Guidance for Industry

Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact CDER Office of Compliance at 301-796-3100 or drugtrackandtrace@fda.hhs.gov, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

June 2014
Procedural

Guidance for Industry

Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

Additional copies are available from:
Office of Communications
Division of Drug Information, WO51, Room 2201
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Silver Spring, MD 20993
Phone: 301-796-3400; Fax: 301-847-8714
druginfo@fda.hhs.gov
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

and/or

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., WO 71, Room 3128
Silver Spring, MD 20993
Phone: 800-835-4709 or 240-402-7800
ocod@fda.hhs.gov
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

June 2014
Procedural

TABLE OF CONTENTS

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

Guidance for Industry[1]
Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. With the exception of section IV.B, [2] it does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended to aid trading partners[3] (manufacturers, repackagers, wholesale distributors, or dispensers) in identifying a suspect product and terminating notifications regarding illegitimate product. Beginning on January 1, 2015, a trading partner who determines that a product in its possession or control is an illegitimate product must notify the Food and Drug Administration (FDA or Agency) and certain immediate trading partners under section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee), as added by the Drug Supply Chain Security Act (DSCSA). This guidance identifies specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain; provides recommendations on how trading partners can identify the product and determine whether the product is a suspect product as soon as practicable; and sets forth the process by which trading partners should notify FDA of illegitimate product and how they must terminate the notifications, in consultation with FDA.

This guidance does not address all provisions of the DSCSA related to suspect and illegitimate products. As FDA works to implement other provisions of the DSCSA, the Agency intends to

[1] This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

[2] Congress gave FDA authority to implement through binding guidance the process for terminating notifications of illegitimate product in consultation with FDA. Thus, the discussion of the termination process in section IV.B, once finalized, will have binding effect.

[3] For this guidance, *trading partner* is defined as described in section 581(23)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 30eee(23)(A)), and refers to a manufacturer, repackager, wholesale distributor, or dispenser. For purposes of this guidance, *trading partner* does not refer to a third-party logistics provider (3PL), though FDA encourages 3PLs to follow the recommendations in this guidance to the extent relevant to the 3PL's operations.

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

issue additional information to support efforts to develop standards, issue guidance and regulations, establish pilot programs, and conduct public meetings.

FDA's guidance documents, in general, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required. Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.[4]

II. BACKGROUND

A. Drug Supply Chain Security Act

On November 27, 2013, the DSCSA (Title II of Public Law 113-54) was signed into law. Section 203 of the DSCSA adds new section 582(h)(2) to the FD&C Act, which requires FDA to issue guidance to aid trading partners in identifying a suspect product and terminating a notification regarding illegitimate product. *Suspect product* is defined in section 581(21) of the FD&C Act as a product for which 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. Starting January 1, 2015, section 582 of the FD&C Act requires trading partners, upon determining that a product in their possession or control is a suspect product, to quarantine the product while they promptly conduct an investigation to determine whether the product is an illegitimate product. *Illegitimate product* is defined in section 581(8) of the FD&C Act as a product for which credible evidence shows that it 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) is the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.[5]

Starting January 1, 2015, section 582 of the FD&C Act requires trading partners, upon determining that a product in their possession or control is illegitimate, to notify FDA and all immediate trading partners (that they have reason to believe may have received the illegitimate product) not later than 24 hours after making the determination. Manufacturers are additionally required under section 582(b)(4)(B)(ii)(II) to notify FDA and immediate trading partners (that

[4] Section 582 of the FD&C Act gives FDA authority to issue binding guidance on the process for terminating notifications of illegitimate product. Specifically, section 582(h)(2)(A) states that FDA "shall issue a guidance document to aid trading partners in the identification of a suspect product and notification termination. Such guidance document shall . . . set forth the process by which manufacturers, repackagers, wholesale distributors, and dispensers shall terminate notifications in consultation with the Secretary regarding illegitimate product . . . ."

[5] For additional definitions applicable to this guidance, please refer to section 581 of the FD&C Act.

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

the manufacturer has reason to believe may possess a product manufactured by or purported to be manufactured by the manufacturer) not later than 24 hours after the manufacturer determines or is notified by FDA or a trading partner that there is a high risk that the product is illegitimate.

The DSCSA outlines critical steps to build an electronic, interoperable system over the next 10 years that will identify and trace certain prescription drugs as they are distributed within the United States. For many years, FDA has been engaged in efforts to improve the security of the drug supply chain to protect U.S. patients from unsafe, ineffective, and poor quality drugs. Since the formation of the first FDA Counterfeit Drug Task Force in 2003, FDA has strongly advocated for a multilayered approach to securing the supply chain. A key component of that approach has been to encourage heightened vigilance and awareness among supply chain partners. The electronic, interoperable system that will be established under the DSCSA will enhance FDA's ability to help protect U.S. consumers by improving detection and removal of potentially dangerous drugs from the drug supply chain.

B. Scope of This Guidance

Pursuant to section 582(h)(2) of the FD&C Act, this guidance identifies specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution chain; provides recommendations on how trading partners can identify the product and determine whether the product is a suspect product as soon as practicable; and sets forth the process by which trading partners must terminate notifications in consultation with FDA regarding illegitimate product under section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B) of the FD&C Act. To assist trading partners in planning for January 1, 2015, this guidance also addresses how trading partners should notify FDA when they determine that a product in their possession or control is an illegitimate product under section 582(b)(4)(B)(ii), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act.

III. IDENTIFICATION OF SUSPECT PRODUCT

Under section 582 of the FD&C Act, and beginning not later than January 1, 2015, trading partners must have systems in place that enable them, upon determining that a product in their possession or control is suspect or upon receiving a request for verification from the FDA, to quarantine suspect product and promptly conduct an investigation, in coordination with other trading partners, as applicable, to determine whether a suspect product is illegitimate.

This section of the guidance identifies some specific scenarios that could significantly increase the risk of suspect products entering the pharmaceutical distribution supply chain and makes recommendations to assist trading partners in identifying and making determinations about suspect product as soon as practicable. The scenarios contained in this guidance are based on Agency experience with suspect product in the drug supply chain. These examples are illustrative and should be viewed as guidance rather than as an exhaustive list of all potential scenarios that increase the likelihood that a suspect product could enter the pharmaceutical distribution supply chain. As trading partners conduct business on a daily basis, they should

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

exercise vigilance, maintain awareness about suspicious activity or potential threats to their supply chain, and devote attention and effort to detect suspect product.

A. Specific Scenarios That Could Significantly Increase the Risk of a Suspect Product Entering the Pharmaceutical Distribution Chain

There may be situations involving trading partners where heightened vigilance would be appropriate. In addition, there could be identifiable characteristics of products that might increase the likelihood that they are suspect products. The following are examples of some specific scenarios that could significantly increase the risk of a suspect product entering the drug supply chain. Trading partners should be particularly diligent when engaging in transactions that involve:

1. Trading Partners and Product Sourcing

- Purchasing from a source new to the trading partner.

- Receiving an unsolicited sales offer from an unknown source. Trading partners might receive unsolicited offers or advertisements through an email, a fax, a telephone call, or an in-person sales call from a person or entity with whom they do not have an established business relationship.

- Purchasing on the Internet from an unknown source. Trading partners might be searching for a better price on the Internet or for a product that they cannot obtain from their usual source, and might be tempted to turn to a person or entity with whom they do not have an established business relationship.

- Purchasing from a source that a trading partner knows or has reason to believe has transacted business involving suspect products, such as:

  - A trading partner that has been involved in business transactions where they sold or delivered suspect or illegitimate product.

  - A trading partner that has a history of problematic or potentially false transaction histories or pedigrees, such as those that contain misspelled words or incomplete information.

  - A trading partner that is reluctant to provide a transaction history or pedigree associated with the product being purchased, or does not do so in a timely manner.

  - Transaction information, a transaction statement, and/or transaction history that appears to be incomplete or suspicious.

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

2. Supply, Demand, History, and Value of the Product

- Product that is generally in high demand in the U.S. market.

- Product that is in higher demand because of its potential or perceived relationship to a public health or other emergency (e.g., antiviral drugs).

- Product that has a high sales volume or price in the United States.

- Product that has been previously or is currently being counterfeited or diverted (e.g., HIV, antipsychotic, or cancer drugs).

- Product that has been previously or is currently the subject of a drug shortage (see a list of current drugs in shortage at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/default.htm and http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm for more information).

- Product that has been or is the subject of an illegitimate product notification under the DSCSA or other alert or announcement related to drug quality.

- Product that has been or is the subject of an FDA counterfeit or cargo theft alert

(See http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/counterfeitmedicine/default.htm and http://www.fda.gov/iceci/criminalinvestigations/ucm182888.htm for more information).

3. Appearance of the Product

- Appearance of a package or a container used for transport (e.g., case or tote) that seems suspicious (e.g., it has a label that contains misspellings or appears different from the standard label for that product in color, font, images, or otherwise).

- Package that uses foreign terms, such as a different drug identification number rather than the National Drug Code (NDC).

- Package that is missing information, such as the lot number or other lot identification, or the expiration date.

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

- Package that is missing anti-counterfeiting technologies normally featured on the FDA-approved product that are easily visible to the eye, such as holograms, color shifting inks, or watermarks.

- Finished dosage form that seems suspicious (e.g., it has a different shape or color from the FDA-approved product, a different or unusual imprint, an unusual odor, or there are signs of poor quality like chips or cracks in tablet coatings or smeared or unclear ink imprints).

B. Recommendations on How Trading Partners Might Identify Suspect Product and Determine Whether the Product Is a Suspect Product as Soon as Practicable

The following are recommendations for trading partners on ways that they can expeditiously identify suspect product and determine whether the product is suspect. In general, trading partners should exercise due diligence when conducting business. Trading partners should discuss with each other any observations, questions, or concerns they have related to the status of a drug as a suspect product to aid them in determining whether the drug should be considered a suspect product. Trading partners should also contact regulatory authorities, law enforcement, or other available resources to aid in that determination when additional expertise is called for to make an accurate assessment of the status of a drug as a suspect product. Strategies to identify suspect product include, but are not limited to, the following recommendations:

- Be alert for offers of product for sale at a very low price or one that is "too good to be true."

- Closely examine the package and the transport container (such as the case or tote):
  - To look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or altered).
  - To see if it has changed since it was last received for an unexplained reason (e.g., a notification about the change from the manufacturer has not been received).
  - To see if product inserts are missing or do not correspond to the product.
  - For shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source.

- Closely examine the label on the package, or the label on the individual retail unit, if applicable, for:
  - Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug.
  - Any altered product information, such as smudged print or print that is very difficult to read.
  - Misspelled words.

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

- Bubbling in the surface of a label.
- Lack of an Rx symbol.
- Foreign language with little or no English provided.
- Foreign language that is used to describe the lot number.
- A product name that differs from the name of the FDA-approved drug.
- A product name that is the product name for a foreign version of the drug.
- A product that is transported in a case or tote, when not expected under the circumstances.
- Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container.

IV. NOTIFICATION OF ILLEGITIMATE PRODUCT

A. Notification to FDA

As discussed above, beginning on January 1, 2015, trading partners must, as applicable, make the notifications described in section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B) of the FD&C Act related to illegitimate product determinations, and, for a manufacturer, the notification of a high risk of illegitimacy described in section 582(b)(4)(B)(ii)(II). This section of the guidance addresses the process by which trading partners should notify FDA regarding illegitimate products under section 582, starting on January 1, 2015.

The following process should be used to notify FDA:

(1) Trading partners should access FDA's Web page at http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm for notifications.

(2) Trading partners should follow the instructions on the Web page for accessing Form FDA 3911 (Attachment A). Using this form, trading partners should provide information about the person or entity initiating the notification, the product determined to be illegitimate or to pose a high risk of illegitimacy that is the subject of the notification to FDA, and a description of the circumstances surrounding the event that prompted the notification.

(3) Form FDA 3911 should be submitted by using the method provided in the form or on the Web page.

B. Termination of Notification in Consultation With FDA[6]

Section 582(h)(2)(A) of the FD&C Act directs FDA to issue guidance setting forth the process that trading partners shall follow for terminating notifications regarding illegitimate product, or for a manufacturer, terminating notification of a high risk of illegitimacy, in consultation with

[6] As described above, this section of the guidance document, upon finalization, will be binding.

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

FDA, under section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B). Beginning January 1, 2015, section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B) require trading partners to have in place systems to enable them to terminate notifications, in consultation with FDA, when appropriate. This section of the guidance addresses the process by which trading partners must terminate such notifications in consultation with FDA. This process must be used when trading partners believe that a notification they made to FDA regarding illegitimate product, or for a manufacturer, a notification of a high risk of illegitimacy, is no longer necessary.

The process for terminating notifications in consultation with FDA is as follows:

(1) Trading partners must access FDA's Web page at http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm for termination of notifications.

(2) Trading partners must follow the instructions on the Web page for accessing Form FDA 3911 (Attachment A). Using this form, trading partners must provide information about the person or entity initiating the request for termination, the illegitimate product or the product with a high risk of illegitimacy, the notification that was issued, and an explanation about what actions have taken place or what information has become available that make the notification no longer necessary to FDA.

(3) This form must be submitted by using the method provided in the form or on the Web page. The trading partner's submission of a request for termination of a notification will be viewed as a request for consultation with FDA, as required in section 582 of the FD&C Act. Additional information might be important to complete the consultation with FDA.

(4) FDA will review the request and consult with the trading partner. The response time will depend on the number of requests for termination and the circumstances surrounding the requests for termination that are received by FDA.

FDA interprets the DSCSA's requirement for trading partners to "mak[e] a determination, in consultation with the Secretary, that a notification is no longer necessary"[7] to require that trading partners provide the Agency with an opportunity to provide its expert views and advice on proposed terminations of notifications. Therefore, a trading partner must wait until FDA responds to the termination request before the trading partner notifies other trading partners that a notification is terminated. FDA intends to respond to requests for termination within 10 business days of submission. In some cases, FDA may contact a trading partner to notify the partner that additional time is needed to respond to the request for termination. If a trading partner believes that exigent circumstances require expedited consideration of a termination request (e.g., a potential drug shortage), the trading partner must describe those circumstances in the termination request to FDA.

[7] FD&C Act § 582(b)(4)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv).

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

Under section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B) of the FD&C Act, after FDA provides its consultation response, and the trading partner determines that the notification is no longer necessary, the trading partner who made the request for termination must promptly notify immediate trading partners that the notification has been terminated. Trading partners may notify trading partners of a termination using existing systems and processes used for similar types of communications to those partners, which might include, but is not limited to, posting of notifications on a company Web site, sending an email, or mailing or faxing a letter or notification.

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

343

ATTACHMENT A: FORM FDA 3911

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. xxxx-xxxx
Expiration Date: Xxxxxxx xx, 201x
See PRA Statement on page 2.

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

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

Description of Illegitimate Product

5. Generic Name

6. Trade Name *(If applicable)*

7. Drug Use *(Select from list)*	8. Drug Description *(Select from list)*	9. Strength of Drug	10. Dosage Form *(Select from list)*

11. Quantity Of Drug *(Number and Unit)*	12. NDC Number *(If applicable)*	13. Serial Number *(If applicable)*

14. Lot Number(s)

15. Expiration Dates

16. For Notification: Description of event/issue

Add Page for Item 16

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

Add Page for Item 17

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

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

FORM FDA 3911 (5/14) **Page 1 of 2** PSC Publishing Services (301) 443-6740 EF

344

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

Company/Facility Information

19. 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

20. Unique Facility Identifier *(of company named in #19)*

21. Reporter Information *(Note: For the telephone, you may enter the number of either the reporter or of the company named in #19.)*

Name	Telephone Number *(Include area code)*
Email Address	Reporter Category *(Select from list)*

SUBMIT BY EMAIL

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3911 (5/14) **Page 2 of 2**

345

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

CONTINUATION PAGE FOR ITEM 16 – For Notification: Description of event/issue

In the space below, please continue the description of the event/issue.

346

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

CONTINUATION PAGE FOR ITEM 17 – For Request for Termination of Notification: Description of why notification is no longer necessary

In the space below, please continue the description of why the notification is no longer necessary.

347

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

INSTRUCTIONS FOR COMPLETION OF FORM FDA 3911 – DRUG NOTIFICATION

(The item numbers below correspond to the numbered areas on the Form FDA 3911)

1. Type of Report – Indicate the type of report by checking the appropriate box.

- Initial Notification – first notification to the FDA of an illegitimate product or product with a high risk of illegitimacy
- Follow-up Notification – subsequent notification to FDA, related to an initial notification already submitted to FDA
- Request for Termination – request for consultation with FDA to terminate a notification of an illegitimate product or product with a high risk of illegitimacy

2. Date of Initial Notification – Enter the date of submission of the initial notification to FDA using the calendar function or enter in MM/DD/YYYY format. Providing the date of initial notification will allow FDA to associate any follow-up notification or request for termination to the submitted event/ issue.

3. Date Illegitimate Product Was Determined by Company – Either use the calendar function or enter the date that the illegitimate product was determined in MM/DD/YYYY format.

4. Classification of Notification – Select the appropriate description of the illegitimate product classification.

- Counterfeit – A product in your possession or control is determined to be counterfeit.
- Diverted – A product in your possession or control is determined to be a diverted product.
- Stolen – A product in your possession or control is determined to be a stolen product.
- Intentional adulteration – A product in your possession or control is intentionally adulterated such that use of the product would result in serious adverse health consequences or death to humans.
- Unfit for distribution – A product in your possession or control appears otherwise unfit for distribution such that use of the product would be reasonably likely to result in serious adverse health consequences or death to humans.
- Fraudulent transaction – A product in your possession or control is the subject of a fraudulent transaction.

Description of Illegitimate Product

5. Generic Name – Provide the chemical or generic name of the product (i.e. amoxicillin).

6. Trade Name *(If applicable)* – Provide the trade name of the product.

7. Drug Use – Select the primary approved use of the drug (i.e. human use).

8. Drug Description – Select the appropriate description of the drug (i.e. finished).

9. Strength of Drug – Provide the strength of the drug, including the unit of measure (i.e. 500 mg).

10. Dosage Form – Select the dosage form which best describes the product. If "OTHER" is selected, provide a description in your response to item 16 or item 17.

- Tablet
- Capsule
- Aerosol
- Oral Liquid
- Injectable
- Topical

348

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

- Suppository
- Other

11. Quantity of Drug *(Number And Unit)* – Provide the quantity of product involved, including the number and unit of measure (i.e., 6 cases, 20 bottles, etc.). Additional information may be included in item 16.

12. NDC Number – Provide the National Drug Code of the product as identified on the product that is subject to the notification if known.

13. Serial Number – Provide the serial number as identified on the product that is subject to the notification if known.

14. Lot Number(s) – Provide any relevant lot numbers of the product that is subject to the notification if known. Separate multiple numbers using a comma.

15. Expiration Date(s) – Provide the expiration date as identified on the product that is subject to the notification if known. Separate multiple expiration dates using a comma.

16. For Notification, Description of Event/Issue – Describe the circumstances surrounding the event that prompted the notification including, when, where in the supply chain, where geographically, and how the product was found.

17. For Request For Termination of Notification, Description of why notification is no longer necessary – Explain why the notification of illegitimate product is no longer needed, include any corrective actions if applicable.

18. If you have submitted the information to FDA through an alternative mechanism, check all other voluntary or required reporting that apply. If "OTHER" is selected, include a short description in the blank space provided.

- FAR- Field Alert Report
- BPDR - Biologic Product Deviation Report
- Medwatch 3500
- Medwatch 3500A
- None
- Other

Company/Facility Information

19. Company Name & Address – Provide the following name and address information for the company that is responsible for the product or for the notification.

- Company Name – Provide the name of the company that is responsible for the notification.
- Address – In Address 1, provide the mailing address including number and street name; and (if applicable) in Address 2 provide room, suite, or department.
- City – Self explanatory.
- State/Province/Region – Self explanatory. *(If U.S., use approved postal two letter abbreviation.)*
- Country – Self explanatory.
- ZIP/Postal Code – Self explanatory. *(If U.S., provide 5 or 9 digit ZIP code.)*

349

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.

20. Unique Facility Identifier – Provide the unique identifier for the facility. The Unique Facility Identifier should be a D-U-N-S Number for the location of the company named in item 19. If the company has not obtained a D-U-N-S number for the relevant location at the time it submits this form, this field should be left blank. For a facility that has not been assigned a number, a number may be obtained for no cost directly from Dun & Bradstreet (*http://www.dnb.com*).

21. Reporter Information – Provide the following information for the person submitting the notification.

- Name of Reporter – Provide the name of the person submitting the notification.
- Email Address – Self explanatory.
- Telephone Number – Provide the telephone number and extension of the reporter ***or*** of the company listed in item 19, which FDA may use to contact a responsible person for any follow-up information.
- Reporter Category – Select the appropriate category that describes the company (listed in item 19) responsible for the notification.
  - Manufacturer
  - Wholesale distributor
  - Dispenser (Pharmacy)
  - Repackager

350

* Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product in consultation with FDA, it will have binding effect upon finalization.