174035

| Report Details - E | ON-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 ES | Т | | | | | |
| 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: | | | | | | |
| | | 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: Phone: Other Phone: Email: (b) (6) | | | | | |
| Adulteration Site: | Organization Name: | н | | | | | |
| Food Facility | -1. 9.27 | | | | | | |

| Site/Discovery Site: | Organization Type(s): | Manufacturer | | | | |
|----------------------|---|---|--|--|--|--|
| | Address: | unknown unknown (b) (6) unkown United States | | | | |
| | Contact: | Name: (L) (C) | | | | |
| | | Phone: Other Phone: (b) (6) | | | | |
| | | 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? | | | | | |
| | Did you receive the reportable food from an outside source? | No | | | | |
| | | Go to the top of the page | | | | |

191303 Contract Health Profession Server For VOLU

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

MEDWATCH

U.S. Department of Health and Human Services

adverse event The FDA Safety Information and Adverse Event Reporting Program pro

| JNTARY reporting of | FDA USE ONLY |
|---|-------------------------------|
| s, product problems and duct use errors | Triage unit sequence # 622860 |
| VV | |

| A. PATIENT INFORMATION | | 2. Dose or Amount | Frequency | Route |
|--|--|--|--|--|
| 1. Patient Identifier (b) (6) 2. Age at Time of Event or Date of Birth: 3. | Sex 4. Weight | #1 | 1554 | 22 |
| 27 Years | ☐ Female170 lb | #2 | | |
| (b) (6) | ✓ Male or kg | #2 | | |
| In confidence | | 2.5-4 | | In Francisco I Advantage |
| B. ADVERSE EVENT, PRODUCT PROB Check all that apply: | LEW OR ERROR | Dates of Use (If unknow (or best estimate) | n, give duration) from/to | 5. Event Abated After Use Stopped or Dose Reduced? |
| 1. ✓ Adverse Event Product Problem (e.g., d | defects/maifunctions) | #1 unknown | | #1 Yes No Does |
| | Manufacturer of Same Medicine | #2 | | Apply #2 Ves No Does |
| 2. Outcomes Attributed to Adverse Event | STATE OF A STATE ASSESSMENT OF STATE OF A ST | 4. Diagnosis or Reason fo | r Use (Indication) | #2 Yes No Does |
| (Check all that apply) | | #1 unknown | | 8. Event Reappeared After Reintroduction? |
| Death: 06/28/2015 Disability (mm/dd/yyyy) | or Permanent Damage | #2 | | #1 Tyes No Does |
| | tal Anomaly/Birth Defect | 18450 | | Apply |
| ☐ Hospitalization - initial or prolonged ☐ Other Set | rious (Important Medical Events) | 6. Lot # | 7. Expiration Date | #2 Yes No Does |
| Required Intervention to Prevent Permanent Impa | airment/Damage (Devices) | #1 | #1 | 9. NDC # or Unique ID |
| The state of the s | this Report (mm/dd/yyyy) | #2 | #2 | |
| 06/28/2015 11/05 | /2015 | E. SUSPECT MEDIC | CAL DEVICE | |
| 5. Describe Event, Problem or Product Use Error | | 1. Brand Name | | |
| | | | | |
| | | 2. Common Device Name | | B SANDANS |
| | | | | CTU |
| See additional page(s) for | complete text | 3. Manufacturer Name, Cit | v and State | 11017 |
| occ additional page (o, lot | Compilete cont. | v. managamer name, en | , | NOV - 6 2015 |
| | 4 | | | |
| | | 4. Model # | Lot# | 5. Operator of Device |
| | | | | Health Profession |
| | | C-1-1# | F-1-8 B-1-7- | —————————————————————————————————————— |
| | | Catalog # | Expiration Date (mi | m/dd/yyyy) Lay User/Patient |
| | | | | Other |
| 8. Relevant Tests/Laboratory Data, Including Dates | | Serial # | Other # | |
| | | | | |
| See additional page(s) for | complete toyt | 6. If Implanted, Give Date | (mm/dd/yyyy) 7. If Ex | planted, Give Date (mm/dd/yyyy) |
| see additional page(s) for | complete text. | | | |
| | | 8. Is this a Single-use Dev | ice that was Reprocess | ed and Reused on a Patient? |
| | | 9. If Yes to Item No. 8, Enter | Name and Address of Re | processor |
| | 1: 10 191 | | | |
| Other Relevant History, Including Preexisting Med allergies, race, pregnancy, smoking and alcohol use, | liver/kidney problems, etc.) | | | |
| | 0.00 | F. OTHER (CONCO | MITANT) MEDICAL | PRODUCTS |
| | | THE RESIDENCE OF THE PARTY OF T | y dates (exclude treatme | SOCIOLO DE CARROL DE CONTROL DE C |
| | V. Name and Company and Compan | i reader names and more | | |
| See additional page(s) for | complete text. | The second secon | To the second of | DEF FERRINGS TO DEVELOP THE STORAGE |
| See additional page(s) for | complete text. | The second secon | l page(s) fo | or complete text. |
| See additional page(s) for | complete text. | See additiona | , Atlanta | |
| | complete text. | The second secon | , Atlanta | T |
| C. PRODUCT AVAILABILITY | | See additiona G. REPORTER (See 1. Name and Address | confidentiality sect | |
| C. PRODUCT AVAILABILITY | | See additiona G. REPORTER (See 1. Name and Address | confidentiality sect | |
| C. PRODUCT AVAILABILITY | uct to FDA) | G. REPORTER (See 1. Name and Address Name: | confidentiality sect | |
| PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product Yes ☑ No ☐ Returned to Manufacturer on | uct to FDA) | G. REPORTER (See 1. Name and Address Name: | confidentiality sect | ion on back) |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product Yes No Returned to Manufacturer on C. SUSPECT PRODUCT(S) | uct to FDA) | G. REPORTER (See 1. Name and Address Name: Address (b) | confidentiality sect | ion on back) |
| PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product Yes No Returned to Manufacturer on SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) Name: Kratom | uct to FDA) | G. REPORTER (See 1. Name and Address Name: Address (b) (city: (b) (6) | 6) | |
| PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product Yes V No Returned to Manufacturer on D. SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) 1 Name: Kratom Strength: | uct to FDA) | G. REPORTER (See 1. Name and Address Name: Address (b) (6) Phone # (b) (6) | 6) Sta | te: (b) (6) (b) (6) |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product Yes No Returned to Manufacturer on D. SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) Name: Kratom Strength: Manufacturer: | uct to FDA) | See additiona G. REPORTER (See 1. Name and Address Name: Address (b) City: (b) (6) Phone # (b) (6) 2. Health Professional? 3 | Sta E-mail | te: (b) (6) (b) (6) 4. Also Reported to: |
| D. SUSPECT PRODUCT(S) T. Name, Strength, Manufacturer (from product label) 1 Name: Kratom Strength: | uct to FDA) | See additiona G. REPORTER (See 1. Name and Address Name: Address (b) City: (b) (6) Phone # (b) (6) 2. Health Professional? 3 | Sta E-mail Occupation edical Doctor (Physician) | te: (b) (6) (b) (6) |

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.)

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Internet Consumer Report

Triage unit sequence # CCS399

FDA Rec. Date

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

198584

| Note: For date pr | Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month | | | | | 3. | Dose or Amount | Frequency | 1 | Route | | | |
|--|--|------------------|--------------------------------|---|--------------------------------------|--|---|--|---------------------|---------------------|----------------|-------------|--------------|
| abbreviation, and | Y22 - 35 13501 1- | | Her to 19 movement (1900—1977) | | Schrand | | #1 | | | | Taken by | mouth | |
| A. PATIENT | INFORM | IATION | 100 | 1-1-1- | | | Work | | | | | | |
| 1. Patient Identif | ier 2. Age | ✓ Year(s) | Month(s) | 3. Sex | 4. W | eight | | | 1 | | | | |
| (b) (6) | 22 | ☐ Week(s) | Day(s) | 0.001 | 248 | 8 | #2 | | | | | | |
| | or Date | e of Birth (e.a. | 08 Feb 1925) | Female | | lb | | | | | | | |
| | □ Male □ | | | | 4. Da | ates of Use (From/T ve duration, or best of | o for each) (if unk | nown, | | t Abated Af | | | |
| In Confidence | | | | | \perp \sqcup | kg | | ve duration, or best t 22-Apr-2016 - 23-A | | п-уууу) | 1975 | | Reduced? |
| 5.a. Ethnicity (C. single best answ | | .b.Race (Check | (all that apply) | | | | #2 | | | | #1 📋 | Yes No | apply |
| 4 | 1 | Asian | American India | an or Alaskan N | Vative | | | agnosis or Reason | for Use (indicatio | n) | #2 🗆 Y | es No | Doesn' |
| ☐ Hispanic/La | atino | Black or Afri | can American | ✓ Whit | te | - 11 | #1 | Help with axiety | | (4.E. | 10 Evan | t Reappear | ☐ apply |
| Not Hispan | ic/Latino | | aiian or Other P | (A) | 200 | | #1 | | | | | troduction? | |
| | | 10-10-07-14-16-1 | | acilic Islanuel | - | | #2 | | | | #1 🗆 Y | res No | Doesn't |
| B. ADVERSE | | PRODUCT | PROBLEM | | - | | | | | | | | □ apply |
| V | 1. Check all that apply Adverse Event Product Problem (e.g., defects/maifunctions) | | | | | | the Product | 7. Is the Produ | THE PERSON NAMED IN | #2 L Y | res No | □ Doesn't | |
| | | | | | 22270 | - | - Control of the control | Over-the-Co | The Land Community | - | | HASP. | |
| Product Us | e Error | Problem with I | Different Manu | facturer of San | ne Me | dicine | - | | #1 Yes | □ No | | | |
| 2. Outcome Att | ributed to A | dverse Event | (Check all that a | apply) | | | _ | Yes No | #2 Yes | ∐ No | | | |
| | Outcome Attributed to Adverse Event (Check all that apply) Death Include date (dd-mmm-yyyy): 24-Apr-2016 | | | | 18 | ALLES | piration Date (dd-mi | 77.77 | | | #2 | | |
| The same and the s | | -mmm-yyyy) | ☐ Disability | or Permanent I | Damao | ie | E. : | SUSPECT MED | ICAL DEVICE | Ē | | | |
| | | | | | 5. II | 1. Br | and Name | | | | | | |
| Y Other Serio | Hospitalization - initial or prolonged Congenital Anomaly/Birth Defects Other Serious (Important Medical Events) | | | | U.S | | | | | | | CTH | |
| Required In | 37 17 | | 1.0 | nt/Damage (De | vices) | | 0.0 | | 100 | | - 3 | ~ - | - 1 - |
| X | Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (dd-mmm-yyyy) 4. Date of this Report (dd-mmm-yyyy) | | | | | 2. C 0 | mmon Device Nam | ie | | - | 2b. Procod | 1 8 2011 | |
| 4 0. Butto 01 Even | | | | | 3. Manufacturer Name, City and State | | | | | Committee Committee | | | |
| | 24-Apr-2016 17-Jul-2016 | | | | | | | | | | | | |
| 5. Describe Eve See addition 6. Relevant Tests | 5. Describe Event, Problem or Product Use Error | | | | | | | Lesson | | | | | |
| See addition | onal page | e(s) for co | omplete te: | kt. | | | 4. MC | odel# | Lot# | | | 5. Operate | or of Device |
| 0 | | | | | | | | | | | | | |
| PE | | | | | | ll- | Cata | log# | | | SENTED ENGINEE | The second | Professional |
| 6. Relevant Tests | s/Laborator | y Data, Includi | ng Dates | | | | | | Expiration | Date (dd-m | тт-уууу | Lay U | ser/Patient |
| E | | | | | | | | | | | | Other | * |
| AS | | | | | | - 1 | Sor | ial# | Unique Ide | ntifier (LID | N # | | |
| LE | | | | | | | 001 | tal ii | Omque ide | intilier (OD | 1) # | <u></u> | |
| /. Other Relevan | nt History, I | ncluding Preex | isting Medical | Conditions (e. | g., | | | | | | | | |
| See addition | | | use, liver/kidne | | :.) | | 6. If I | mplanted, Give Dat | e (dd-mmm-yyyy) | 7. If Exp | anted, G | ive Date (d | d-mmm-yyyy, |
| See addictor | nar page | (3) 101 00 | mprece cex | | | | | | | | | | |
| | | | | | | | 8. Is | this a single-use de processed and reus | evice that was | | Yes [| □ No | |
| C DRODUCT | AVIAILA | DUITY | _ | | _ | | - 6 | | | | 1.000 WAY 1 | | |
| C. PRODUCT 2. Product Availa | | | at send product | to EDA) | - | | 9, 11 1 | es to Item 8, Enter N | vame and Address | of Reproci | ISSOF | | |
| | | ACADA TRANSPORT | 12 1V | | | | | | | | | | |
| ✓ Yes | No [| Returned to Ma | nufacturer on: | (dd-mmm-y | (vvv) | - 1 | E | OTHER (CONC | OMITANT) ME | EDICAL | PRODI | ICTS | |
| D. SUSPECT | T PRODU | ICTS | | | ,,,, | | F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (Exclude treatment of event) | | | | | | |
| 1. Name, Manufa | cturer/Com | | | | | | | additional page | | | | .00 | |
| #1 - Name and St Kratom | trength | | #1 - ND0 | C # or Unique II | D | | | REPORTER (Se | e confidentialit | y section | on bac | k) | |
| AL a COM | | | 1 | | | II- | 1. Name and Address Last Name: (b) (6) Firs | | First Nam | e (h) (| 6) | | |
| |) | | | | | | Addr | | | 1.09637(40) | (5) | 9) | |
| | | | | | | | | 7. | | | | | |
| #1 - Manufacturer | r/Compound | ler | #1- Lot # | S. C. | | | City | (b) (6) | IS | state/Provin | ce/Regio | n(b) (6 |) |
| | | | | | | | | | | | (2) (3 | / | |
| #0 No | 4 | | #0 ND0 | # 1/1 | | | Cour | ntry: US | | ZIP | Postal C | ode (b) (6 | 3) |
| #2 - Name and S | trength | | #2 - NDC | # or Unique ID |) | | Phon | | F-mail: | (h) | (G) | | |
| | | | | | | |) | (b) (6) | 7 | (b) | (0) | - | |
| | | | | | | | 2. He | alth Professional? | 3. Occupation | | l a | Also Repo | orted to: |
| Same and the same | 709D=17.0=07 | 1501 | | ė. | | | Ε | Yes No | | | 4. | Manufa | |
| #2 - Manufacture | r/Compound | ler | #2- Lot # | ė. | | | 7.5 | 540 E8-435 | | | 25 | Compo | under |
| | | | | | | | | ou do NOT want ye | | | 3 | User Fa | 39. |
| | | | | | | | to | the manufacturer, | please mark this | box: | | Distribut | tor/Importer |
| | | | | | | | 200-5 | | | | | | |

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

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 |
| \square | | (b) (6) | | |

Generated by: system Generated on: 26-May-2017 12:15:07 Page 1 of 5

CTU #: FDA-CDER-CTU-2017-32266 | Dept: CFSAN | RCT #: RCT-56416 | CTU Triage Date: 26-May-2017 | Total Pages: 5

Receipt No: RCT-56416 FDA 3500B Form

| AND #118 TO THE TO THE PROPERTY OF AND AND THE SECTION OF A THE STOCK OF A THE SECTION OF A | | | 2000 000 CO 1000 000 000 000 000 000 | | | | |
|--|---|--|--|--|--|--|--|
| Section A - About the Problem | | | | | | | |
| What kind of problem was it? | Were hurt or had a bad | side effect (including new or worseni | ng symptoms) | | | | |
| (Check all that apply) | Used a product incorrec | tly which could have or led to a prob | em | | | | |
| | Noticed a problem with the quality of the product | | | | | | |
| | Had problems after swit | Had problems after switching from one product maker to another maker | | | | | |
| Did any of the following happen? | Hospitalization - admitt | ed or stayed longer | | | | | |
| (Check all that apply) | Required help to preven | nt permanent harm (for medical devic | es only) | | | | |
| | Disability or health prol | blem | | | | | |
| | Birth defect | | | | | | |
| | Life-threatening | | | | | | |
| | Death | | | | | | |
| | Other serious/important | t medical incident | | | | | |
| Date of Death | 02-Feb-2017 | | | | | | |
| Date the problem occurred | 02-Feb-2017 | | | | | | |
| Tall us what happened and how it | hannanad (Include a | s many datails as possible | Y . | | | | |
| Tell us what happened and how it | 3.5 | X (2) | n (Kratom) was the accidental cause of death. | | | | |
| rashes, losing hair, vomiting, loss of effects but we believe he picked it be in bed (b) (6) chose Kratom because he supplement (b) (6) has never been a ha research and laws are currently being conversations and support when nec be provided to consumers at the very | appetite and irritable. Our ack up mid January and he was under the impression ord drug user so he was not g discussed on this suppler essary. We strongly believ to least. As we are currently s much as I can to increase | family was under the impressi- passed away during his sleep la from false marketing and inter- using Kratom as an alternative ment/drug, I would like our evi- re warning labels of the side eff y seeing Kratom sold next to ca | oring of 2017 ^{(b) (6)} then began getting skin on he stopped in July because of the side Feb 1st/Feb 2nd. There was vomit next to him net messages that it was a safe alternative drug like many Kratom advocates. As dence to be included in future studies, ects and suggested dosage regulation should not at the gas station, at bars, restaurants, dethis rapidly growing and very trendy drug. | | | | |
| List any relevant tests or laborato | | hem (Include dates) | | | | | |
| Diagnosis: Mitragynine intoxication microscopically) Toxicology: Mitrag | | | Aspiration of gastric contents (confirmed one, 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 | 1 | | | | | | |
| 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 | | | | | | | |

Generated by: system Generated on: 26-May-2017 12:15:07 Page 2 of 5

CTU #: FDA-CDER-CTU-2017-32266 | Dept. CFSAN | RCT #: RCT-56416 | CTU Triage Date: 26-May-2017 | Total Pages: 5

Receipt No: RCT-56416 using the product Did the problem stop after the Yes person reduced the dose or stopped taking or using the product? Did the problem return if the Yes person started taking or using the product again? Do you still have the product in No case we need to evaluate it? 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 Section D - About the Person Who Had the Problem (b)(6)Person's Initials Male Age (specify unit of time for age) (b)(6)Date of Birth 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

Generated by: system Generated on: 26-May-2017 12:15:07 Page 3 of 5

Black or African American

| CTU #: FDA-CDER-CTU-2017-32266 Dep Receipt No: RCT-56416 | t: CFSAN RCT #: RCT-56416 CTU Triage Date: 26-May-2017 Total Pages: 5 FDA 3500B Form | |
|--|---|----|
| | ich as diabetes, high blood pressure, cancer, heart disease, or others) | |
| | ten us timberes, high blood pressure, cunter, heure tiseuse, or veners) | 1 |
| n/a | | |
| | | |
| | | |
| | | |
| | | |
| Please list all allergies (such as to | drugs, foods, pollen or others) | 4 |
| n/a | | |
| | | |
| | | |
| | | |
| | | |
| List any other important informa | ion about the person (such as smoking, pregnancy, alcohol use, etc.) | |
| very limited marijuana and alcohol u | se in the last 1.5 years. No other drug use. During college would party but nothing abnormal. | 1 |
| NED NED | | |
| | | |
| | | |
| | | |
| List all current prescription medi | cations and medical devices being used. | |
| n/a | • | Т |
| | | |
| | | |
| | | |
| | | |
| | | .1 |
| I ist all over_the_counter medicati | ons and any vitamins, minerals, supplements, and herbal remedies being used | |
| | ons and any vitamins, minerals, supplements, and herbal remedies being used. | 1 |
| List all over-the-counter medicati Kratom | ons and any vitamins, minerals, supplements, and herbal remedies being used. | |
| | ons and any vitamins, minerals, supplements, and herbal remedies being used. | |
| | ons and any vitamins, minerals, supplements, and herbal remedies being used. | |
| | ons and any vitamins, minerals, supplements, and herbal remedies being used. | |
| | ons and any vitamins, minerals, supplements, and herbal remedies being used. | |
| Kratom | | |
| OTHER (CONCOMITANT) ME | | |
| OTHER (CONCOMITANT) ME Product Name | DICAL PRODUCTS 1 of 1 | |
| OTHER (CONCOMITANT) ME Product Name Strength | | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date | DICAL PRODUCTS 1 of 1 | |
| OTHER (CONCOMITANT) ME Product Name Strength | DICAL PRODUCTS 1 of 1 | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date | DICAL PRODUCTS 1 of 1 If Other | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli | DICAL PRODUCTS 1 of 1 If Other ag Out This Form | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli Last name | DICAL PRODUCTS 1 of 1 If Other ag Out This Form | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli Last name First name | DICAL PRODUCTS 1 of 1 If Other | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli Last name First name Number/Street | DICAL PRODUCTS 1 of 1 If Other ag Out This Form | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli Last name First name Number/Street City | DICAL PRODUCTS 1 of 1 If Other ag Out This Form | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli Last name First name Number/Street City State/Province | DICAL PRODUCTS If Other If Other Out This Form (b) (6) | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli Last name First name Number/Street City State/Province Country | DICAL PRODUCTS 1 of 1 If Other ag Out This Form | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli Last name First name Number/Street City State/Province Country ZIP or Postal code | DICAL PRODUCTS If Other Ig Out This Form (b) (6) | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli Last name First name Number/Street City State/Province Country | DICAL PRODUCTS If Other Ig Out This Form (b) (6) | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli Last name First name Number/Street City State/Province Country ZIP or Postal code | DICAL PRODUCTS If Other If Other Out This Form (b) (6) | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli Last name First name Number/Street City State/Province Country ZIP or Postal code Telephone number | DICAL PRODUCTS If Other Ig Out This Form (b) (6) | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli Last name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address Today's date Did you report this problem to the | DICAL PRODUCTS 1 of 1 If Other Ig Out This Form (b) (6) USA (b) (6) 26-May-2017 | |
| OTHER (CONCOMITANT) ME Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filli Last name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address Today's date | DICAL PRODUCTS 1 of 1 If Other Ig Out This Form (b) (6) USA (b) (6) 26-May-2017 | |

Generated by: system Generated on: 26-May-2017 12:15:07 Page 4 of 5

CTU #: FDA-CDER-CTU-2017-32266 | Dept: CFSAN | RCT #: RCT-56416 | CTU Triage Date: 26-May-2017 | Total Pages: 5

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CTU No.: FDA-CDER-CTU-2017-63579 | Department: Other(s), CFSAN | RCT No.: RCT-88139 | CTU Triage Date: 05-10-2017 | To

tal Pages: 4

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

| Company Unit | | nit | CDER-CTU | Originating Account | FAERS | | | |
|-------------------------|------------|--|--|-----------------------------------|---|--|--|--|
| Source Medium | | | MWO (Drug) | Source Form Type | E2B XML 3500B | | | |
| Pı | riority | | High | | 1 | | | |
| FI | DA Receiv | red Date | 05-Oct-2017 | CTU Received Date | 05-Oct-2017 | | | |
| C | TU Triage | Date | | | <u> </u> | | | |
| R | eport Type | | Spontaneous | Report Classification | Drug | | | |
| A | ssign To | | User | | | | | |
| | ser/Group | | | _ | | | | |
| | | Department | D open (open open | | -00) | | | |
| | | • | ☑ CDER (CDER-OSE-R | SS-CTU@fda.nns.gov) (E | =2B) | | | |
| | | | | | | | | |
| C | ase | First Name | Last Name | Email Address | Phone | | | |
| _ | eporter | - not riamo | Lactitaine | Ziliaii / taai ooo | | | | |
| $\overline{\mathbf{v}}$ | 3 | | | | | | | |
| | | | <u> </u> | <u> </u> | | | | |
| | T | | | | | | | |
| | | nd of problem was it? all that apply) | Were hurt or had a bad side e | ffect (including new or worsening | g symptoms) | | | |
| | (Oncore | an triat apply) | Used a product incorrectly wh | ich could have or led to a proble | m | | | |
| | | | Noticed a problem with the qu | ality of the product | | | | |
| | | | Had problems after switching | from one product maker to anoth | ner maker | | | |
| | | of the following happen? all that apply) | Hospitalization - admitted or stayed longer | | | | | |
| | (CHECK a | ян инас арргу) | 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 I | Death | 23-Jun-2017 | | | | | |
| | Date the | problem occurred | 23-Jun-2017 | | | | | |
| | | | | | | | | |
| | | | | | He took Kratom regularly for about 6 original cause of death was terminal | | | |
| | seizure. | The autopsy results dete | | | xic Effects of Mitragynine (Kratom)", | | | |
| | not natu | ral from the seizure. | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | ocumentation from the | | | amended 9/29/2017 to accidental | | | |
| | | om "Toxic Effects of Mitra It exists, I just do not hav | | process of obtaining the | official Medical Examiner's report/ | | | |
| | autopsy. | it exists, i just do not nav | ve a copy at this time. | | | | | |
| | | | | | | | | |
| | | | | | <u></u> | | | |
| | | | NATION AND ADDRESS OF THE PARTY | | | | | |
| | | the product as it on the box, bottle, | Mitragynine (Kratom) | | | | | |
| | or packa | ige (Include as many | | | | | | |
| | names a | is vou see) | | | | | | |

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 $CTU\ No.:\ FDA-CDER-CTU-2017-63579\ |\ Department:\ Other(s),\ CFSAN\ |\ RCT\ No.:\ RCT-88139\ |\ CTU\ Triage\ Date:\ 05-10-2017\ |\ Tolerand CTU\ No.:\ RCT-88139\ |\ CTU\ Triage\ Date:\ 05-10-2017\ |\ Tolerand CTU\ No.:\ RCT-88139\ |\ CTU\ Triage\ Date:\ 05-10-2017\ |\ Tolerand CTU\ No.:\ RCT-88139\ |\ CTU\ Triage\ Date:\ 05-10-2017\ |\ Tolerand CTU\ No.:\ RCT-88139\ |\ RCT\ No.:\ RCT-88139\ |\ RCT-88$

tal Pages: 4

| | 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 rel | ief | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | Name of medical device | | | |
| | Name of the company that makes the medical device | | | _ |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| ! | | | | |
| | | | | |
| | NA - d - l // | | | |
| | Model # | | | _ |
| | Catalog # | | | |
| | Catalog # Serial # | | | |
| | Catalog # Serial # Lot # | | | |
| | Catalog # Serial # | | | |

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CTU No.: FDA-CDER-CTU-2017-63579 | Department: Other(s), CFSAN | RCT No.: RCT-88139 | CTU Triage Date: 05-10-2017 | To

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| | Was someone operating the medical device when the problem occurred? | | | | _ |
|----|---|---|-----------|--|---|
| Da | ate 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 Alasl Native Hawaiian or Othe Asian White Black or African America | er Pacifi | | |
| | | | | | |
| | High blood pressure, non-epileption | c adult onset seizure disc | order | of unknown origin | = |
| | D. : III | | | | |
| | Penicillin | | | | |
| | | | | | |
| | Alcohol and tobacco use | | | | |
| | | | | | |
| | Dilantin | | | | |
| , | | | | | |
| | Mitragynine (kratom) | | | | |

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CTU No.: FDA-CDER-CTU-2017-63579 | Department: Other(s), CFSAN | RCT No.: RCT-88139 | CTU Triage Date: 05-10-2017 | To

tal Pages: 4

| IF. | OTHER (CONCOMITANT) ME | EDICAL PRODUC | CTS | | |
|-----|--|---------------|------|-------|---|
| | Product Name | | | | = |
| | Strength | | lf (| 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, | | | | |

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CTU No.: FDA-CDER-CTU-2017-63441 | Department: CFSAN | RCT No.: RCT-87997 | CTU Triage Date: 05-10-2017 | Total Pages:

4

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

| Со | mpany U | nit | CDER-C | TU | Origin | nating Account | FAERS | | |
|-------------------|------------|--|--|-----------------------------|-----------------------------|----------------------------------|---------------|---------|--|
| So | urce Med | ium | MWO (D | Prug) | Source Form Type E2B XML 35 | | E2B XML 3500B | | |
| Pri | ority | | High | | | | | | |
| FDA Received Date | | 04-Oct-2 | 2017 | CTU | Received Date | 04-Oct-2017 | | | |
| СТ | U Triage | Date | | | | | 1 | | |
| Re | port Type | , | Spontan | eous | Repo | rt Classification | Drug | | |
| As | sign To | | User | | | | 1 | | |
| Us | er/Group | | | | | | • | | |
| Fo | rward to [| Department | Исы | ER (CDER-OSE-RS | S-CTI | J@fda.hhs.gov) (E2B) | | | |
| | | | <u> </u> | LIT (OBLIT OOL IT | 0001 | Jegida:iiii3.gov) (LZD) | | | |
| | | | | | | | | | |
| Са | se | First Name | Las | st Name | | Email Address | Phone | | |
| | porter | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| П | What kin | d of problem was it? | Word h | ourt or bad a bad aide off | inat (inal | uding new or worsening symptoms) | | | |
| | (Check a | II that apply) | | a product incorrectly which | | | | | |
| | | | | d a problem with the qua | | | | | |
| | | | | | | product maker to another maker | | | |
| | | of the following happen? | Hospitalization - admitted or stayed longer | | | | | | |
| | (Check a | ll that apply) | Required help to prevent permanent harm (for medical devices only) | | | | | | |
| | | | | lity or health problem | 21101111110 | m (ioi modical devices smy) | | | |
| | | | Birth d | | | | | | |
| | | | Life-thi | reatening | | | | | |
| | | | Death | - | | | | | |
| | | | Others | serious/important medica | al incider | nt | | | |
| | Date of D | Death | 22-Dec-2 | 2016 | | | | | |
| | Date the | problem occurred | 22-Dec-2 | 2016 | | | | | |
| | | | | | | | | | |
| | The coro | ner determined that my 3 | 31 year old | son died from the | toxic e | ffects of Kratom tea. He stopped | d breathing. | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | <u></u> | |
| | | | | | | | | | |
| | | the product as it | Kratom t | ea leaves | | | | | |
| | | on the box, bottle, ge (Include as many | | | | | | | |
| | | s you see) | | | | | | | |

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CTU No.: FDA-CDER-CTU-2017-63441 | Department: CFSAN | RCT No.: RCT-87997 | CTU Triage Date: 05-10-2017 | Total Pages:

| 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 | | | |
| Do you still have the product in | No | | | |
| Do you still have the product in case we need to evaluate it? Ulcerative Colitis | No | | | |
| Do you still have the product in case we need to evaluate it? | No | | | |
| Do you still have the product in case we need to evaluate it? Ulcerative Colitis | No | | | |
| Do you still have the product in case we need to evaluate it? Ulcerative Colitis Name of medical device Name of the company that | No | | | |
| Do you still have the product in case we need to evaluate it? Ulcerative Colitis Name of medical device Name of the company that | No | | | |
| Do you still have the product in case we need to evaluate it? Ulcerative Colitis Name of medical device Name of the company that makes the medical device | No | | | |
| Do you still have the product in case we need to evaluate it? Ulcerative Colitis Name of medical device Name of the company that makes the medical device Model # | No | | | |
| Do you still have the product in case we need to evaluate it? Ulcerative Colitis Name of medical device Name of the company that makes the medical device | No | | | |
| Do you still have the product in case we need to evaluate it? Ulcerative Colitis Name of medical device Name of the company that makes the medical device Model # | No | | | |
| Do you still have the product in case we need to evaluate it? Ulcerative Colitis Name of medical device Name of the company that makes the medical device Model # Catalog # | No | | | |

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CTU No.: FDA-CDER-CTU-2017-63441 | Department: CFSAN | RCT No.: RCT-87997 | CTU Triage Date: 05-10-2017 | Total Pages:

Was someone operating the medical device when the problem occurred? Date the implant was taken out (If Date the implant was put in relevant) Person's Initials 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.

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CTU No.: FDA-CDER-CTU-2017-63441 | Department: CFSAN | RCT No.: RCT-87997 | CTU Triage Date: 05-10-2017 | Total Pages:

| F. | OTHER (CONCOMITANT) ME | EDICAL PRODUC | TS | | |
|----|--|---------------|----|----------|--|
| | 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 : | | | | |

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CTU No.: FDA-CDER-CTU-2017-60290 | Department: CFSAN | RCT No.: RCT-84826 | CTU Triage Date: 19-09-2017 | Total Pages:

4

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

| С | ompany U | nit | CDE | R-CTU | Origii | nating Account | FAERS | | |
|---------------|-------------|---------------------------|--|--|------------|----------------------------------|-----------------------|---|--|
| Source Medium | | MWO (Drug) | | Source Form Type | | E2B XML 3500B | | | |
| Priority | | High | | | | J | | | |
| F | DA Receiv | ed Date | 18-S | Sep-2017 | CTU | Received Date | 18-Sep-2017 | | |
| C | TU Triage | Date | | | | | | | |
| Re | eport Type | | Spoi | ntaneous | Repo | rt Classification | Drug | | |
| As | ssign To | | Use | r | | | | | |
| Us | ser/Group | | | | | | | | |
| Fo | orward to [| Department | | CDER (CDER-OSE-RS | SS-CTI | J@fda.hhs.gov) (E2B) | | | |
| | | | | | | <u> </u> | | | |
| | | | | | | | | | |
| | ase | First Name | | Last Name | | Email Address | Phone | | |
| | eporter | | | | | | | | |
| ~ | 1 | | | | | | | | |
| | | | | | | | | | |
| | | d of problem was it? | Ζv | Vere hurt or had a bad side ef | fect (incl | uding new or worsening symptoms) | | | |
| | (Check a | ll that apply) | | lsed a product incorrectly which | | | | | |
| | | | | loticed a problem with the qua | | | | | |
| | | | | Had problems after switching from one product maker to another maker | | | | | |
| | | of the following happen? | Hospitalization - admitted or stayed longer | | | | | | |
| | (Check a | ll that apply) | Required help to prevent permanent harm (for medical devices only) | | | | | | |
| | | | | Disability or health problem | | | | | |
| | | | | Birth defect | | | | | |
| | | | | ife-threatening | | | | | |
| | | | | Death | | | | | |
| | | | | Other serious/important medical | al incide | nt | | | |
| | Date of D | Death | | ul-2017 | | | | | |
| | Date the | problem occurred | 07-Jul-2017 | | | | | | |
| | | | | | | <u> </u> | | | |
| | My son p | ourchased OPMS brand h | Kraton | n at a gas station in | | . He took it and died in his | sleep. The death | Π | |
| | | e, signed by | . 1.1:1 | ., Associate Med | ical Ex | aminer, | dated 8/22/2017 reads | | |
| | cause of | death as "Intoxication by | viviitra | gynine (Kratom)". | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | We have | Autoney roport and Toxi | cology | report dated 8/0/2017 | licting | "Mitragynine 1.8 mg/L Peripher | ral Blood" signed by | | |
| | vveriave | , MS, D-ABFT, Assistant | | | | County Medical Exam | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | - | | | | | | |
| | | | | | | | | | |
| | Name of | the product as it | GOL | D Mitragynia Speciosa | Botan | cal Extract | | | |
| | appears | on the box, bottle, | | • | | | | | |
| | or packa | ge (Include as many | | | | | | | |

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U Triage Date: 19-09-2017 | Total Pages:

| CTU No.: FDA-CDER-CTU-2017-60290 | Department: | CFSAN | RCT No.: | RCT-84826 C | Τl |
|----------------------------------|-------------|-------|----------|---------------|----|
| | | | | | |

| makes (or compounds) the product | O.P.M.S. Optimize | 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 | Doesn't Apply | | | | | |
| Do you still have the product in | Yes | | | | | | |
| case we need to evaluate it? To detox from Opiates, to help wit | h anxiety and depre | ssion | | | | | |
| case we need to evaluate it? | h anxiety and depre | ssion | | | | | |
| To detox from Opiates, to help wit | h anxiety and depre | ssion | | | | | |
| case we need to evaluate it? | h anxiety and depre | ssion | | | | | |
| To detox from Opiates, to help wit Name of medical device Name of the company that | h anxiety and depre | ssion | | | | | |
| To detox from Opiates, to help wit Name of medical device Name of the company that | h anxiety and depre | ssion | | | | | |
| To detox from Opiates, to help wit Name of medical device Name of the company that | h anxiety and depre | ssion | | | | | |
| Case we need to evaluate it? To detox from Opiates, to help with the company that makes the medical device | h anxiety and depre | ssion | | | | | |
| Case we need to evaluate it? To detox from Opiates, to help with the company that makes the medical device. Model # | h anxiety and depre | ssion | | | | | |
| Case we need to evaluate it? To detox from Opiates, to help wit Name of medical device Name of the company that makes the medical device Model # Catalog # | h anxiety and depre | ssion | | | | | |
| Case we need to evaluate it? To detox from Opiates, to help with the company that makes the medical device Model # Catalog # Serial # | h anxiety and depre | ssion | | | | | |

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| | Was someone operating the medical device when the problem occurred? | | | |
|----|--|--|---|--|
| Da | ate 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 Na Native Hawaiian or Other Pacit Asian White Black or African American | | |
| | | | | |
| | None that we knew of, but autops Examiner said neither contributed none | | al thyroid and left ventrical myocardial hypertrophy. Medical | |
| | | | | |
| | Citralopram, Cyclobenzaprine (the | erapeutic amount in system a | nd ME says neither contributed to death) | |
| | | | | |
| | Just this Kratom | | | |

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS **Product Name** If Other Strength 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 No company that makes the product (the manufacturer/compounder)? If you do NOT want your identity \square disclosed to the manufacturer,

place an X in this box :

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4

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

| Cc | mpany U | nit | CDER-CTU | Origi | nating Account | FAERS | | |
|----------|-----------|--|--|---------------|--|-------------|----|--|
| Sc | urce Med | ium | MWO (Drug) | Sour | Source Form Type E2B XML 35 | | ЭВ | |
| Priority | | | High | ' | | | | |
| FD | A Receiv | ed Date | 02-Oct-2017 | CTU | Received Date | 02-Oct-2017 | | |
| СТ | U Triage | Date | | | | | | |
| Re | port Type |) | Spontaneous | Repo | ort Classification | Drug | | |
| As | sign To | | User | | | | | |
| | er/Group | | | | | | | |
| | | Department | Donen (onen oce | DOC OT | H@fda.hha.aaa.\/F2D\ | | | |
| | | • | CDER (CDER-OSE | -RSS-C1 | U@fda.nns.gov) (E2B) | | | |
| | | | | | | | | |
| Ca | ise | First Name | Last Name | | Email Address | Phone | | |
| | porter | | | | | 1 | | |
| abla |] | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | d of problem was it? all that apply) | Were hurt or had a bad sid | e effect (inc | luding new or worsening symptoms | ;) | | |
| | (Oncor a | iii triat appry) | Used a product incorrectly | which could | have or led to a problem | | | |
| | | | Noticed a problem with the | quality of th | ne product | | | |
| | | | Had problems after switching from one product maker to another maker | | | | | |
| | | of the following happen? | Hospitalization - admitted or stayed longer | | | | | |
| | (Crieck a | all that apply) | Required help to prevent permanent harm (for medical devices only) | | | | | |
| | | | Disability or health problem | | | | | |
| | | | Birth defect | | | | | |
| | | | Life-threatening | | | | | |
| | | | Death | | | | | |
| | | | Other serious/important me | dical incide | nt | | | |
| | Date of D | Death | 01-Mar-2017 | | | | | |
| | Date the | problem occurred | 01-Mar-2017 | | | | | |
| | | | | | | | | |
| | | | | | th his bad knees and hips a | | | |
| | | | | | (300 ft) to walking with a car tractor. I strongly suspect it | | | |
| | that he w | as taking. He bought it fr | rom California on a monthl | | le either mixed it with water | | | |
| | capsules | with the powder and ing | gested them. | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | the product as it | Kratom | | | | | |
| | | on the box, bottle, ge (Include as many | | | | | | |
| | | s you see) | | | | | | |

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| 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 | | | | |
| | | | | |
| | | | <u> </u> | |
| | | | | |
| | | | | |
| | | | | |
| Model # | | | | |
| Catalog # | | | | |
| | | | | |
| Seriai # | | | | |
| Serial # | | | | |
| Lot # | | | | |
| | | | | |

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CTU No.: FDA-CDER-CTU-2017-62885 | Department: CFSAN | RCT No.: RCT-87448 | CTU Triage Date: 02-10-2017 | Total Pages:

Was someone operating the medical device when the problem occurred? Date the implant was taken out (If Date the implant was put in relevant) Person's Initials 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

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CTU No.: FDA-CDER-CTU-2017-62885 | Department: CFSAN | RCT No.: RCT-87448 | CTU Triage Date: 02-10-2017 | Total Pages:

| F. OTHER (CONCOMITANT) MEDICAL PRODUCTS | | | | | | | |
|---|--|-------------|---|---------|---|---|--|
| | Product Name | | | | | | |
| | Strength | | | If Othe | r | | |
| | 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 : | | | | | | |

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