help industry supply chain stakeholders understand the appropriate steps they should take when they encounter specific scenarios. This regulatory clarity will help alert stakeholders to scenarios where risks are highest, and it will also assist them with targeting their resources.

FDA should differentiate scenarios by level of risk and identify distinct responses from industry supply chain stakeholders for each scenario.

The draft guidance describes a broad range of scenarios that could significantly increase the risk of a suspect product, but the degree of risk will vary for each. For example, product that is "the subject of an FDA counterfeit or cargo theft alert" should be immediately treated as suspect product when received, and should be duly quarantined and investigated. But product that is "generally in high demand in the U.S. market" should not, as a category, be immediately treated as suspect since this description broadly characterizes most drugs with high rates of utilization in the U.S. consumer market.

FDA should add detail to more carefully define the characteristics of specific scenarios, and specify concrete steps that trading partners should take to ensure sufficient diligence when encountering these different scenarios.

FDA suggests that trading partners should be particularly diligent when engaging in transactions that involve the scenarios described, but the guidance does not expand on what steps or increased vigilance are needed. This additional guidance would be particularly useful for the more general scenarios that stakeholders are likely to encounter, such as when they have no option but to purchase or source product from a new trading partner, or to purchase product that has historically experienced shortages and is in generally high demand in the U.S. market. These situations should not be ignored, and stakeholders would benefit from clarity on how they should be addressed.

2. Add specificity on handling incomplete transaction information

The draft guidance flags scenarios where the transaction information, transaction history, or transaction statement may appear "incomplete," but does not provide next steps or offer best practices that stakeholders should follow upon encountering missing information.

FDA should include recommendations to industry supply chain stakeholders on how to address incomplete transaction information that may be due to inadvertent errors.

While criminals may seek to deliberately omit or provide incomplete transaction information, these problems could also arise due to inadvertent errors with electronic data transmission. While this information is legally required, guidance should specify that trading partners may identify and resolve inadvertent errors in a timely manner without necessarily entering into the full quarantine and investigation process for suspect products. This will be especially important when the supply chain transitions to a fully electronic system that can trace each individual package of medicine in November 2023.

3. Clarify validation of transaction history (chain of custody)

When suspect product is identified, the Drug Supply Chain Security Act requires all supply chain sectors starting in January 1, 2015 to conduct an investigation that includes validating the product's transaction information and transaction history.

The FDA should identify and explain the steps industry supply chain stakeholders should take to validate transaction histories (chain of custody) when investigating suspect product.
As presently written, the statute is not clear on the specific steps that are required in order to validate a product's transaction history. FDA should clarify this in the final guidance. In addition, FDA should consider encouraging stakeholders to proactively validate transaction information, transaction history, and transaction statements in high-risk scenarios, when screening for suspect product. Validating the chain of custody is a powerful investigative tool that will not only help companies identify suspicious prior sales of the drug, but also helps ensure suppliers are legitimate and responsible participants in the supply chain.

4. Include standard operating procedures to screen for suspect product

The draft guidance outlines recommendations for how trading partners might identify suspect product, and lists strategies to detect suspicious sales offers or problems with a product's packaging or physical appearance.

FDA should recommend that companies develop and implement standard operating procedures for screening and designating a product as potentially suspect.
Companies should make a decision based on set criteria as to whether a product is suspect and thus must be quarantined and investigated. Trading partners should also have processes to monitor information on issues such as theft and counterfeiting to support suspect product designation when product is received. As of January 1, 2015, the law requires all supply chain sectors to have systems in place to support suspect product investigation. Standard operating procedures to screen for suspect product support this requirement, and will help stakeholders demonstrate their compliance.

5. Encourage proactive serial number checking as screen for suspect and illegitimate product

One of the most important new features of drug distribution established by the law is the application of unique serial numbers to every package of prescription drugs. Serialized drugs will be phased-in to the

supply chain over a four year period from late 2017 to late 2020, and the law requires companies to make use of serial numbers when investigating suspect products or processing saleable returned products. However the use of serial numbers is most effective when used as a screening tool rather than solely as an investigative tool.

FDA should define best practices in guidance to not only allow industry supply chain stakeholders to comply with the law, but to also encourage proactive and possibly automated checks of unique serial numbers on individual packages of drug product at routine points of distribution throughout the supply chain.

Use of serial numbers in this way can allow companies to quickly and easily identify product with counterfeit serial numbers, or products with serial numbers that have been flagged, such as medicines that have been stolen or illegally diverted. A legitimate product that is diverted may have no packaging issues that would otherwise make it appear suspect. Proactive serial number checks would help identify these illegitimate drugs.

We appreciate the opportunity to provide comments on draft guidance for the identification of suspect pharmaceutical product.

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