

Mock FDA 3500A Report

report_id: AEV-00001

intake_method: Phone

report_date: 2025-07-15

event_date: 2025-07-10

report_type: ['Adverse Event']

outcome: ['Hospitalization', 'Life-threatening']

patient_age: 67

patient_sex: Male

weight_kg: 72.5

ethnicity: Not Hispanic/Latino

race: ['White']

description: Patient developed severe rash and shortness of breath after 3 days on DrugA.

suspect_product_name: DrugA

dose: 500

frequency: Twice a day

route: Oral

start_date: 2025-07-01

stop_date: 2025-07-10

indication: Hypertension

reporter_profession: Nurse

report_source: ['Health Professional']

manufacturer_name: PharmaCo Inc.

report_sent_to_FDA: Yes