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.

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)*: _____

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

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."