MediNatura

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):

_____
_____
_____
_____

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: ☐ No: ☐			
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: ☐ No: ☐	Did the event disappear?	Yes: ☐	No: ☐
Are any other drugs being used?	Yes: ☐ Please list:_____			No: ☐

"Because this is an adverse event, we are required to ask you the following questions, per FDA regulations".

Did the event cause death?	Yes: ☐	No: ☐
Was the event life threatening?	Yes: ☐	No: ☐
Did the event require an emergency room visit?	Yes: ☐	No: ☐
Did the event require hospitalization?	Yes: ☐	No: ☐
Did the event result in disability?	Yes: ☐	No: ☐
Did the event result in a congenital anomaly or birth defect?	Yes: ☐	No: ☐
Did the event require intervention to prevent permanent impairment or damage?	Yes: ☐	No: ☐
Did the event cause other serious issues (Important Medical Events)?	Yes: ☐	No: ☐
Outcome of the adverse event?	Recovered: ☐ Recovering: ☐	Not recovered: ☐

QA Use ONLY: **Manufacturer**_____

Batch record review ☐Yes ☐No Reserve Sample checked ☐Yes ☐No **Notify FDA Required** ☐Yes ☐No
Previous Complaints ☐Yes ☐ No Additional Testing required ☐Yes ☐ No Added to Trending Program ☐Yes

QA Summary:_____
_____
_____
_____
_____
_____

QA Signature / Date:_____