NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

August 8, 2014

Submitted to http://www.regulations.gov
Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Commissioner Hamburg:

Re: FDA Docket FDA-2014-D-0609 - Comments on Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

The National Association of Chain Drug Stores (NACDS) thanks the Food and Drug Administration for the opportunity to submit our comments on the Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' 125 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries. For more information, visit www.NACDS.org.

Introduction

We thank the FDA for considering our comments on the agency's draft guidance on identification of suspect products and notification. The draft guidance presents helpful information for pharmacies. We appreciate that the agency has provided a number of factors to consider for identification of suspect products and Form FDA 3911 for notifying the agency regarding illegitimate products.

Recognizing the importance of the draft guidance, and in the spirit of the optimal implementation of the new law, we urge the agency to provide further guidance now, as well as in the future, to aid the supply chain stakeholders relative to suspect and illegitimate products. We anticipate that additional questions will arise with the initial implementation of the Drug Supply Chain Security Act (DSCSA) in the short term, as well as in the long term. We believe that additional guidance would be beneficial to supply chain stakeholders and FDA, especially considering that the DSCSA is a

comprehensive new law being implemented for the most part without regulatory guidance. As such, we thank the agency in advance, for aiding the supply chain stakeholders to the fullest extent possible with further guidance. Our specific comments and recommendations are provided below.

Request for further guidance on suspect product determinations:
We appreciate the draft guidance provided by the agency and ask the agency to provide further guidance as discussed below.

Specific Scenarios
We seek guidance for the following matters:

- The ability of pharmacies to consider the surrounding circumstances when addressing suspect product determinations given that, depending on the circumstances, some scenarios and factors may have different weight or not be applicable.
- Whether pharmacies may seek assistance from the agency to aid pharmacies with timely and appropriate suspect product determinations and, if so, the appropriate process, and whom to contact.

First, the relevance, application, and meaning of the factors and scenarios for suspect product determinations may readily differ depending on the circumstances. For example, in the draft guidance, the FDA has listed factors such as drug shortages, products in high demand, and purchasing from a trading partner that has previously transacted business in suspect products, however, these may or may not be associated with potential suspect products depending on the circumstances. We provide some examples below:

- A drug shortage in the past may not necessarily indicate a permanent factor for a product to be considered suspect in the future. The supply chain is dynamic with a variety of ongoing and ever-changing drug shortages.
- A drug may be experiencing high demand due to seasonal or other factors, e.g., winter cold or flu season, and thus high demand should not necessarily be a cause for a product to be considered suspect.
- Purchasing from a trading partner that previously sold or delivered suspect product may not be relevant or a predictor of future suspect products being delivered. Additional guidance on how a pharmacy should consider a trading partner that supplied suspect product in the past would be welcomed.

Similar concerns would arise, more or less, with the FDA's other factors and scenarios. For instance, problematic or incomplete transaction information, history, or statements could be due to technical matters or computer issues, and not suggest a suspect product issue.

We ask FDA to provide pharmacies the ability to consider the surrounding circumstances when addressing suspect product determinations.

Second, we request the FDA's assistance for pharmacies relative to suspect product determinations. Such assistance would be very helpful to pharmacies in making timely and appropriate determinations. We do understand the issue of limited FDA resources, but believe that it would be helpful for supply chain stakeholders, and ultimately the agency, for supply chain stakeholders to be able to consult with FDA on these matters.

For instance, FDA could provide assistance through an FDA website and/or telephone number. Having the FDA involvement and expertise would aid the supply chain stakeholders in making appropriate determinations, streamline the process for suspect product determinations, and avoid inconsistent alerts from different supply chain sectors, for example, if one supply chain stakeholder believes that a product is suspect and another does not.

Request for further guidance on termination of illegitimate products

We thank the FDA for guidance on notification of illegitimate products and for developing Form FDA 3911. We seek further guidance on the bulleted requests below, which are discussed in more detail following the bullets.

- Reducing the 10 day time frame for the agency to notify the supply chain stakeholders that an illegitimate product notification may be terminated.
- The role of pharmacies in notifying the FDA of illegitimate drug products as the pharmacy is required to coordinate illegitimate product determinations with the drug manufacturer on the determination.
- For notification to immediate trading partners, pharmacies would notify the applicable wholesale drug distributor or distributors or the drug manufacturer from whom the dispenser purchased the product.
- The pharmacy notification to the drug manufacturer of illegitimate drug products is accomplished through the pharmacy coordination with the drug manufacturer on the illegitimate product determination. The pharmacy would indicate such coordination on the Form FDA 3911 (if FDA approves having such information on the Form FDA 3911, see next bullet).
- Advice from the agency on whether it would be helpful to FDA to have the FDA Form 3911 include space for the manufacturer and the pharmacy to provide information on the coordination with the drug manufacturer for illegitimate drug product determinations such as date(s), identities of persons involved, contact information, date of manufacturer determination, etc.
- Advice from the FDA on whether the agency wants both the manufacturer and dispenser to notify FDA of an illegitimate drug product determination where the manufacturer and the dispenser have coordinated on such a determination.
- The process the FDA will use for advising the supply chain stakeholders of products determined to be illegitimate, how the FDA will distribute notice to the supply chain stakeholders , and if the agency will have a standardized form to advise the supply chain stakeholders .

Shortening the 10 day response time period for termination of a notification of illegitimate drug products

We have concerns with the 10 day timeframe for the agency to notify the supply chain stakeholders that an illegitimate product notification has been terminated. This length of time could pose problems for patient care as patients would not be able to access such drugs.

For example, if a widely used medication is awaiting FDA approval to terminate the illegitimate product notification, it could lead to widespread drug shortages. Many patients could run out of their medication and the pharmacy would not be able to refill the patients' prescriptions. We ask that the FDA consider shortening the time period for the agency to terminate the notification from 10 days to considerably fewer days. It is critical that notification back to the supply chain stakeholders be provided as quickly as possible given the potential impact on patients and medication availability. Our recommendation is fewer than 5 days and preferably 3 days.

Pharmacy role in notification of illegitimate drug products

We ask the FDA to clarify the role of the pharmacy (dispenser) in making notifications to the FDA and others regarding illegitimate product in the dispenser's possession or control. We have the following requests.

- The Drug Supply Chain Security Act (DSCSA) provides that dispensers, upon determining, in coordination with the manufacturer, that a product is illegitimate, would notify the FDA and all immediate trading partners. We ask the agency to clarify that the chain pharmacy's immediate trading partners would be the wholesale drug distributor or distributors and/or the drug manufacturer from whom the dispenser purchased the product, and not their intracompany pharmacies.
- The pharmacy is required to coordinate the illegitimate product determination with the drug manufacturer. Accordingly, the drug manufacturer would have been notified and involved in the illegitimate product determination. We ask that the agency provide guidance that this coordination process would meet the requirement for the pharmacy to provide notification to the drug manufacturer of an illegitimate drug product.
- In addition, we seek clarifying guidance from the FDA on whether the agency wants both the manufacturer and dispenser to notify FDA of an illegitimate drug product determination where the manufacturer and the dispenser have coordinated on such a determination.

Form FDA 3911

We note that the Form FDA 3911 as drafted does not have any fields for dispensers or manufacturers to provide information relative to coordination on the illegitimate product determination. We seek clarifying guidance from the agency on whether it would be

helpful to FDA to have the form include space for such information to indicate the specifics of the coordination, identities of persons involved, etc.

If the agency agrees that having such information on the Form FDA 3911 would be helpful, we ask that the FDA add section(s) in the Form FDA 3911 for the pharmacy (dispenser) and other applicable supply chain stakeholders to indicate their coordination with the drug manufacturer on determining whether the drug product is illegitimate. In this regard, we believe it would be helpful to have spaces to indicate the manufacturer's name, name of the contact person at the manufacturer and contact information, date contacted and the manufacturer's response, similar information for the pharmacy or other supply chain stakeholder, and any other appropriate information as the agency finds would be helpful.

FDA notice to the supply chain for handling illegitimate drug products

We ask that the FDA provide further guidance on the process the FDA will use for advising the supply chain stakeholders on the handling of illegitimate products, how the FDA will distribute notice to the supply chain stakeholders, and whether the agency will have a standardized form to advise the supply chain stakeholders. Ideally, FDA would develop a uniform process for notifying supply chain stakeholders of illegitimate products and, in particular, what to do with such products, e.g., return to the manufacturer or wholesaler. We ask that the agency use a process similar to that for recalled drug products. Having a process that the supply chain stakeholders are familiar with would offer clarity and advantages. In any event, we would greatly appreciate further guidance detailing the process, and having it available on the FDA website.

Conclusion

We thank FDA for the opportunity to provide our comments on the draft guidance for Identification of Suspect Product and Notification. For any questions, please do not hesitate to contact Diane Darvey at 703-837-4182 or ddarvey@nacds.org.

Sincerely,

Diane L. Darvey

Diane Darvey, Pharm.D., J.D.
Director Government Affairs and
Public Policy