Printer: CDPEDQ5
User: STEPPERH
Date - Time: 23-Feb-2018 10:54 AM
Total Number of Cases (Non-Esub): 4
Total Number of Pages: 8
Print Job Number: 16132

Disclaimers:
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Processed Case Id's for Images:
14554565 14554619 14554625 14554687

Failed Case Id's for Images:

Total Failed Cases: 0

CTU #: FDA-CDER-CTU-2018-16862 | Department: CDER,CFSAN | RCT #: RCT-127048 | CTU Triage Date: 20-Feb-2018 | AER #: 1455 4565 | Total Pages: 2

(b) (6)

Age/Gender: 53 years/female

CFSAN
CDER

Substances: 1 Acetaminophen/Diphyenhdramine, 2 Mitragyna speciosa korthals (botanic name), Ethanol

Relative Contribution to Fatality: 3 Undoubtedly responsible

Chronicity of Exposure: Chronic

Route of Exposure: Ingestion

Reason for Exposure: Intentional-Intentional - Misuse

Pre-Hospital Arrest: No

Abstract:

Scenario/Substances: A 53-year-old woman was admitted with 24 hours of confusion after taking multiple doses of acetaminophen/diphyenhdramine for several days with ethanol and possibly kratom. The last dose of apap was about 36 hours prior to admission.

Past Medical History: Not Provided.

Medications: Unknown

Physical Exam: Drowsy, confused, BP 89/45, HR 80.

B-6 **Laboratory Data:** Initial ALT 460, AST 1791, INR 5.2 and peaked at 7.5. APAP and aspirin negative. Creatinine 3.4 mg/dL. Bicarbonate 15. Ammonia peaked at 566 micrograms/dL, total bilirubin peaked at 18 mg/dL. Lactate rose to 25 mg/dL.

Clinical Course: She developed fulminant hepatic failure and encephalopathy despite intravenous N-acetylcysteine. Her course was complicated by renal failure and anuruia, treated with continuous renal replacement therapy, sepsis treated with antibiotics, coagulopathy that was treated with vitamin K, fresh

CTU #: FDA-CDER-CTU-2018-16862 | Department: CDER,CFSAN | RCT #: RCT-127048 | CTU Triage Date: 20-Feb-2018 | AER #: 1455 4565 | Total Pages: 2

frozen plasma and cryoprecipitate, and hypotension that was treated with IV fluids and 3 vasopressors. She was intubated, given oxygen, placed on the ventilator and given sedation medications on the 4th hospital day for respiratory failure. She failed to respond to these therapies and died on the 8th hospital day.

Tissue/Substance Concentrations: Not available.

Autopsy Findings: Not done.

CTU #: FDA-CDER-CTU-2018-16860 | Department: CDER,CFSAN | RCT #: RCT-127039 | CTU Triage Date: 20-Feb-2018 | AER #: 1455 4619 | Total Pages: 2

(b) (6)

CFSAN
CDER

Age/Gender:	22 years/male
Substances:	1 Mitragyna speciosa korthals (botanic name) (kratom)
Relative Contribution to Fatality:	Probably responsible
Chronicity of Exposure:	Unknown
Route of Exposure:	Ingestion
Reason for Exposure:	Unknown-Unknown reason
Pre-Hospital Arrest:	Yes

Abstract:

Scenario/Substances: 22 year old male using Kratom was found unresponsive by his mother in the morning.

Past Medical History: None.

Medications: Unknown.

Physical Exam: Temperature 29 oC on arrival.

Laboratory Data: Serum APAP, ethanol and salicylate: not detected. UDS was positive for benzodiazepine. INR 2.7; Lactate 4.6. Creatinine 1.18; AST 6846, ALT 8295; CPK 5684.

Clinical Course: Patient received prehospital ACLS, intubation and ventilation. He was hypothermic on arrival and rewarmed. He had no brainstem reflexes throughout his hospitalization. Elevated CPK and transaminases were felt to be consistent with rhabdomyolysis, suggesting a long down time. These values decreased to AST 4088 and ALT 4496; CPK rose to 7761. Patient was treated with supportive care and IV fluids. An EEG showed no CNS activity. After 2 days a family meeting was held and he was allowed to expire.

Tissue/Substance Concentrations: Not available.

Autopsy Findings: Not performed.

CTU #: FDA-CDER-CTU-2018-16861 | Department: CDER,CFSAN | RCT #: RCT-127041 | CTU Triage Date: 20-Feb-2018 | AER #: 1455 4625 | Total Pages: 2

(b) (6)

CDER, CFSAN

Age/Gender: 38 years/female

Substances: 1 Mitragyna speciosa korthals (botanic name), Diphenhydramine 2

Relative Contribution to Fatality: Probably responsible

Chronicity of Exposure: Acute

Route of Exposure: Ingestion

Reason for Exposure: Intentional-Intentional - Suspected suicide

Pre-Hospital Arrest: No

Abstract:

Scenario/Substances: 38-year-old female presented to ED via EMS after an intentional ingestion of unknown amount of diphenhydramine and Kratom, mitragyna substance of abuse.

Past Medical History: Not Provided.

Medications: Unknown

Physical Exam: Unresponsive and intubated.

Laboratory Data: ECG: QRS 160

Clinical Course: In the ED, she had a seizure, not controlled with benzodiazepines and subsequently went into cardiac arrest. She was intubated, CPR/ACLS initiated, with intermittent ROSC, but with bradycardia in 30s bpm and hypotension. In the effort, physostigmine and Lipid Emulsion Rescue Therapy was given without improvement. Resuscitative efforts were conducted for over an hour, and was ultimately unsuccessful.

Tissue/Substance Concentrations: Not available.

CTU #: FDA-CDER-CTU-2018-16861 | Department: CDER,CFSAN | RCT #: RCT-127041 | CTU Triage Date: 20-Feb-2018 | AER #: 1455 4625 | Total Pages: 2

Autopsy Findings: Not available.

CTU #: FDA-CDER-CTU-2018-16863 | Department: CDER,CFSAN | RCT #: RCT-127050 | CTU Triage Date: 20-Feb-2018 | AER #: 1455 4687 | Total Pages: 2

(b) (6)

CDER
CFSAN

Age/Gender:	29 years/female
Substances:	1 Mitragyna speciosa korthals (botanic name), Benzodiazepines 2
Relative Contribution to Fatality:	Unknown
Chronicity of Exposure:	Unknown
Route of Exposure:	Ingestion
Reason for Exposure:	Unknown-Unknown reason
Pre-Hospital Arrest:	Yes

Abstract:

Scenario/Substances: 29-year-old female found down and unresponsive by her spouse. Upon EMS arrival, patient was apneic and pulseless. Patient was intubated, CPR/ACLS initiated, and transported to ED. Per family, patient had history of taking Kratom, a botanical called Mitragyna, substance of abuse.

Past Medical History: Bipolar Disorder

Medications: Unknown

Physical Exam: Unresponsive and intubated. BP 110/70, HR 71, O2 sat 100% on ventilator, T 93F.

B-6 **Laboratory Data:** ABG-pH 7.16 / pCO2 381 / pO2 55 / HCO3 10.0 BMP: Na 137_/ K 4.4 / Cl 100 / CO2 18 / BUN 19 / Cr 1.5 / Glu 270 / AG 25 LACTATE: 14.6 mMol/L CK: 713 U/L Serum APAP 2.8 Ethanol and salicylate were not detected. UDS was positive for benzodiazepine. CXR: Aspiration ECG: HR 80, QRS 108, QTc 406

Clinical Course: In the ED, patient had ROSC, however coded 4 additional times. Post-resuscitation, she was placed on ventilator management, had a metabolic acidosis, a CXR showing an aspiration pneumonia, was

CTU #: FDA-CDER-CTU-2018-16863 | Department: CDER,CFSAN | RCT #: RCT-127050 | CTU Triage Date: 20-Feb-2018 | AER #: 1455 4687 | Total Pages: 2

hemodynamically unstable, requiring 3 vasopressors for support, and started on the amiodarone. Patient remained unresponsive and hemodynamically unstable. Based on the prognosis, the family opted for institution of comfort measures and she died on Day #3.

Tissue/Substance Concentrations: Not available.

Autopsy Findings: Not available.

FDA Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Disclaimers:

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The FOIA case report information may include both Electronic Submissions (Esubs) and Report Images (Non-Esubs). Case ID(s) will be displayed under separate cover pages for the different submission types.

Cover page Case ID(s) with an asterisk ('*') indicate an invalid status and are not captured in the body of the report.

Esub Case ID(s) Submitted:

14254346 **14449343**

Run by: **STEPPERH**

Date - Time: **23-FEB-2018 11:49 AM**

Total number of cases (Esub): **2**

Total number of inactive cases: **0**

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 14254346

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** **Outcomes:** DE,OT, **Application Type:** NDA

FDA Rcvd Date: 05-Dec-2017 **Mfr Rcvd Date:** 30-Nov-2017 **Mfr Control #:** US-GLAXOSMITHKLINE-US2017GSK183857 **Application #:** 018644

Patient Information:

Age: 27 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Bupropion			Unknown	UNK			
2	Dextromethorphan			Unknown	UNK			
3	Ethanol			Unknown	UNK			
4	MITRAGYNA SPECIOSA (MITRAGYNINE)			Unknown	UNK			

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Bupropion		NA	NA				GLAXOSMITHKLINE	
2	Dextromethorphan		NA	NA				GLAXOSMITHKLINE	
3	Ethanol		NA	NA				GLAXOSMITHKLINE	
4	MITRAGYNA SPECIOSA (MITRAGYNINE)		NA	NA					

Event Information:

Preferred Term (MedDRA Â® Version: 20.1)	ReC
Cardio-respiratory arrest	NA
Death	NA
Drug abuse	NA

Case ID: 14254346

Event/Problem Narrative:

This case was reported in a literature article and described the occurrence of unknown cause of death in a 27-year-old male patient who received bupropion hydrochloride (Bupropion) tablet for an unknown indication. (Gummin DD, Mowry JB, Spyker DA, Brooks DE, Fraser MO, Banner W. 2016 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 34th Annual Report. Clinical Toxicology 2017; : .)

Co-suspect products included dextromethorphan hydrobromide (Dextromethorphan) unknown for an unknown indication, ethanol unknown for an unknown indication and mitragyna speciosa for an unknown indication.

On an unknown date, the patient started Bupropion (unknown) at an unknown dose and frequency, Dextromethorphan (unknown) at an unknown dose and frequency, ethanol (unknown) at an unknown dose and frequency and mitragyna speciosa (unknown) at an unknown dose and frequency.

On an unknown date, an unknown time after starting Bupropion, Dextromethorphan and ethanol, the patient experienced unknown cause of death (serious criteria death and GSK medically significant), drug abuse (serious criteria death and GSK medically significant) and cardiopulmonary arrest (serious criteria GSK medically significant). On an unknown date, the outcome of the unknown cause of death and drug abuse were fatal and the outcome of the cardiopulmonary arrest was unknown. The reported cause of death was unknown cause of death and drug abuse. An autopsy was performed.

The reporter considered the unknown cause of death, drug abuse and cardiopulmonary arrest to be related to Bupropion, Dextromethorphan and ethanol.

Additional Information:

This case corresponds to case number 358 in the literature article.
Suspect drug U-47700 was deemed by the reporter to be most responsible for the patient's death.

Following exposure to the suspect drugs for an unspecified time (described as acute), the patient died due to death NOS and drug abuse. Autopsy was performed and details reviewed- u-47700 was measured at 4.6 mg/kg, Dextromethorphan 12 mg/kg, Diphenhydramine 3.7 mg/kg in lever at autopsy. Ethanol 70 mg/dL in brain at autopsy. No information was provided about the patient's medical history or any concurrent medication. No dates were provided.

The reporter considered the suspect drugs were undoubtedly responsible for the patient's death, commenting "In the opinion of the Clinical Review Team the clinical case evidence established beyond a reasonable doubt that the (suspect drug) actually caused the death. No further information was available.

Case ID: 14254346

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	**Start Date**	**End Date**	**Indications**	**Events**

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Drug level	12	mg/kg			N
Drug level	4.6	mg/kg			N
Drug level	70	mg/dL			N
Drug level	3.7	mg/kg			N

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No

Sender Organization: GLAXOSMITHKLINE

503B Compounding Outsourcing Facility?:

Literature Text: Gummin DD, Mowry JB, Spyker DA, Brooks DE, Fraser MO, Banner W. 2016 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 34th Annual Report. Clinical Toxicology. 2017

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 14449343

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** **Outcomes:** DE, **Application Type:** ANDA

FDA Rcvd Date: 27-Jan-2018 **Mfr Rcvd Date:** 02-Jan-2018 **Mfr Control #:** US-ENDO PHARMACEUTICALS INC-2018-013940 **Application #:** 077284

Patient Information:

Age: 27 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Bupropion HCl XL			Unknown	UNK UNK, Unknown	Product used for unknown indication		
2	DEXTROMETHORPHAN			Unknown	UNK UNK, Unknown	Product used for unknown indication		
3	DIPHENHYDRAMINE			Unknown	UNK UNK, Unknown	Product used for unknown indication		
4	ETHANOL			Unknown	UNK UNK, Unknown	Product used for unknown indication		
5	Mitragyna speciosa korthals			Unknown	UNK UNK, Unknown	Product used for unknown indication		
6	U-47700			Unknown	UNK UNK, Unknown	Product used for unknown indication		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Bupropion HCl XL		NA	NA				PAR	
2	DEXTROMETHORPHAN		NA	NA					
3	DIPHENHYDRAMINE		NA	NA					
4	ETHANOL		NA	NA					
5	Mitragyna speciosa korthals		NA	NA					
6	U-47700		NA	NA					

Case ID: 14449343

Event Information:

Preferred Term (MedDRA Â Version: 20.1)	ReC
Cardio-respiratory arrest	NA
Drug abuse	NA

Event/Problem Narrative:

This is case 3 out of 49 cases for bupropion hydrochloride found in the 2016 American Association of Poison Control Centers (AAPCC) toxicology report received on 02-Jan-2018.

This domestic literature report involved a human poison exposure report on a 27-year-old male (Case 358 from the 2016 AAPCC toxicology report Table 21. Listing of fatal non pharmaceutical and pharmaceutical exposures) who was exposed to bupropion (strength, dose and manufacturer unspecified) in combination with unknown dosage of U-47700, dextromethorphan, diphenhydramine, ethanol and mitragyna speciosa korthals. The reason for exposure was intentional abuse. The patient had an acute exposure and experienced a pre-hospital cardiac and/or respiratory arrest and subsequently died in 2016 (exact date unknown).

Autopsy records were reviewed. The analytes reported for the case were U-47700, dextromethorphan, diphenhydramine and ethanol. At the time of autopsy, U-47700 concentration in liver was 4.6mg/kg. At the time of autopsy, dextromethorphan concentration in liver was 12mg/kg. At the time of autopsy, diphenhydramine concentration in liver was 3.7mg/kg. At the time of autopsy, ethanol concentration in brain was 70mg/dL.

Author's Comments: Bupropion was ranked 6 out of 6 suspect substances and was ranked sixth as the cause rank by the Case Review Team. In the opinion of the Case Review Team the Clinical Case Evidence establishes beyond a reasonable doubt that the SUBSTANCES actually caused the death.

Citation: Gummin D D, Mowry J B, Spyker D A, Brooks D E, Fraser M O, Banner W. 2016 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 34th Annual Report. Clinical Toxicology. 2017; 55 (10): 1072-1254.

On Oct 01, 2013, FDA granted Par Pharmaceutical Inc., a waiver of the requirement under 21 CFR 314.80, to submit post marketing 15 day "Alert Reports", resulting from the Annual Report of the American Association of Poison Control Centers (AAPCC) Toxic Exposure Surveillance System, within 30 days of initial receipt of information instead of 15 days. This waiver is in effect for ANDA 077284 until written notification of discontinuation.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 14449343

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No

Sender Organization: ENDO

503B Compounding Outsourcing Facility?:

Literature Text: Gummin D D, Mowry J B, Spyker D A, Brooks D E, Fraser M O, Banner W.. 2016 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 34th Annual Report. Clinical Toxicology. 2017;55 (10):1072-1254

Printer: CDPEDQ5
User: STEPPERH
Date - Time: 23-Feb-2018 11:51 AM
Total Number of Cases (Non-Esub): 4
Total Number of Pages: 32
Print Job Number: 16142

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Processed Case Id's for Images:
14190720 14291010 14291011 14356493

Failed Case Id's for Images:

Total Failed Cases: 0

CaseID: 14291010

(b) (6)
1, Expires: 9/30/2018
tatement on reverse.

ED ATCH

The FDA Safety Information and Adverse Event Reporting Program

product use errors

FDA USE ONLY

Triage unit sequence #

FDA Rec. Date

PLEASE TYPE OR USE BLACK INK

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier** (b) (6)

In Confidence

2. **Age** ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s)

or Date of Birth *(e.g., 08 Feb 1925)* __ – ___ – ____

3. **Sex** ☐ Female ☒ Male

4. **Weight** ☐ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/La ino
☐ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. **Check all that apply**
☒ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☒ Death *Include date (dd-mmm-yyyy):* (b) (6)
☐ Life-threatening
☐ Hospitalization – initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects

3. **Date of Event** *(dd-mmm-yyyy)* (b) (6)

4. **Date of this Report** *(dd-mmm-yyyy)* 15-Dec-2017

5. **Describe Event, Problem or Product Use Error**
This report refers to (b) (6)

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc)*

C. PRODUCT AVAILABILITY

2. **Product Available for Evaluation?** *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on *(dd-mmm-yyyy)* __ – ___ – ____

D. SUSPECT PRODUCTS

1. **Name, Manufacturer/Compounder, Strength** *(from product label)*

#1 – Name and Strength Kratom	#1 – NDC # or Unique ID
#1 – Manufacturer/Compounder	#1 – Lot #
#2 – Name and Strength	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

3. **Dose or Amount** / **Frequency** / **Route**
#1
#2

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1
#2

6. **Is the Product Compounded?**
#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No

7. **Is the Product Over-the-Counter?**
#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)*
#1 __ – ___ – ____ #2 __ – ___ – ____

9. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** | 2b. **Procode**

3. **Manufacturer Name, City and State**

4. **Model #** | **Lot #** | 5. **Operator of Device** ☐ Health Professional ☐ Lay User/Patient ☐ Other

Catalog # | **Expiration Date** *(dd-mmm-yyyy)* __ – ___ – ____

Serial # | **Unique Identifier (UDI) #**

6. **If Implanted, Give Date** *(dd-mmm-yyyy)* __ – ___ – ____

7. **If Explanted, Give Date** *(dd-mmm-yyyy)* __ – ___ – ____

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(Exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**

Last Name: | First Name:

Address:

City: | State/Province/Region:

Country: | ZIP/Postal Code:

Phone #: | Email:

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Also Reported to:** ☐ Manufacturer/ Compounder ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

(b) (6)

The FDA Safety Information and Adverse Event Reporting Program

FORM FDA 3500 (10/15) *(continued)*

adverse events and product problems

B.5. **Describe Event or Problem** *(continued)*

Please see the attached articles for further details.

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (continued)*

CaseID: 14291011

(b) (6)
91, Expires: 9/30/2018
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ED ATCH

The FDA Safety Information and Adverse Event Reporting Program

product use errors

FDA USE ONLY

Triage unit sequence #

FDA Rec. Date

PLEASE TYPE OR USE BLACK INK

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier**

In Confidence

2. **Age** ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s)

or Date of Birth *(e.g., 08 Feb 1925)* __ – ___ – ____

3. **Sex** ☐ Female ☒ Male

4. **Weight** ☐ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/La ino
☒ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☒ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. **Check all that apply**
☐ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☒ Death *Include date (dd-mmm-yyyy):* __ – ___ – ____
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization – initial or prolonged ☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(dd-mmm-yyyy)* __ – ___ – ____

4. **Date of this Report** *(dd-mmm-yyyy)* __ – ___ – ____

5. **Describe Event, Problem or Product Use Error**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc)*

C. PRODUCT AVAILABILITY

2. **Product Available for Evaluation?** *(Do not send product to FDA)*
☐ Yes ☒ No ☐ Returned to Manufacturer on *(dd-mmm-yyyy)* __ – ___ – ____

D. SUSPECT PRODUCTS

1. **Name, Manufacturer/Compounder, Strength** *(from product label)*

#1 – Name and Strength Kratom	#1 – NDC # or Unique ID
#1 – Manufacturer/Compounder	#1 – Lot #
#2 – Name and Strength	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

3. **Dose or Amount** / **Frequency** / **Route**

	Dose or Amount	Frequency	Route
#1			
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1
#2

6. **Is the Product Compounded?**
#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No

7. **Is the Product Over-the-Counter?**
#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)*
#1 __ – ___ – ____ #2 __ – ___ – ____

9. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name** / 2b. **Procode**

3. **Manufacturer Name, City and State**

4. **Model #** / **Lot #** / 5. **Operator of Device**
☐ Health Professional
☐ Lay User/Patient
☐ Other

Catalog # / **Expiration Date** *(dd-mmm-yyyy)* __ – ___ – ____

Serial # / **Unique Identifier (UDI) #**

6. **If Implanted, Give Date** *(dd-mmm-yyyy)* __ – ___ – ____

7. **If Explanted, Give Date** *(dd-mmm-yyyy)* __ – ___ – ____

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(Exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**

Last Name: (b) (6) First Name: (b) (6)

Address:

City: State/Province/Region:

Country: ZIP/Postal Code:

Phone #: (b) (6) Email (b) (6)

2. **Health Professional?** ☐ Yes ☒ No

3. **Occupation** Non-Healthcare Professional

4. **Also Reported to:**
☐ Manufacturer/ Compounder
☐ User Facility
☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

(b) (6)

The FDA Safety Information and Adverse Event Reporting Program

FORM FDA 3500 (10/15) *(continued)*

adverse events and product problems

B.5. **Describe Event or Problem** *(continued)*

DDI received a call from reporter (b) (6). CDER/OC/Incident team followed up with the reporter, who was too distraught to provide details regarding her (b) (6) death, other than to state that the coroner said death was due to Kratom. CDER/OC/Incident team also contacted the reporter's (b) (6) (b) (6), at (b) (6) and via telephone, who promised to complete a MedWatch and provide coroner and toxicology reports. Those reports have not been received.

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc) (continued)*

F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (continued)*

(b) (6)

CaseID: 14356493

(b) (6)

(b) (6)

CaseID: 14356493

(b) (6)

(b) (6)

CaseID: 14356493

(b) (6)

(b) (6)

CaseID: 14356493

(b) (6)

(b) (6)

(b) (6)

CaseID: 14356493

(b) (6)

(b) (6)

CaseID: 14356493

(b) (6)

(b) (6)

CaseID: [redacted]

(b) (6)

(b) (6)

CaseID: 14356493

(b) (6)

(b) (6)

CaseID: 14356493

(b) (6)

(b) (6)

CaseID: 44356493

(b) (6)

(b) (6)

CaseID: [illegible]

(b) (6)

(b) (6)

CaseID: 14356493

(b) (6)

(b) (6)

CaseID: 44356493

(b) (6)

(b) (6)

CaseID: 14356493

(b) (6)