



TANZANIA FOOD AND DRUGS AUTHORITY FORM FOR REPORTING POOR QUALITY PRODUCTS

Note: Identities of reporter(s) will remain confidential

PRODUCT IDENTITY			
Brand Name:.....	Name and Address of Distributor/Supplier:		
Generic Name:.....		
Batch/Lot Number:.....		
Date of Manufacture:.....		
Expiry Date:.....		
Country of Origin:.....		
PRODUCT FORMULATION (Tick appropriate box)	COMPLAINT (Tick appropriate box(es))		
<input type="checkbox"/> Tablets/Capsules	<input type="checkbox"/> Colour change		
<input type="checkbox"/> Oral Suspension/Syrup	<input type="checkbox"/> Turbid Solution		
<input type="checkbox"/> Injection	<input type="checkbox"/> Change of Odour		
<input type="checkbox"/> Cream/Ointment/Liniment/Paste	<input type="checkbox"/> Caking		
<input type="checkbox"/> Powder for reconstitution of suspension	<input type="checkbox"/> Moulding		
<input type="checkbox"/> Powder for reconstitution of injection	<input type="checkbox"/> Separating		
<input type="checkbox"/> Eye drops	<input type="checkbox"/> Powdering/Crumbling		
<input type="checkbox"/> Ear drops	<input type="checkbox"/> Incomplete Pack		
<input type="checkbox"/> Nebulizer solution	<input type="checkbox"/> Mislabeling		
<input type="checkbox"/> Diluent	<input type="checkbox"/> Other, please specify:		
<input type="checkbox"/> Other, please specify:			
Describe the complaint in detail:			
STORAGE CONDITIONS			
Does the product require refrigeration?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Other details (if necessary)
Was the product available at the facility?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Was the product dispensed and returned by client?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Was the product stored according to manufacturer's recommendations?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Comments (if any)			
REPORTER NAME AND CONTACT ADDRESS			
Name of Reporter:	Contact Address:		
Contact Phone No: _____			
E-mail: (if available) _____			
Date of this report: _____			
<i>Thank you for your cooperation</i>	Ref No. (for official use)		

PLEASE WRITE ANY OTHER RELEVANT ADDITIONAL INFORMATION :

Four horizontal lines for writing additional information.

First Fold

Guide to filling the form

How to report?

Dully fill in the form as required
Report direct to TFDA through the following addresses:-



Mail : Tanzania Food and Drugs Authority,
P. O. Box 77150, Dar es Salaam



Fax:: 22- 2450793



Phone: 22-2450512 / 2450751



Internet; <http://www.tfda.or.tz>
E-mail: adr@tfda.or.tz

The poor quality reporting form and guidelines are also available
for downloading at <http://www.tfda.or.tz>

What to report?

Please report all product defects suspected to be associated with
drugs, vaccines, cosmetics or medical devices use.

When to report?

As soon as possible

MAH should report product quality defects and measures taken to
TFDA in writing within 15 calendar days after becoming aware of the
defect.

Moisten gum and fold. For maximum adhesion, press down for few seconds

Second Fold

POSTAGE WILL
BE PAID BY
LICENCEE

No postage stamp required
If posted in Tanzania

BUSINESS REPLY SERVICE
LICENCE No. BRS 01

TO: THE DIRECTOR GENERAL
TANZANIA FOOD AND DRUGS AUTHORITY
P. O. BOX 77150
DAR ES SALAAM

