

# REPORT INFORMATION

## Report Profile

**Report Version** FPSR.FDA.DSR.M.V1

**Report Category** Mandatory Dietary Supplements Report

**Submitted** 2021-10-18 16:30:53 EST

**FDA ICSR ID** 2120694

**Submitted by** emmab@modere.com

## Report Identifying Information

Please enter a title to help you identify this report. Consider using your firm's internal case tracking number for simplified recordkeeping

2021-US-021885

**What type of report are you submitting?**

Serious adverse event and Product Problem (e.g., defects that may have caused or contributed to a serious adverse event)

**Enter the date you received the initial report:**

10/15/2021

**How did the initial reporter learn of the serious adverse event or product problem? (check all that apply)**

Consumer

**Regulatory Status**

Mandatory

# Contact Information - Manufacturer, Packer, or Distributor Site Information

My account address is the same as the manufacturer, packer, or distributor address

Yes

Organization name

Modere, INC.

Organization type

Manufacturer, Packer, Distributor

Food facility registration number

<blank>

Country

UNITED STATES

Street address line 1

588 S 2000 W

Street address line 2

<blank>

City/Town

Springville

State

Utah

Mail/ZIP Code

84663

I am the point of contact for the facility listed above

No

First name

Callie

Last name

Brink-Lee

Job title

<blank>

Email

callieb@modere.com

Confirm email

callieb@modere.com

Primary phone

18014182487

Other phone

<blank>

Fax

<blank>

# Contact Information- Report Submitter

# Contact Information - Initial Reporter

Did the initial reporter indicate that they also reported the event to the FDA?

No

Does the initial reporter wish to remain anonymous to the FDA?

Yes

Salutation

<blank>

First name

<blank>

**Last name** Withheld

**Email** <blank>

**Confirm email** <blank>

**Phone** <blank>

**Country** <blank>

**Street address line 1** <blank>

**Street address line 2** <blank>

**City/Town** <blank>

**State** <blank>

**Mail/ZIP code** <blank>

**Was the initial reporter a healthcare professional?** No

## Relevant Details

**Patient identifier** JO

**Sex** Female

**Age at time of event, <i>if unknown, please enter Date of birth below</i>** 41

**Select unit of measure** Year(s)

**Date of birth** 05/27/1980

**Weight** 157

**Select unit of measure** Pound(s)

**Height** <blank>

**Select unit of measure** <blank>

## Problem Details

**Outcomes attributed to adverse event (check all that apply)** Other serious (important medical events)

**If other, please describe** <blank>

This spontaneous report was received from a consumer via telephone on 04-Oct-2021. The consumer is a 41-year-old female who is five weeks post-partum and currently breastfeeding, with an otherwise healthy medical history and no known drug allergies. She takes a multivitamin as a concomitant supplement. On 06-Sep-2021, the consumer started taking Trim Chocolate and Liquid BioCell Life with an unspecified dose taken once daily. On 23-Sep-2021, the consumer experienced right upper quadrant pain, which prompted her to see her provider. An abdominal ultrasound and unspecified "other" lab tests were performed yielding results within normal limits. On 23-Sep-2021, she also had a liver function test performed, which yielded the following values (in units/L): ALK 131, AST 434, ALT 228. On 24-Sep-2021, another liver function test was performed to confirm the initial results and yielded the following results (in units/L): ALK 192, AST 356, ALT 376. The consumer

**Please describe the event or problem**

mentioned a liver function test performed in early pregnancy on an unspecified date in Nov-2020, which yielded values (in units/L) of ALK 62, AST 20, ALT 18. The consumer spoke with her provider about the "collagen product" before starting it. The consumer also noted that she was using both products while breastfeeding and was told it was safe to do so from a company representative selling her the products. On 23-Sep-2021, her provider advised her to discontinue use of the products, commenting that this is not the first time she has seen elevated enzymes with various supplements. The right upper quadrant pain resolved within six to eight hours on 23-Sep-2021. The elevated liver Enzymes were ongoing at time of last report and the consumer is having labs drawn in one and a half weeks relative to 04-OCT-2021. On 15-Oct-2021, an attempt to contact the consumer after her follow up appointment with her provider was attempted via telephone, but no response was received at the time of this report.

**Date of event** 09/23/2021

**Duration of adverse event** 8

**Select unit of measure** hour

**Please provide relevant medical history, including pre-existing conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) :**

Gave birth 5 weeks ago and currently breast feeding Pregnant Status No The consumer mentioned a liver function test performed in early pregnancy on an unspecified date in Nov-2020, which yielded values (in units/L) of ALK 62, AST 20, ALT 18.

**Do you have any relevant tests/laboratory data information to report?** Yes

## Adverse Event Terms

## Relevant Tests/Laboratory Data

**Lab test name** Liver funtion test

**If other, please describe** Liver funtion test

**Date of lab test** 09/23/2021

**Test result(s)** ALK 131, AST 434, ALT 228 24-SEP-2021: Liver...

## Product Information

**Select full name of product as it appears on the package label** Other

**Full name of product as it appears on the package label** Trim Chocolate 450ml

**Product manufacturer, packer or distributor** Modere, Inc.

**Product strength** <blank>

**Select unit of measure** <blank>

**Barcode identifier** Other

Select identifier type Other

If other, please describe Code 39 Barcode

Diagnosis or reason for use (indication): Dietary Supplement

Lot number 656119

Expiration/use-by date 07/06/2022

## Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:

09/06/2021

End: 09/23/2021

Duration of product use 17

Select unit of measure day(s)

Frequency of consumption 1

Select unit of measure day(s)

Amount consumed per serving 15

Select unit of measure ml

Administration route oral

Did the event stop when product use stopped or amount consumed was reduced? Yes

Did the event reoccur when product use resumed? Not Applicable

Please provide any notes describing the product's usage.

DIRECTIONS: Shake well. Take 1 tablespoon directly by mouth daily, preferably in the morning. CAUTION: Consult your health care provider prior to use if you are nursing or pregnant. have a medical condition, or when taking any medication. KEEP OUT OF REACH OF CHILDREN. STORAGE: Refrigerate after opening to maintain shelf life. Store unopened container out of direct sunlight and at room temperature.

## Ingredient Details

## Product Information

Select full name of product as it appears on the package label Other

Full name of product as it appears on the package label Liquid BioCell Life 450ml

Product manufacturer, packer or distributor Modere, Inc.

**Product strength** <blank>

**Select unit of measure** <blank>

**Barcode identifier** Other

**Select identifier type** Other

**If other, please describe** 39 Barcode

**Diagnosis or reason for use (indication):** Dietary Supplement

**Lot number** 656525

**Expiration/use-by date** 01/27/2023

## Product Use Details

**Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:** 09/06/2021

**End:** 09/23/2021

**Duration of product use** 17

**Select unit of measure** day(s)

**Frequency of consumption** 1

**Select unit of measure** day(s)

**Amount consumed per serving** 15

**Select unit of measure** ml

**Administration route** oral

**Did the event stop when product use stopped or amount consumed was reduced?** Yes

**Did the event reoccur when product use resumed?** Not Applicable

**Please provide any notes describing the product's usage.** DIRECTIONS: Shake well before each serving. Take 1 tablespoon twice daily for optimal results. CAUTION: Consult your health care provider prior to use if you are nursing or pregnant, have a medical condition, or when taking any medication. KEEP OUT OF REACH OF CHILDREN. STORAGE: Refrigerate after opening to maintain shelf life. Store unopened container out of direct sunlight and at room temperature.

## Ingredient Details

## Product Relevant Details

# Concomitant Product Information

## Concomitant Product Relevant Details

### HL7 Batch Information

### HL7 Batch Control Information

Submitting Organization Id   SRPCIT

### HL7 Batch Sender Information

Sender Id   SRPCIT

Job Title   Mandatory Dietary Supplement Submitter

Phone   7027422061

Email   emmab@modere.com

### HL7 Batch Receiver Information

Batch Receiver (Root)   USFDA

Batch Receiver (Extension)   US Food and Drug Administration

### HL7 Message Information

### HL7 Message Control Information

Unique Sender Identifier   SRPCIT

Profile Identifier   FPSR.FDA.DSR.M.V1.ACCOUNT.AEPP

# HL7 Message Sender Information

Unique Sender IdentifierID-NOTGIVEN

Organization NameModere, INC.

TitleMandatory Dietary Supplement Submitter

# HL7 Message Receiver Information

Message Receiver IdUSFDA

# Attached Files

- FILENAME

2021-US-021885 MedWatch.pdf

Description of Attachment

MedWatch

Attachment Type

Medical Records
- FILENAME

LBL 01133 Liq BioCell Life 450ml sw r4 wo specs.pdf

Description of Attachment

BioCell Life

Attachment Type

Labeling Materials
- FILENAME

LBL 01217 Trim Chocolate 450mL sw r5olNoSpec.pdf

Description of Attachment

Trim Chocolate

Attachment Type

Labeling Materials