REPORT INFORMATION

Report Profile

Report Version	FPSR.FDA.DSR.M.V1
Report Category	Mandatory Dietary Supplements Report
Submitted	2021-10-18 13:47:44 EST
FDA ICSR ID	2120680
Submitted by	r.ridge@biocodex.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	BXHQ-210843 / US-BIOCODEX2-2021001279
What type of report are you submitting?	Serious adverse event (a serious adverse health-related event associated with the product)
Enter the date you received the initial report:	10/04/2021
How did the initial reporter learn of the serious adverse event or product problem? (check all that apply)	Other
If other, please describe	Literature review
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	Biocodex
Organization type	Manufacturer
Food facility registration number	<blank>
Country	UNITED STATES
Street address line 1	550 Hills Drive Suite 200B
Street address line 2	<blank>
City/Town	Bedminster
State	New Jersey
Mail/ZIP Code	07921
I am the point of contact for the facility listed above	Yes
First name	Rachelle
Last name	Ridge
Job title	<blank>
Email	r.ridge@biocodex.com
Confirm email	r.ridge@biocodex.com
Primary phone	(908) 521-4400
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?	Unknown
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	Privacy
Gender	Male
Age at time of event, if unknown, please enter Date of birth below	45
Select unit of measure	Year(s)
Date of birth	<blank>
Weight	<blank>
Select unit of measure	<blank>
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	Fungemia, contraindicated use
Please describe the event or problem	Case description : This serious initial case was found as invalid on 02-Oct-2021 in a literature article from United States by a Biocodex employee and transmitted to Biocodex Vigilance department HQ on the same date. The case became valid on 04-Oct-2021 at the reception of full article and was transmitted to Biocodex Vigilance Department HQ on 06-Oct-2021. WOMBWELL Eric. Incidence of Saccharomyces cerevisiae Fungemia in Hospitalized Patients Administered 11 Saccharomyces boulardii Probiotic, doi: 10.1111/MYC.13375. A 45-year-old male patient experienced blood culture positive to Saccharomyces cerevisiae following administration of FLORASTOR (saccharomyces boulardii lyophilised) as primary prevention of Hospital Onset Clostridium Difficile Infection. (Time to onset = 8.5 days) Patient's current conditions included hospitalization for spinal cord injury and lung contusion secondary to MVA, diabetes (A1C 6.0 mg/dl), central line. There was no information about

	concomitant medication provided. The patient was already hospitalized for 10 days. The patient received FLORASTOR per tube for prophylaxis against Hospital Onset Clostridium Difficile Infection. The patient experienced fungemia with blood culture positive to Saccharomyces cerevisiae after 8.5 days. Blood culture became negative into 3 days. The patient received micafungin as corrective treatment. The final outcome for fungemia was considered as recovered. The patient was hospitalized for 29 days and was discharged. No further information was provided regarding this patient.
Date of event	<blank>
Duration of adverse event	<blank>
Select unit of measure	<blank>
Please provide relevant medical history, including pre-existing conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) :	# 1 Hospitalization # 2 Diabetes # 3 Spinal cord injury # 4 Lung injury # 5 Motor vehicle accident # 6 Central line placement
Do you have any relevant tests/laboratory data information to report?	Yes

Adverse Event Terms

Adverse event term	Fungaemia

Adverse Event Terms

Adverse event term	Administration to a patient with central line [Contraindicated drug administered]
If other, please describe	Administration to a patient with central line [Contraindicated drug administered]

Relevant Tests/Laboratory Data

Lab test name	Blood culture
If other, please describe	Blood culture
Date of lab test	<blank>
Test result(s)	Positive Culture to S. cerevisiae

Relevant Tests/Laboratory Data

Lab test name	Glucose - Blood
Date of lab test	<blank>
Test result(s)	HbA1C 6.0 milligram per decilitre

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	FLORASTOR (SACCHAROMYCES BOULARDII LYOPHILISED)
Product manufacturer, packer or distributor	<blank>
Product strength	<blank>
Select unit of measure	<blank>
Barcode identifier	<blank>
Select identifier type	<blank>
Diagnosis or reason for use (indication):	Prophylaxis
Lot number	<blank>
Expiration/use-by date	<blank>

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank>
End:	<blank>
Duration of product use	<blank>
Select unit of measure	<blank>
Frequency of consumption	<blank>
Select unit of measure	<blank>
Amount consumed per serving	<blank>
Select unit of measure	<blank>
Administration route	<blank>
Did the event stop when product use stopped or amount consumed was reduced?	Unknown
Did the event reoccur when product use resumed?	Unknown
Please provide any notes describing the product's usage.	Contraindicated use with central line

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 6508302093

Email r.ridge@biocodex.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.AE

HL7 Message Sender Information

Unique Sender Identifier ID-NOTGIVEN

Organization Name Biocodex

Title Mandatory Dietary Supplement Submitter

HL7 Message Receiver Information

Message Receiver Id USFDA

Attached Files

FILENAME 2021001279 CIOMS INI.pdf

Description of Attachment CIOMS report

Attachment Type Other