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Dear Doctor Jung:


HDA represents primary pharmaceutical distributors – the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

HDA appreciates FDA’s release of the Draft Guidance and the effort to clarify the meaning of the terms “counterfeit,” “diverted,” “fraudulent transaction” and “unfit for distribution” within the definitions of suspect product and illegitimate product in the Federal Food, Drug and Cosmetic Act (FD&C Act) in § 581(21) and § 581(6), respectively. We offer the following additional comments:
1. **Definition of “Counterfeit”**

   HDA supports the reliance upon the definition of “counterfeit” in § 201(g)(2) of the FD&C Act and the Draft Guidance’s incorporation of that preexisting definition.

2. **Definition of “Diverted”**

   FDA proposes the following definition of “diverted”:

   1. Product that left the prescription drug distribution system in the United States and is reintroduced in a transaction with an authorized trading partner. For example, this would include product that is dispensed to a consumer or patient and then reintroduced into the U.S. prescription drug distribution system to an authorized trading partner; or

   2. Product that is labeled for sale in a non-U.S. market and that is introduced into the U.S. prescription drug distribution system to an authorized trading partner.

   A product generally would not be considered diverted as described in B.1, above, and therefore would not be a suspect or illegitimate product under DSCSA, if a trading partner obtains that drug product:

   - Through surveillance activities outside the U.S. prescription drug distribution system; or

   - From a consumer or patient who obtained the product from outside the U.S. prescription drug distribution system, unless the trading partner has reason to believe that the product could be introduced into the U.S. prescription drug distribution system to an authorized trading partner.

   Draft Guidance at lines 123-142.

   HDA generally supports the direction FDA appears to be taking in this proposed definition. However, we believe further clarity is needed. For example, we interpret the phrase “prescription drug distribution system in the United States” in lines 123-127 to mean that once a drug has been dispensed to a patient, it is outside the prescription drug distribution system in the U.S. If this is indeed the correct interpretation, we suggest the Guidance state this clearly.

   Lines 123-130 would also benefit from additional clarity regarding the use of the phrases “to an authorized trading partner,” “with an authorized trading partner” and “introduced into the U.S. prescription drug distribution system.”

   - First, HDA believes the intent of these provisions would be clearer if it were tied to a “transaction” as this term is defined in § 581(24). We believe that risks to the supply chain arise, and merit further and more aggressive action, when there is an attempt to introduce or reintroduce a diverted product in a transaction – that is, an entity attempts to engage in a transaction involving the product.
• Second, we are concerned that limiting diversion to “authorized trading partners” may be too restrictive as bad actors may not necessarily be “authorized.”

• Third, we understand that a common vector for diverted products entering the U.S. is through individual consumer purchases, either over the Internet, or as a personal purchase made abroad and then personally imported back into the U.S. We suggest adding this conduct in point 2 as an example to clarify the intent of the Guidance. In this way, point 2 would also mirror point 1.

Given the above, we suggest amending lines 122-130 of the Draft Guidance as follows (additions in blue bold and deletions in strikeout):

1. Product that left the prescription drug distribution system in the United States and is reintroduced in a transaction with an authorized trading partner. For example, this would include product that is dispensed to a consumer or patient and then reintroduced in a transaction into the U.S. prescription drug distribution system to an authorized trading partner or other entity; or

2. Product that is not labeled for sale in the non-U.S. market and that is introduced in a transaction into the U.S. prescription drug distribution system to an authorized trading partner. For example, this would include a patient purchasing product abroad or over the Internet that is not labeled for sale in the U.S. and then attempting to sell or otherwise exchange ownership of that product in a transaction.

We also suggest that FDA clarify that product being imported into the U.S. pursuant to an emergency use authorization or other public health emergency is not “diverted” under this definition.

We also support the bullet point clarifications in lines 136-142 as especially helpful for manufacturers who have had lingering questions regarding whether their international counterfeit surveillance programs could trigger illegitimate product notifications to FDA. We believe that lines 139-142 would, like lines 129-130 above, be clearer if tied to a transaction. For example:

• From a consumer or patient who obtained the product from outside the U.S. prescription drug distribution system, unless the trading partner has reason to believe that the product could be introduced in a transaction into the U.S. prescription drug distribution system to an authorized trading partner.

3. Definition of “Fraudulent Transaction”

It is well-established in the law that “fraudulent” presupposes that a person acts intentionally with knowledge of the falsity.1 We believe that the DSCSA also specifically supports this concept by the elements included in the Transaction Statement’s definition in section 581(27), specifically:

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1 See, e.g., https://definitions.uslegal.com/f/fraud/ (fraud includes knowledge of falsity); https://www.law.cornell.edu/wex/fraudulent_misrepresentation (knowing or reckless falsity); Restatement (Second) Of Torts §§ 525, 531.
TRANSACTION STATEMENT.—The ‘transaction statement’ is a statement, in paper or electronic form, that the entity transferring ownership in a transaction…

(D) did not knowingly ship a suspect or illegitimate product…

(F) did not knowingly provide false transaction information; and

(G) did not knowingly alter the transaction history. [emphasis added]

Thus, HDA suggest the following modification to lines 146-149:

For purposes of section 581(8) and (21) of the FD&C Act, and the verification provisions (including notification) in sections 582(b)(4), (c)(4), (d)(4) and (e)(4), FDA interprets the term fraudulent transaction as referring to a transaction in which the transaction information, transaction history, or transaction statement contains knowingly falsified information.

4. Definition of “Unfit for Distribution”

The Draft Guidance interprets the term “unfit for distribution” as referring to a prescription drug whose sale would violate the FD&C ACT, including drugs that are suspect or illegitimate, and drugs that are adulterated or misbranded. We believe that the Guidance should explicitly incorporate the important further clarification in § 581(8) and § 581(21) that a drug is unfit for distribution only where such product “would result in serious adverse health consequences or death to humans.” We suggest amending lines 153-160 as follows:

For purposes of section 581(8) and (21) of the FD&C Act, and the verification provisions (including notification) in sections 582(b)(4), (c)(4), (d)(4) and (e)(4), FDA interprets the term unfit for distribution as referring to a prescription drug whose sale would violate the FD&C Act where such product would result in serious adverse health consequences or death to humans. This includes prescription drugs identified as suspect or illegitimate (see 582(c)(4) of the FD&C Act); adulterated (see section 501), including drugs rendered nonsaleable because conditions (such as return, recall, damage, or expiry) cast doubt on the drug’s safety, identity, strength, quality, or purity (see section 501(2)(B) of the FD&C Act); or misbranded (see section 502 of the FD&C Act), where such product would result in serious adverse health consequences or death to humans.

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HDA thanks FDA for this opportunity to comments and suggestions on FDA’s Draft Guidance. If you have any questions, please contact me at 703-885-0240 or at aducca@hda.org.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs