STUDY PRODUCT COMPLAINT (FORM M)

Division of Allergy, Immunology and Transplantation (DAIT) National Institute of Allergy and Infectious Diseases (NIAID) National Institutes of Health (NIH)

INSTRUCTIONS ON HOW TO COMPLETE Form M

Pharmacist of Record (PoR) OR Study Personnel Responsibilities

1. Type or handwrite legibly. File a copy of this form in the study Pharmacy Binder.
2. Provide Study, Site and a detailed complaint description by completing **Sections A, B, C, and D** of this form.
3. If an associated Adverse Event (AE)/ Serious Adverse Event (SAE) occurs, in addition to completing this form, complete and submit an AE/SAE electronic case report form (eCRF) in Electronic Data Capture (EDC). The PoR will communicate with the study coordinator & Principal Investigator (PI) to complete the eCRF.
4. If an associated Major Protocol Deviation (mPD) related to the product complaint occurs (e.g. when a defective/damaged/malfunctioned product/ Device has been prepared and/or administered to/ for a participant OR participant did not receive IP on schedule as per protocol due to any of the stated reasons), in addition to completing this form, complete and submit mPD eCRF in EDC. The PoR will communicate with the study coordinator to complete the eCRF.
5. Include Participant ID # when a defective/ damaged/ malfunctioned Study Product(s) has been prepared and/or administered to/ for a participant. Do not include Personal Identifiable (PII)/Protected Health Information (PHI) on this form.
6. This form must be filled out and **submitted**** within 24 hours of event occurrence by email to:
   - **DAIT Pharmacist/ Pharmaceutical Specialist (PS);** DAITPS@mail.nih.gov, Tel:(301)761-6462 or (240) 627-3512.
7. Do not send any affected Study Product(s) prior to receiving an authorization from DAIT PS.

DAIT Pharmaceutical Procurement Center (PPC) Personnel Responsibilities:

1. Complete **Section D** of this form.
2. Upon receipt of complaint Form M, DAIT PS/ PSS will assign a product complaint number and notify DAIT Project Manager (PM), Medical Officer (MO), Regulatory Officer (RO), and Safety (in a blinded fashion for blinded studies). Provide safety report # when applicable.
3. DAIT PS/ PSS will report the complaint to the Manufacturer, DAIT Clinical Product Center (CPC) EMINENT Services Corporation and DAIT Clinical Data and Safety Management Center (CDSMC), as applicable within 72 hours of receipt.
4. DAIT PS will provide the AE listing or Individual Case Safety Report (ICSR), as applicable.
5. For complaints requiring mandatory safety reporting to Health Authorities (HA), DAIT PS will communicate with PM, MO, RO, and Safety to ensure a MedWatch FDA Form 3500A is filed by the responsible entity.

DAIT Clinical Products Center (CPC) Responsibilities [If involved as the distributor or purchaser]:

1. Complete **Section E** of this form, only when applicable.
2. Upon receipt of Form M, DAIT CPC will immediately inform DAIT PS/ PSS.
3. If products are purchased by DAIT CPC, the complaint must be reported to the Manufacturer within 72 hours, inform DAIT PS/ PSS and provide report references. If not purchased by DAIT CPC, refer to DAIT PS/PSS section above.
4. Assist with product return to the manufacturer, as applicable.

***** This form may contain information susceptible to unblind the blinded study staff. Please ensure blinding is maintained during communications.***

STUDY PRODUCT/ DEVICE COMPLAINT (FORM M)

Division of Allergy, Immunology and Transplantation (DAIT)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)

A. Study Site Information

Clinical Site Name & Number:		Study Name & Number :
Date & Time of Complaint	PI's Name:	Participant ID# (if Applicable):

B. Study Product Information

Product/ Device Name:	Strength/Dosage Form/Formulation (if applicable):	
# of Affected Products:	Manufacturer:	Lot Number:
Unique #(s) or Kit #(s) (if Applicable):	Expiration Date:	Package Size:

C. Type of Product/ Device Complaint	**Comments**
☐ Product/ Device Unit or Carton with Missing or Illegible Labeling	
☐ Damaged Product/ Device (i.e. cracked/broken vial, syringes, bottles, etc.)	
☐ Damaged Shipping Box (If available, include shipment ID number)	
☐ Product/ Device Malfunction or Incomplete Dose During Preparation or Administration	
☐ Unexpected Color Appearance; Particles Observed in Product/ Device	
☐ Other (Suspected Transmission of Infectious Agent by Medical Product (STIAMP) or etc.	

D. Complaint Details/ Description (Attach pictures if available)

☐ Product/ Device Available for Return

☐ Picture(s) Available (If Yes, Attach Pictures)

☐ Product/ Device was Prepared for Participant(s)

☐ Product/ Device was Administered or Used in Participant(s)

☐ Adverse Event (AE) or SAE Occurred; If Yes, Submit AE/SAE in EDC

☐ Protocol Deviation Occurred; If Yes, Submit a Protocol Deviation in EDC

Pharmacist of Record or Site Personnel Reporting Complaint:

Name: Signature: Date:

E. NIAID/DAIT Product Complaint Processing

1. Notified DAIT: ☐PM ☐MO ☐RO Yes☐ NA☐ Date:
2. DAIT Safety Notified: Yes☐ NA☐ Date:
3. Complaint Reported to Manufacturer, DAIT CPC and/or CDSMC Yes☐ NA☐ Date:
4. AE/SAE eCRF Submitted from Site: Yes NA If Yes, AE/SAE Report# (If Applicable): Date:
5. Complaint Required Mandatory Reporting via FDA Form 3500A to HA Yes NA Date:

DAIT PS Signature & Date (for Blinded Studies):	DAIT PM Signature & Date (for Unblinded Studies ONLY):

F. DAIT CPC Product Complaint Processing (to be completed, Only when applicable)

If Product Purchased by CPC, Complaint Reported to Manufacturer : Yes☐ No☐ Date

CPC Personnel Receiving the Complaint (Name Signature):

Product Complaint #