Guidance for Industry Drug Supply Chain Security Act (DSCSA) Implementation: Identification of Suspect Product and Notification

U.S. Food and Drug Administration

December 2016

Objectives

The purpose of this webinar is to:

- Provide an overview of the guidance
- Highlight the changes
  - High Risk of Illegitimacy
  - Required process for Requesting a Termination
  - Fillable Form FDA 3911

DSCSA Requirements

Trading partners (manufacturers, repackagers, wholesale distributors, dispensers) must have systems:

- to quarantine and conduct investigations of suspect products;
- to notify FDA and immediate trading partners within 24 hours, if a product is illegitimate; and
- to terminate notifications about illegitimate product in consultation with FDA.

Definitions
[Section 581(21) of the FD&C Act]

Suspect product - there is reason to believe it:

A. is potentially counterfeit, diverted, or stolen;
B. is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
C. is potentially the subject of a fraudulent transaction; or
D. appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

Definitions
[Section 581(8) of the FD&C Act]

Illegitimate Product - credible evidence shows that the product is:

A. counterfeit, diverted, or stolen;
B. intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
C. subject of a fraudulent transaction; or
D. appears otherwise unfit for distribution such that it would be reasonably likely to result in serious adverse health consequences or death to humans

Identification of a Suspect Product

- Specific scenarios concerning suspect products
- Recommendations on how to identify a suspect product

Identify specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain

Example scenarios grouped by:

- Trading Partners and Product Sourcing
- Supply, Demand, History, and Value of the Product
- Appearance of the Product

Trading Partners and Product Sourcing

- Purchasing from a source new to the trading partner
- Receipt of an unsolicited sales offer from an unknown source
- Purchasing on the Internet from an unknown source
- Purchasing from a source that a trading partner knows or has reason to believe has engaged in questionable or suspicious business practices that could increase the risk of suspect product entering the supply chain

Product Supply, Demand, History & Value

- Is generally in high demand in the U.S. market
- Is in higher demand because of its potential relationship to a public health or other emergency
- Has a high sales volume or price in the U.S.
- Has been previously or is currently being counterfeited or diverted
- has been or is currently the subject of a drug shortage

Product Appearance

- Packaging or container seems suspicious
- Package uses foreign terms
- Package is missing information
- Packaging is missing anti-counterfeiting technologies it normally features
- Finished dosage form seems suspicious

Provide recommendation on how trading partners may identify such product and make a determination on whether the product is a suspect product as soon as practicable

- Be alert for price that's "too good to be true"
- Closely examine the package and transport container
- Closely examine the label on the package, or the label on the individual retail unit (missing information, misspelled words, language in a foreign language, etc.)

High Risk of Illegitimacy

Section 582(b)(4)(B)(ii)(II) *HIGH RISK OF ILLEGITIMACY.--A manufacturer shall notify the Secretary and immediate trading partners that the manufacturer has reason to believe may have in the trading partner's possession a product manufactured by, or purported to be a product manufactured by, the manufacturer not later than 24 hours after determining or being notified by the Secretary or a trading partner that there is a high risk that such product is an illegitimate product. For purposes of this subclause, a 'high risk' may include a specific high risk that could increase the likelihood that illegitimate product will enter the pharmaceutical distribution supply chain and other high risks as determined by the Secretary in guidance pursuant to subsection (h).*

High Risk of Illegitimacy Scenario 1

There is a high risk that a product that the manufacturer has reason to believe is in an immediate trading partner's possession is an illegitimate product.

High Risk of Illegitimacy Scenario 2

Specific high risks that could increase the likelihood of an illegitimate product entering the U.S. pharmaceutical distribution supply chain

High Risk of Illegitimacy Scenario 3

- Other high risks as determined by FDA

Notifications to FDA

- Guidance describes the process trading partners should use for notifying FDA about illegitimate product
- Trading partners **must** use this process for terminating notifications
- Form FDA 3911 has been developed to serve both of these purposes

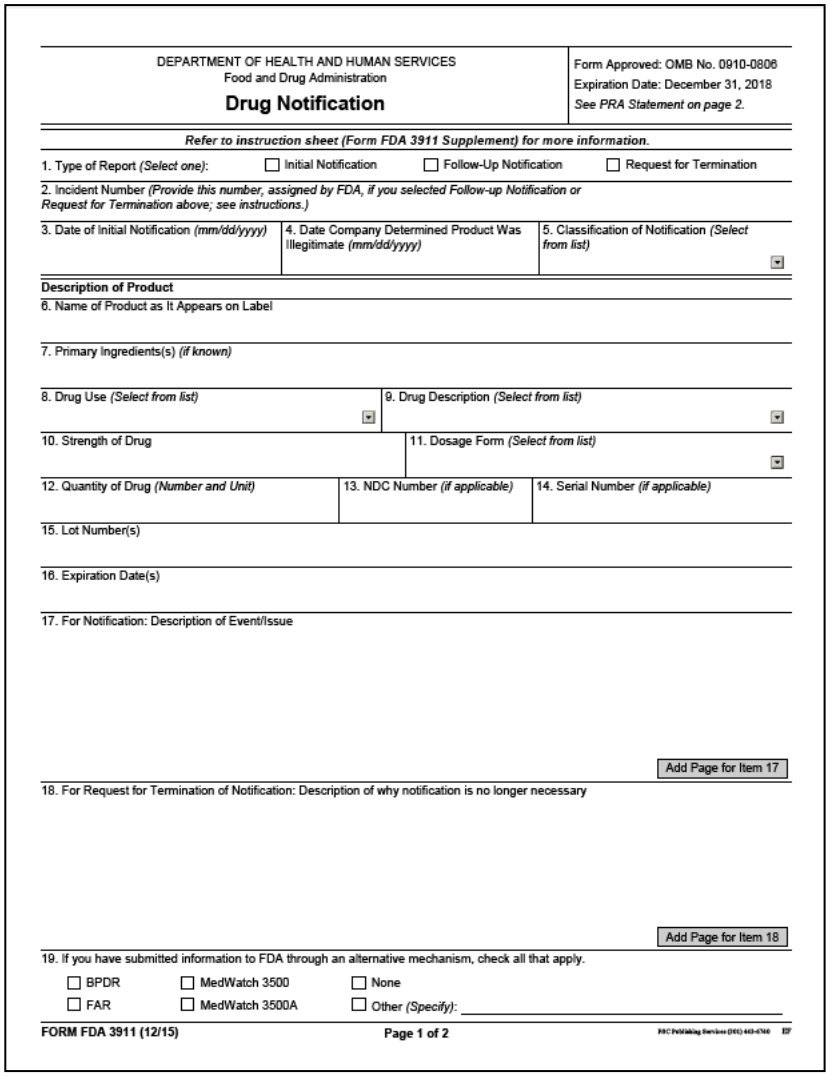
Notifications to FDA

1) Trading partners should access FDA's Drug Notification Web page at to make notifications. http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm
2) Trading partners should follow the instructions on the Web page for accessing Form FDA 3911 and to provide information.
3) Form FDA 3911 should be submitted by using the method provided in the form.

Termination of Notifications to FDA

1) Trading partners must follow the instructions on the Web page for accessing Form FDA 3911 and provide information.
2) This form must be submitted by using the method provided in the form.
3) FDA will review the request and consult with the trading partner.

Drug Notifications – Form FDA 3911



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0806
Expiration Date: December 31, 2018
See PRA Statement on page 2.

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report *(Select one)*: ☐ Initial Notification ☐ Follow-Up Notification ☐ Request for Termination

2. Incident Number *(Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)*

3. Date of Initial Notification *(mm/dd/yyyy)* | 4. Date Company Determined Product Was Illegitimate *(mm/dd/yyyy)* | 5. Classification of Notification *(Select from list)*

Description of Product

6. Name of Product as It Appears on Label

7. Primary Ingredients(s) *(if known)*

8. Drug Use *(Select from list)* | 9. Drug Description *(Select from list)*

10. Strength of Drug | 11. Dosage Form *(Select from list)*

12. Quantity of Drug *(Number and Unit)* | 13. NDC Number *(if applicable)* | 14. Serial Number *(if applicable)*

15. Lot Number(s)

16. Expiration Date(s)

17. For Notification: Description of Event/Issue

Add Page for Item 17

18. For Request for Termination of Notification: Description of why notification is no longer necessary

Add Page for Item 18

19. If you have submitted information to FDA through an alternative mechanism, check all that apply.

☐ BPDR ☐ MedWatch 3500 ☐ None
☐ FAR ☐ MedWatch 3500A ☐ Other *(Specify)*: _____

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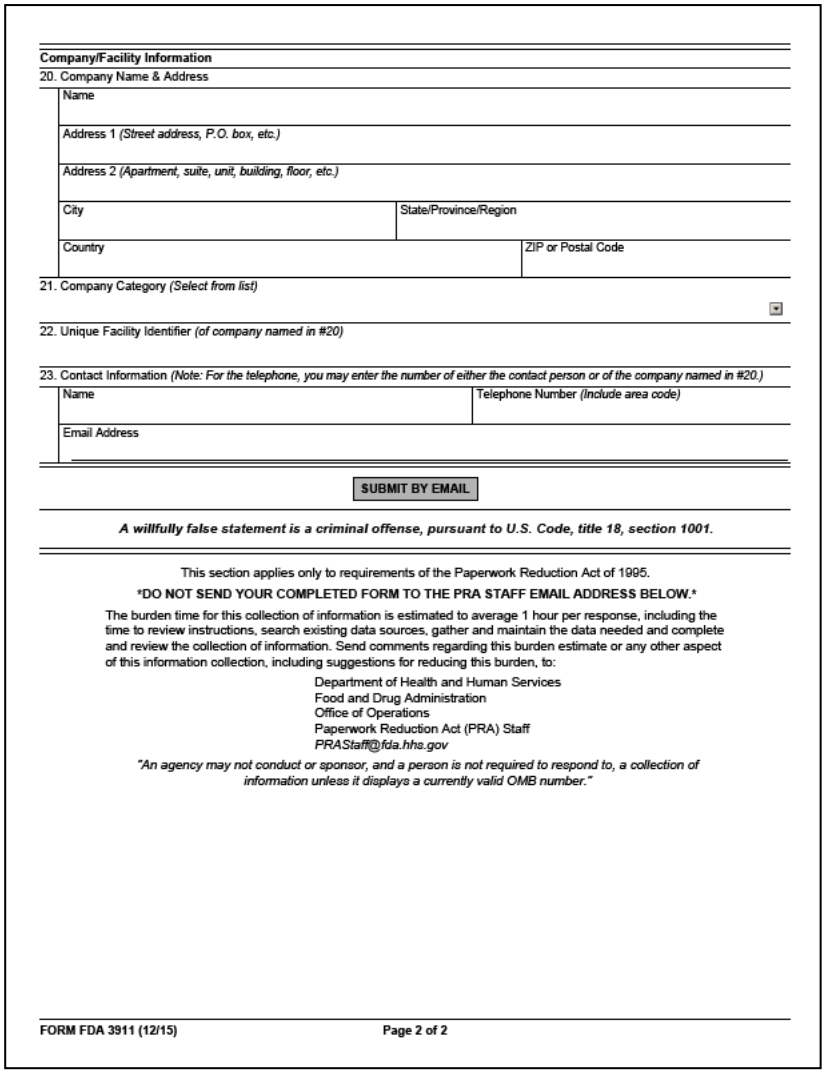

Company/Facility Information

20. Company Name & Address

Name

Address 1 *(Street address, P.O. box, etc.)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City | State/Province/Region

Country | ZIP or Postal Code

21. Company Category *(Select from list)*

22. Unique Facility Identifier *(of company named in #20)*

23. Contact Information *(Note: For the telephone, you may enter the number of either the contact person or of the company named in #20.)*

Name | Telephone Number *(Include area code)*

Email Address

SUBMIT BY EMAIL

A willfully false statement is a criminal offense, pursuant to U.S. Code, title 18, section 1001.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Form FDA 3911

- Fillable
- Incident Number will be assigned by FDA in the acknowledgement of the receipt of the Initial Notification.
- Put the Incident Number on all subsequent submissions related to the notification (Field 2)
- An additional page can be added to describe the notification event or to describe when the notification is no longer necessary (Field 17 or 18).

Submitting Form FDA 3911

- Submit by clicking on “Submit By Email”
- Will generate e-mail addressed to drugnotifications@fda.hhs.gov
- Other attachments such as pictures or additional information can be added
- Do not save as a “static” pdf

Comments or Questions

drugnotifications@fda.hhs.gov


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