INSTRUCTIONS FOR COMPLETION OF FORM FDA 3911 – DRUG NOTIFICATION

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

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

- Initial Notification – Your 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. Incident Number – This number will be assigned by FDA when the initial notification is received by FDA and sent to the reporter with the FDA receipt acknowledging the initial notification. Please utilize the incident number that corresponds to the initial notification in all future correspondence with the FDA about the notification, including the request for termination.

3. Date of Initial Notification to FDA – Enter the date that you are submitting the initial notification to FDA. For follow-up notifications or a request for termination, enter the date the initial notification was submitted to FDA. Use the calendar function or enter the date in MM/DD/YYYY format. If you do not have the incident number, then providing the date of initial notification will allow FDA to associate any follow-up notification or request for termination with the initial notification.

4. Date Illegitimate Product Was Determined by Company – Use the calendar function or enter the date in MM/DD/YYYY format that the product was determined to be illegitimate or to have a high risk of illegitimacy (manufacturers only).

5. Classification of Notification – Select the appropriate classification of the illegitimate product or product with a high risk of illegitimacy (manufacturers only).

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

Description of Product

6. Name of Product as it appears on the label– Indicate the name of the product as it appears on the label.

7. Primary Ingredient(s) – List active pharmaceutical or biological ingredient(s) if known and not listed in item 6 above.

8. Drug Use – Select the approved use of the product. If “other” is selected, please provide a description in your response to item 17 or 18. Note: Section 582 of the FD&C Act notifications are for human-use products only

- Human use
- Other

9. Drug Description – Select the most specific description available from the list that describes the illegitimate product or product with high risk of illegitimacy (manufacturers only).

- Finished prescription drug
- Vaccine
- Plasma derivative (coagulation factors, immunoglobulins, albumin)
- Allergenic (standardized and non-standardized)
- Multiple

10. Strength of Drug – Provide the strength of the product, including the unit of measure (e.g., 500 mg, 1g/10mL).

11. Dosage Form – Select the dosage form that best describes the product. If "OTHER" is selected, provide a description in your response to item 17 or item 18.

- Tablet
- Capsule
- Aerosol
- Oral Liquid
- Sublingual
- Injectable
- Topical
- Suppository
- Other
- Multiple

12. Quantity of Drug (Number and Unit) – Provide the quantity of product involved, including the number and unit of measure (e.g., 6 cases, 20 bottles, etc.). Additional information may be included in item 17 or item 18.

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

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

15. 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.

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

17. 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. If you are a trading partner other than a manufacturer, you may indicate which manufacturer you have coordinated with to make the determination that the product is illegitimate here. If this notification is for a product with a high risk of illegitimacy (manufacturers only), indicate it here.

18. For Request for Termination of Notification: Description of why notification is no longer necessary – Explain why the notification is no longer needed including any corrective actions taken, if applicable. If expedited consultation with FDA is requested, please indicate the rationale here.

19. If you have also submitted the information to FDA through an alternative mechanism, check all other voluntary or required reporting that apply. Identify any voluntary or required reporting that the company has sent to FDA for the related event/issue that prompted the notification. If "OTHER" is selected, include a short description in the blank space provided. If the specific case number(s) is known, please indicate the number(s) in the response in item 17 or item 18.

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

Company/Facility Information

20. Company Name & Address – Provide the following information for the company responsible for making the notification.

- Company Name – Provide the name of the company that is responsible for making 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.*)

21. Company Category – Select the appropriate category that describes the company responsible for making the notification (listed in item 20).

- Manufacturer
- Wholesale distributor
- Dispenser (Pharmacy)
- Repackager

22. Unique Facility Identifier – Provide the unique identifier for the company making the notification. The Unique Facility Identifier should be a D-U-N-S Number for the location of the company named in item 20. 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*).

23. Contact Information – Provide the following contact information for a person at the company identified in item 20. FDA may use this information to contact a responsible person for follow-up information about the notification.

- Name of Contact Person– Self explanatory.
- Telephone Number – Provide the telephone number and extension of the contact person or of the company listed in item 20.
- Email Address of Contact Person – Self explanatory