174035

Report Details - EON-157349

Print [--]

ICSR:	1033815
Type Of Submission:	Initial
Report Version:	FPSR.FDA.RFR.V.V1
Reporting Type:	Voluntary
Report Submission Date:	2014-02-17 16:35:35 EST
Additional Documents:	No

Reported Problem:

Problem Description:	The problem was the recreational use of an herbal product called Kratum, which lead to a patient's death. The nurologist's final impression of this patient was severe hypoxic ischemic encephalopathy. The cause has been presumed to be secondary to use of a natural pain substance called "KRATOM". Patient prognosis is very poor and there is no hope for meaningful recovery of neurologic function. Patient was pronounced brain dead on February 5,2014 at 22:40 and time of death was February 6, 2014 at 23:15. [-]
Date the article of food was determined to be a Reportable Food:	02/05/2014
Product Intentionally Adulterated:	Unknown
Human Symptoms Present Indicator:	Yes
Description Of Human Adverse Events:	A patient presented to this hospital unresponsive with primary differential diagnosis including cardiorespiratory arrest versus drug intoxication/overdose. Patient was intubated and hypothermic protocol was initiated. Throughout the hospital stay the patient's history was further disclosed by the husband; on day 2 of admission the husband stated the patient was taking Kratum. Upon research of this medication, it is a likely explanation of this patient's presentation to the hospital leading to expiration of this patient's life. The length of time this medication was abused by the patient is unknown, although the patient was also a known to have a history of heroin abuse and supposedly did not use heroin for 1-2 years. However, the patient could not speak for themselves and the husband's information of the patient was not consistent throughout the hospital stay.
Animal Symptoms Present Indicator:	Unknown
How did you first learn about the Reportable Food?	Other

Sender:

Organization Name:	(b) (6) [-]
Address:	(b) (6)
Contact:	**Name:** (b) (6) **Phone:** **Other Phone:** **Email:**

Adulteration Site:

Organization Name:	[-]

Food Facility

Organization Name:	Not on site. Herbal product is likely at deceased's home. [-]

Site/Discovery Site:	**Organization Type(s):**	Manufacturer
	Address:	unknown unknown (b) (6) unkown United States
	Contact:	**Name:** (b) (6) **Phone:** **Other Phone:** **Email:**
Product(s):	**Product Name:**	Kratum (mitrgyninem) [-] Generate One Page Notification
	Product Type:	Food Additive or Ingredient
	Intended Use Code:	Unknown
	Product Distribution Type:	Bulk
	Was the product recalled?	Unknown
	Did you receive the reportable food from an outside source?	No
		Go to the top of the page

191303

CFSAN

U.S. Department of Health and Human Services

Internet Health Professional Report

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

1/2

FDA USE ONLY

Triage unit sequence # 622860

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	27 Years (b) (6)	☐ Female ☑ Male	170 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

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

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☑ Death: 06/28/2015 *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/28/2015	11/05/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

See additional page(s) for complete text.

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

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

#1 Name: Kratom
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1	--	--
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 unknown	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*	8. Event Reappeared After Reintroduction?
#1 unknown	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

CTU

3. Manufacturer Name, City and State

NOV – 6 2015

4. Model #	Lot #	5. Operator of Device
		☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
		☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

See additional page(s) for complete text.

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

1. Name and Address

Name: (b) (6)
Address

City: (b) (6) State: (b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Medical Doctor (Physician)	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

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

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

An otherwise healthy 27 yo white male in good physical shape died to due cardiac arrhythmia while swimming. He had high levels of Kratom in his system, likely from an herbal supplement. The coroner called the cause of death cardiac arrhythmia with contributing factors of acute mitragynine and o-desmethyltramadol intoxication.

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

From autopsy: mitragynine positive o-desmethyltramadol 1900 ng/mL

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

The decedent had a history of cardiac arrhythmia 2-3 years prior for which he had been fully evaluated and medically cleared. Brugada syndrome was ruled out, and genetic testing was negative.

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

No other medications. Toxicology screen was positive for blood alcohol of 0.01 g/dL, consistent with moderate consumption the night prior. (Pt died around 10 am.)

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Internet Consumer Report

CFSAN

For VOLUNTARY reporting of adverse events, product problems and product use errors

198584

Form Approved: OMB No. 0910-0291, Expires: 09/30/2018
See PRA statement on reverse.

FDA USE ONLY

Triage unit sequence # 1e1e8399

FDA Rec. Date

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	2. Age	3. Sex	4. Weight
(b) (6)	22 ☑ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)	☐ Female ☑ Male	248 ☑ lb ☐ kg
In Confidence	or Date of Birth *(e.g., 08 Feb 1925)*		

5.a. Ethnicity *(Check single best answer)*
- ☐ Hispanic/Latino
- ☑ 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):* 24-Apr-2016
- ☐ 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)*	4. Date of this Report *(dd-mmm-yyyy)*
24-Apr-2016	17-Jul-2016

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

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.)*

See additional page(s) for complete text.

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	#1 - NDC # or Unique ID
Kratom (1)	
#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	--	Taken by mouth
#2		

4. Dates of Use *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
- #1 22-Apr-2016 - 23-Apr-2016
- #2

5. Diagnosis or Reason for Use *(indication)*
- #1 Help with axiety
- #2

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

9. Event Abated After Use Stopped or Dose Reduced?	10. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't apply	#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply	#2 ☐ Yes ☐ No ☐ Doesn't apply

8. Expiration Date *(dd-mmm-yyyy)* #1 #2

E. SUSPECT MEDICAL DEVICE

1. Brand Name CTU

2. Common Device Name | **2b. Procode** JUL 18 2016

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(dd-mmm-yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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)*

See additional page(s) for complete text.

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

1. Name and Address

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

Address: (b) (6)

City (b) (6) State/Province/Region (b) (6)

Country: US ZIP/Postal Code (b) (6)

Phone #: (b) (6) E-mail: (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer/ Compounder ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (10/15) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

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

My son died after consuming Kratom. Received it on Friday and died on Sunday. Prepared as a tea

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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)*

Medical Conditions:

Allergies: Hayfever

Important Information:

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

RX Meds: Zoloft

OTC Meds:

Receipt No: RCT-56416 **FDA 3500B Form**

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	**Originating Account**	FAERS
Source Medium	MWO (Drug)	**Source Form Type**	E2B XML 3500B
Priority	Routine		
FDA Received Date	26-May-2017	**CTU Received Date**	26-May-2017
CTU Triage Date			
Report Type	Spontaneous	**Report Classification**	
Assign To	User		
User/Group			
Forward to Department	☑ CDER		

Contact

Source Form Type	First Name	Last Name	Email Address	Phone
☑	(b) (6)			

Receipt No: RCT-56416 **FDA 3500B Form**

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☑ Death ☐ Other serious/important medical incident
Date of Death	02-Feb-2017
Date the problem occurred	02-Feb-2017

Tell us what happened and how it happened (Include as many details as possible)

(b) (6) , my twin brother, age 25, passed away Feb 2nd, 2017, and Mitragynine intoxication (Kratom) was the accidental cause of death. From our knowledge (b) (6) began taking this supplement as an energy and mood enhancer the spring of 2017 (b) (6) then began getting skin rashes, losing hair, vomiting, loss of appetite and irritable. Our family was under the impression he stopped in July because of the side effects but we believe he picked it back up mid January and he passed away during his sleep Feb 1st/Feb 2nd. There was vomit next to him in bed (b) (6) chose Kratom because he was under the impression from false marketing and internet messages that it was a safe alternative supplement (b) (6) has never been a hard drug user so he was not using Kratom as an alternative drug like many Kratom advocates. As research and laws are currently being discussed on this supplement/drug, I would like our evidence to be included in future studies, conversations and support when necessary. We strongly believe warning labels of the side effects and suggested dosage regulation should be provided to consumers at the very least. As we are currently seeing Kratom sold next to candy at the gas station, at bars, restaurants, coffeeshops etc. I would like to do as much as I can to increase risk awareness and truth behind this rapidly growing and very trendy drug. Please let me know what else I can do going forward.

List any relevant tests or laboratory data if you know them (Include dates)

(b) (6) Death Pronouncement: 2/2/17 0637 Hours Inspection:2/3/17 0700 Hours Diagnosis: Mitragynine intoxication A. Lethal level of mitragynine B. Pulmonary Edema C. Aspiration of gastric contents (confirmed microscopically) Toxicology: Mitragynine, femoral blood 92 ng/mL Caffeine/lidocaine/naloxone, femoral blood positive

Section B - About the Products 1 of 1

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Kratom		
Name of the company that makes (or compounds) the product			
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)			
Is the Product Over-the-Counter?	Yes		
Expiration date			
Lot number			
NDC number			
Strength (for example, 250 mg per 500 ml or 1g)		**If Other**	
Quantity		**If Other**	
Frequency		**If Other**	
How was it taken or used	Oral	**If Other**	
Date the person first started taking or using the product	06-May-2016		
Date the person stopped taking or			

using the product	
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes
Did the problem return if the person started taking or using the product again?	Yes
Do you still have the product in case we need to evaluate it?	No

Why was the person using the product? (such as what condition was it supposed to treat)

boost energy and mood enhancer

Section C - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	
Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		**Date the implant was taken out (If relevant)**	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Male
Age (specify unit of time for age)	
Date of Birth	(b) (6)
Weight	112.5 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Choose all that apply)	☐ **American Indian or Alaskan Native** ☐ **Native Hawaiian or Other Pacific Islander** ☐ **Asian** ☑ **White** ☐ **Black or African American**

Receipt No: RCT-56416 **FDA 3500B Form**

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

n/a

Please list all allergies (such as to drugs, foods, pollen or others)

n/a

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

very limited marijuana and alcohol use in the last 1.5 years. No other drug use. During college would party but nothing abnormal.

List all current prescription medications and medical devices being used.

n/a

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Kratom

OTHER (CONCOMITANT) MEDICAL PRODUCTS 1 of 1

Product Name			
Strength		**If Other**	
Therapy Start Date			
Therapy End Date			

Section E - About the Person Filling Out This Form

Last name	(b) (6)
First name	
Number/Street	
City	
State/Province	
Country	USA
ZIP or Postal code	(b) (6)
Telephone number	
Email address	
Today's date	26-May-2017
Did you report this problem to the company that makes the product	No

(the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☐

All dates displayed in the report are in EST(GMT-05:00) time zone

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	High		
FDA Received Date	05-Oct-2017	CTU Received Date	05-Oct-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

Case Reporter	First Name	Last Name	Email Address	Phone
☑				

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☑ Death ☐ Other serious/important medical incident
Date of Death	23-Jun-2017
Date the problem occurred	23-Jun-2017

My husband was using Kratom for pain relief, as a way to avoid prescription pain pills. He took Kratom regularly for about 6 months for pain associated with knee surgery. On June 23, 2017 he had a seizure, and original cause of death was terminal seizure. The autopsy results determined that cause of death was accidental, due to "Toxic Effects of Mitragynine (Kratom)", not natural from the seizure.

I have documentation from the [redacted], indicating that his death certificate was amended 9/29/2017 to accidental death from "Toxic Effects of Mitragynine (Kratom)." I am in the process of obtaining the official Medical Examiner's report/ autopsy. It exists, I just do not have a copy at this time.

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Mitragynine (Kratom)

	Name of the company that makes (or compounds) the product	n/a			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?	Yes			
	Expiration date				
	Lot number	n/a			
	NDC number	n/a			
	Strength		If Other		
	Quantity		If Other		
	Frequency	As needed	If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started taking or using the product				
	Date the person stopped taking or using the product				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
	Did the problem return if the person started taking or using the product again?	No			
	Do you still have the product in case we need to evaluate it?	No			

	Pain management and anxiety relief

	Name of medical device	
	Name of the company that makes the medical device	

	Model #	
	Catalog #	
	Serial #	
	Lot #	
	Unique Identifier (UDI) #	
	Expiry Date	

Was someone operating the medical device when the problem occurred?	

Date the implant was put in		Date the implant was taken out (If relevant)	

Person's Initials	
Sex	Male
Age (specify unit of time for age)	
Date of Birth	
Weight	99 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

High blood pressure, non-epileptic adult onset seizure disorder of unknown origin

Penicillin

Alcohol and tobacco use

Dilantin

Mitragynine (kratom)

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

	Product Name			
	Strength		If Other	
	Therapy Start Date			
	Therapy End Date			

	Last name	
	First name	
	Number/Street	
	City	
	State/Province	
	Country	USA
	ZIP or Postal code	
	Telephone number	
	Email address	
	Today's date	05-Oct-2017
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
	If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☐

All dates displayed in the report are in EST(GMT-05:00) time zone

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	High		
FDA Received Date	04-Oct-2017	CTU Received Date	04-Oct-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

Case Reporter	First Name	Last Name	Email Address	Phone
☑				

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☑ Death ☐ Other serious/important medical incident
Date of Death	22-Dec-2016
Date the problem occurred	22-Dec-2016

The coroner determined that my 31 year old son died from the toxic effects of Kratom tea. He stopped breathing.

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Kratom tea leaves

	Name of the company that makes (or compounds) the product	Unknown			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?	Yes			
	Expiration date				
	Lot number				
	NDC number				
	Strength		If Other		
	Quantity		If Other		
	Frequency	Daily	If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started taking or using the product	01-Jan-2008			
	Date the person stopped taking or using the product	23-Dec-2016			
	Did the problem stop after the person reduced the dose or stopped taking or using the product?				
	Did the problem return if the person started taking or using the product again?				
	Do you still have the product in case we need to evaluate it?	No			

	Ulcerative Colitis

	Name of medical device	
	Name of the company that makes the medical device	

	Model #	
	Catalog #	
	Serial #	
	Lot #	
	Unique Identifier (UDI) #	
	Expiry Date	

Was someone operating the medical device when the problem occurred?	

Date the implant was put in		Date the implant was taken out (If relevant)	

Person's Initials	
Sex	Male
Age (specify unit of time for age)	
Date of Birth	
Weight	56.25 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

Ulcerative Colitis

Smoked cigarettes and e-cigarettes. Drank alcohol daily.

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

	Product Name			
	Strength		If Other	
	Therapy Start Date			
	Therapy End Date			

	Last name	
	First name	
	Number/Street	
	City	
	State/Province	
	Country	USA
	ZIP or Postal code	
	Telephone number	
	Email address	
	Today's date	04-Oct-2017
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
	If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☑

All dates displayed in the report are in EST(GMT-05:00) time zone

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	High		
FDA Received Date	18-Sep-2017	CTU Received Date	18-Sep-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

Case Reporter	First Name	Last Name	Email Address	Phone
☑				

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☑ Death ☐ Other serious/important medical incident
Date of Death	07-Jul-2017
Date the problem occurred	07-Jul-2017

My son purchased OPMS brand Kratom at a gas station in . He took it and died in his sleep. The death certificate, signed by ., Associate Medical Examiner, dated 8/22/2017 reads cause of death as "Intoxication by Mitragynine (Kratom)".

We have Autopsy report and Toxicology report dated 8/9/2017 listing "Mitragynine 1.8 mg/L Peripheral Blood" signed by , MS, D-ABFT, Assistant Chief Forensic Toxicologist for County Medical Examiner.

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	GOLD Mitragynia Speciosa Botanical Extract

Name of the company that makes (or compounds) the product	O.P.M.S. Optimized Plant Mediated			
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
Is the Product Over-the-Counter?	Yes			
Expiration date				
Lot number	Unknown			
NDC number	Unknown			
Strength	Other	If Other	Unknown not listed	
Quantity	Other	If Other	1 Capsule(s)	
Frequency	Other	If Other	No dosage listed	
How was it taken or used	Oral	If Other		
Date the person first started taking or using the product	07-Jul-2017			
Date the person stopped taking or using the product	07-Jul-2017			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Do you still have the product in case we need to evaluate it?	Yes			

To detox from Opiates, to help with anxiety and depression

Name of medical device	
Name of the company that makes the medical device	

Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	

Was someone operating the medical device when the problem occurred?	

Date the implant was put in		Date the implant was taken out (If relevant)	

Person's Initials	
Sex	Male
Age (specify unit of time for age)	27 Year(s)
Date of Birth	
Weight	92.25 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

None that we knew of, but autopsy showed he had an abnormal thyroid and left ventrical myocardial hypertrophy. Medical Examiner said neither contributed to his death.

none

Citralopram, Cyclobenzaprine (therapeutic amount in system and ME says neither contributed to death)

Just this Kratom

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

	Product Name			
	Strength		If Other	
	Therapy Start Date			
	Therapy End Date			

	Last name		
	First name		
	Number/Street		
	City		
	State/Province		
	Country	USA	
	ZIP or Postal code		
	Telephone number		
	Email address		
	Today's date	18-Sep-2017	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☑	

All dates displayed in the report are in EST(GMT-05:00) time zone

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	High		
FDA Received Date	02-Oct-2017	CTU Received Date	02-Oct-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		

Case Reporter	First Name	Last Name	Email Address	Phone
☑				

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm (for medical devices only) ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☑ Death ☐ Other serious/important medical incident
Date of Death	01-Mar-2017
Date the problem occurred	01-Mar-2017

My husband had been taking Kratom for several months. It helped with his bad knees and hips and actually improved his quality of life, from one who couldn't walk from the house to the barn (300 ft) to walking with a cane only. However, on March 1, 2017 he died of an apparent heart attack out in the barnyard in his tractor. I strongly suspect it was this herbal supplement that he was taking. He bought it from California on a monthly basis. He either mixed it with water and drank it, or he made capsules with the powder and ingested them.

Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Kratom

Name of the company that makes (or compounds) the product				
Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
Is the Product Over-the-Counter?	Yes			
Expiration date				
Lot number				
NDC number				
Strength	unk mg milligram(s)	If Other		
Quantity	Other	If Other	1 Tablespoon(s)	
Frequency		If Other		
How was it taken or used	Oral	If Other		
Date the person first started taking or using the product	01-Apr-2016			
Date the person stopped taking or using the product	01-Mar-2017			
Did the problem stop after the person reduced the dose or stopped taking or using the product?				
Did the problem return if the person started taking or using the product again?				
Do you still have the product in case we need to evaluate it?	Yes			

osteoarthritis, pain

Name of medical device	
Name of the company that makes the medical device	

Model #	
Catalog #	
Serial #	
Lot #	
Unique Identifier (UDI) #	
Expiry Date	

Was someone operating the medical device when the problem occurred?	

Date the implant was put in		Date the implant was taken out (If relevant)	

Person's Initials	
Sex	Male
Age (specify unit of time for age)	63 Year(s)
Date of Birth	
Weight	81 kg(s)
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

mild hypertension, borderline hyperlipidemia

NKDA

smoker for 40 years

lopid, metoprolol

Kratom

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

	Product Name			
	Strength		If Other	
	Therapy Start Date			
	Therapy End Date			

	Last name		
	First name		
	Number/Street		
	City		
	State/Province		
	Country	USA	
	ZIP or Postal code		
	Telephone number		
	Email address		
	Today's date	02-Oct-2017	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, place an X in this box :	☐	