

Date:12/08/2022 7:06:54

Created Date Created by

2019-06-06 08:27:03.0 fer38163

Registration Expiration Date Registration Renewed Date

2024-12-31 2022-12-08

Last Updated Registration Status Reason

2022-12-08 Biennial Registration Renewal - 2020

Registration Status

VALID

Is this facility engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States?

•Yes ONo

Section 1: Type of Registration

Facility Location: Foreign Registration

UPDATE OF REGISTRATION INFORMATION:

Registration Number: 15731026290 Pin No cAbb9aeJ

Are you the new owner of a previously registered facility?

Oyes ONo

Previous Owner's Title:

Previous Owner's Name:

Previous Owner's Registration Number:

Section 2: Facility Name/Address Information

Facility Name Telephone Number

Fermentis Life Sciences Pvt Ltd 091 124 414188

Facility Name Suffix Fax Number

Company

Facility Street Address, Line 1 E-Mail Address

Plot No. - 41 Sector - 8 IMT prakash@fermentislife.com

Facility Street Address, Line 2 Unique Facility Identifier (UFI)

Manesar

City

Gurugram

State/Province/Territory

Haryana

Zip Code (Postal Code)

122051

Country/Area

INDIA



Section 3: Preferred Mailing Address Information

INDIA

Complete this section if different from Section 2 Facility Nat	ne/Address Information (OPTIONAL)	
Is the preferred mailing address the same as the facility add	dress (Section 2)? Yes	
Name	Telephone Number	
Fermentis Life Sciences Pvt Ltd	091 124 414188	
Address, Line 1	Fax Number	
Plot No 41 Sector - 8 IMT		
Address, Line 2	E-Mail Address	
Manesar	prakash@fermentislife.com	
City		
Gurugram		
State/Province/Territory		
Haryana		
Zip Code (Postal Code)		
122051		
Country/Area		
INDIA		
Section 4: Parent Company Name/Address I	nformation	
(If applicable and if different from Sections 2 and 3). If infor	mation is the same as another section, check which section:	
Same as Facility Address (Section 2)		
OSame as Preferred Mailing Address (Section 3)		
ONone of the above		
Company Name	Telephone Number 091 124 414188	
Fermentis Life Sciences Pvt Ltd		
Company Name Suffix	Fax Number	
Company		
Address, Line 1	E-Mail Address	
Plot No 41 Sector - 8 IMT	prakash@fermentislife.com	
Address, Line 2		
Manesar		
City		
Gurugram		
State/Province/Territory		
Haryana		
Zip Code (Postal Code)		
122051		
Country/Area		



Section 5: Facility Emergency Contact Information

If information is the same as another section, check wh	nich section:
OSame as Facility Address (Section 2)	
Same as U.S. Agent Information (Section 7)	
ONone of the above	
Individual's Title (Optional)	Emergency Contact Phone
	001 954 3911400
Individual's Name (Optional)	E-Mail Address
BioAnthem LLC	khetwal@gmail.com
Individual's Middle Name (Optional)	Job Title (Optional)
Individual's Last Name (Optional)	
Section 6: Trade Names	
Are there alternate trade names used by your facility in	addition to the name provided in Section 2: Facility Name/Address Information?
OYes ⊙No	
⊙ _{No} Section 7: United States Agent	or territory of the United States, District of Columbia, or The Commonwealth of Puerto Rico)
 No Section 7: United States Agent (To be completed by facilities located outside any state) 	e or territory of the United States, District of Columbia, or The Commonwealth of Puerto Rico) Telephone Number
 No Section 7: United States Agent (To be completed by facilities located outside any state Name 	
ONO Section 7: United States Agent (To be completed by facilities located outside any state) Name BioAnthem LLC	Telephone Number
	Telephone Number 817 5017558 null
ONO Section 7: United States Agent (To be completed by facilities located outside any state) Name BioAnthem LLC Address, Line 1 19431 Paddock View Dr	Telephone Number 817 5017558 null Emergency Contact Phone
ONO Section 7: United States Agent (To be completed by facilities located outside any state) Name BioAnthem LLC Address, Line 1 19431 Paddock View Dr	Telephone Number 817 5017558 null Emergency Contact Phone 954 3911400
Section 7: United States Agent (To be completed by facilities located outside any state Name BioAnthem LLC Address, Line 1 19431 Paddock View Dr Address, Line 2	Telephone Number 817 5017558 null Emergency Contact Phone 954 3911400 City
Section 7: United States Agent (To be completed by facilities located outside any state Name BioAnthem LLC Address, Line 1 19431 Paddock View Dr Address, Line 2 E-Mail Address	Telephone Number 817 5017558 null Emergency Contact Phone 954 3911400 City Tampa
Section 7: United States Agent (To be completed by facilities located outside any state Name BioAnthem LLC Address, Line 1 19431 Paddock View Dr Address, Line 2 E-Mail Address	Telephone Number 817 5017558 null Emergency Contact Phone 954 3911400 City Tampa State/Province/Territory
⊙ _{No} Section 7: United States Agent	Telephone Number 817 5017558 null Emergency Contact Phone 954 3911400 City Tampa State/Province/Territory Florida
No Section 7: United States Agent (To be completed by facilities located outside any state Name BioAnthem LLC Address, Line 1 19431 Paddock View Dr Address, Line 2 E-Mail Address	Telephone Number 817 5017558 null Emergency Contact Phone 954 3911400 City Tampa State/Province/Territory Florida Zip Code (Postal Code)
No Section 7: United States Agent (To be completed by facilities located outside any state Name BioAnthem LLC Address, Line 1 19431 Paddock View Dr Address, Line 2 E-Mail Address	Telephone Number 817 5017558 null Emergency Contact Phone 954 3911400 City Tampa State/Province/Territory Florida Zip Code (Postal Code) 33647

End Month

End Month

Section 9: General Product Categories - Human/Animal/Both

Harvest 1
Start Month

Harvest 2

Start Month

Give the approximate dates that your facility is open for business, if its operations are on a seasonal basis (Optional).



☑ Food for Human Consumption	Food for Animal Consumption	

Section 9a: General Product Categories - Food for Human Consumption; and Type of Activity Conducted at the Facility

Facility	Facility												
To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37	Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Refrigerated Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks)	Frozen Food Storage Warehouse / Holding Facility (e.g., storage facilities)	Acidified Food Process or	Low- Acid Food Process or	Interstat e Conveya nce Caterer / Catering Point	Contract	Labeler / Relabele r	Manufact urer / Process or	Packer / Repacke r	Salvage Operator (Recondi tioner)	Farm Mixed- Type Facility	Other Activity Conduct ed (Please Specify)
	MENT CATEGORIES												
a.Proteins, Amino Acids, Fats and Lipid Substances _{[21 CFR} 170.3(o) (20)]	☑								Ø	Ø			
b.Vitamins and Minerals	\square								Ø	Ø			
d.Herbals and Botanicals	Ø								Ø				
15.FOOD ADDITIVES, GENERALLY RECOGNIZED AS SAFE (GRAS) INGREDIENTS, OR OTHER INGREDIENTS USED FOR PROCESSING[21 CFR 170.3 (n) (42): 21 CFR 170.3 (o) (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32]									Ø				
16.FOOD SWEETENERS (NUTRITIVE) (21 CFR 170.3 (n) (9) (41), 21 CFR 170.3 (o) (21)]									V				



To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY,	Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Refrigerated Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks)	Frozen Food Storage Warehouse / Holding Facility (e.g., storage facilities)	Acidified Food Process or	Low- Acid Food Process or	Interstat e Conveya nce Caterer / Catering Point	Contract	Labeler / Relabele r	Manufact urer / Process or	Packer / Repacke r	Salvage Operator (Recondi tioner)	Farm Mixed- Type Facility	Other Activity Conduct ed (Please Specify)
37.IF NONE OF THE ABOVE FOOD CATEGORIES APPLY, THEN PRINT THE APPLICABLE FOOD CATEGORY OR CATEGORIES (THAT DOES NOT OR DO NOT	✓	Ø							Ø				
Probiotic and Prebiotic	c supplement with FDA	apply, then print the a	ed from FDA approved	suppliers.	0								

Probiotic and Prebiotic supplement with FDA approved strains sourced from FDA approved suppliers.							
Section 10: Owner, Operator, or Agent-in-Charge Information							
Provide the following information, if different from all other section:	sections on the form. If information is the same as another section of the form, check which						
If information is the same as Section 2, check the box:							
● Section 2 - Facility Address Information							
OSection 3 - Preferred Mailing Address Information	. 00. 00.						
OSection 4 - Parent Company Address Information	2,0 2,0 2,0						
OSection 7 - US Agent Address Information							
ONone of the above	O^{r} O^{r} O^{r} O^{r}						
Name of Entity or Individual Who is the Owner, Operator, o	or Agent-in-Charge: Doctor Prakash Bhatt						
Address, Line 1	Telephone Number						
Plot No 41 Sector - 8 IMT	091 124 414188						
Address, Line 2	Fax Number						
Manesar							
City	E-Mail Address						
Gurugram	prakash@fermentislife.com						
State/Province/Territory							
Haryana							



Zip Code (Postal Code)

122051

Country/Area

INDIA

Section 11: Inspection Statement

FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug, and Cosmetic Act.

Section 12: Certification Statement

The owner, operator, or agent-in-charge of the facility, or an individual authorized by the owner, operator, or agent-in-charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent-in-charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator or agent-in-charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent-in-charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

NAME OF PERSON SUBMITTING THIS REGISTRATION RENEWAL: prakash chandra bhatt

CHECK ONE BOX

Oa. INDIVIDUAL ASSOCIATED WITH THE INFORMATION IN SECTION 10 (STOP HERE, FORM IS COMPLETED)

OB. ANOTHER AUTHORIZED INDIVIDUAL

Address Information for the Authorizing Individual:

Individual's Name Telephone Number

-N/A- -N/A-

Address, Line 1 Fax Number

-N/A- -N/A-

Address, Line 2 E-Mail Address

-N/A- -N/A-

-N/A-

City

State/Province/Territory

-N/A-

Zip Code (Postal Code)

-N/A-

Country/Area

-N/A-