



# Drug Product Complaint Form

DPC No. \_\_\_\_\_

Adverse Event: Quality: Efficacy: 

Date of complaint: \_\_\_\_\_

**Section A: Customer Support Associate Introduction:**

**"We take product concerns and reports very seriously. In order for us to assist we will need to ask you several questions to understand the nature of your concern. This process can take a few minutes to complete. Would you like to proceed with this process now?"** Customer answer: Yes:  No:

Customer Name			
Customer Phone No.		Customer email	
Person completing form			

**Section B: Description of Complaint**

Description in customer's own words (encourage the customer to be specific):

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**Section C: Product Information via Customer (for ALL complaints)**

Product Name (include package size)		Dosage Form	
Product Lot No.		Exp. Date	

**Section D: Efficacy / Adverse Event Questions**

Diagnosis for use? (Why using?)	
Dose Used? (How much, how many?)	
Frequency Used? (How often?)	

\*If Efficacy only then STOP here. If Adverse Event then Proceed to section E.

**Section E: Adverse Event Questions (For Adverse Events):**

Was medical attention sought?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>		
Name and Contact of doctor	Name:		
	Phone:	Email	
How soon after taking did the event begin?	_____ Minutes	_____ Hours	_____ Days _____ Weeks
How long did it last?	_____ Minutes	_____ Hours	_____ Days _____ Weeks
Was use of the product discontinued?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>	Did the event disappear?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
Are any other drugs being used?	Yes: <input type="checkbox"/> Please list: _____ No: <input type="checkbox"/>		
<b>"Because this is an adverse event, we are required to ask you the following questions, per FDA regulations".</b>			
Did the event cause death?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>		
Was the event life threatening?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>		
Did the event require an emergency room visit?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>		
Did the event require hospitalization?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>		
Did the event result in disability?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>		
Did the event result in a congenital anomaly or birth defect?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>		
Did the event require intervention to prevent permanent impairment or damage?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>		
Did the event cause other serious issues (Important Medical Events)?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>		
Outcome of the adverse event?	Recovered: <input type="checkbox"/>	Recovering: <input type="checkbox"/>	Not recovered: <input type="checkbox"/>

**QA Use ONLY:**Batch record review  Yes  NoPrevious Complaints  Yes  NoReserve Sample checked  Yes  NoAdditional Testing required  Yes  No**Manufacturer** \_\_\_\_\_Notify FDA Required  Yes  NoAdded to Trending Program  Yes**QA Summary:** \_\_\_\_\_

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QA Signature / Date: \_\_\_\_\_