

Date: Mar 26, 2020 8:26:30 AM

Section 1 Type of Registration

1a. FOREIGN REGISTRATION

1b. INITIAL REGISTRATION: 17359982772 PIN NUMBER: 65a0E4c4

ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY? Yes No

1c. PREVIOUS OWNER'S TITLE : PREVIOUS OWNER'S NAME : PREVIOUS OWNER'S REGISTRATION NUMBER :

Section 2 Facility Name/Address Information

FACILITY NAME: Elan Impex

FACILITY NAME SUFFIX: Manufacturing

FACILITY STREET ADDRESS, Line1: 312 Vikas Kunj, Vikas Puri

FACILITY STREET ADDRESS, Line2:

CITY: New Delhi STATE/PROVINCE/TERRITORY: Delhi

ZIP CODE (POSTAL CODE): 110018

COUNTRY/AREA: INDIA

PHONE NUMBER (Include Area/Country Code): 91 866 9269638

FAX NUMBER (Include Area/Country Code):

E-MAIL ADDRESS: contact@elanimpex.in

Section 3 Preferred Mailing Address Information

(Complete this section only if different from Section 2, Facility Name/Address Information)

If information is the same as section 2, check the box:

NAME: Elan Impex

ADDRESS, Line1: 312 Vikas Kunj, Vikas Puri

ADDRESS, Line2:

CITY: New Delhi STATE/PROVINCE/TERRITORY: Delhi

ZIP CODE (POSTAL CODE): 110018

COUNTRY/AREA: INDIA

PHONE NUMBER (Include Area/Country Code): 91 866 9269638

FAX NUMBER (Include Area/Country Code):

E-MAIL ADDRESS: contact@elanimpex.in

Section 4 Parent Company Name/Address Information

(If applicable and If different from sections 2 and 3). If information is the same as another section, check which section:

- Section 2 - Facility Address Information
- Section 3 - Preferred Mailing Address Information
- None of the above

NAME OF PARENT COMPANY: Elan Impex

PARENT COMPANY SUFFIX: Manufacturing

STREET ADDRESS OF PARENT COMPANY, Line 1: 312 Vikas Kunj, Vikas Puri

STREET ADDRESS OF PARENT COMPANY, Line2:

CITY: New Delhi STATE/PROVINCE/TERRITORY: Delhi

ZIP CODE (POSTAL CODE): 110018

COUNTRY/AREA: INDIA

PHONE OF INDIVIDUAL AT PARENT COMPANY (Include Area/Country Code): 91 866 9269638

FAX # OF INDIVIDUAL AT PARENT COMPANY (Include Area/Country Code):

E-MAIL ADDRESS OF INDIVIDUAL AT PARENT COMPANY: contact@elanimpex.in

Section 5 Emergency Contact Information

For foreign facilities, FDA will use your U.S. agent as your emergency contact unless you choose to designate a different contact here.

If information is the same as another section, check which section:

- Same as Facility Address (Section 2)
- Same as U.S. Agent Information (Section 7)
- None of the above

INDIVIDUAL'S TITLE: INDIVIDUAL'S TITLE OTHER:

INDIVIDUAL'S NAME: _____
 INDIVIDUAL'S MIDDLE NAME: _____
 INDIVIDUAL'S LAST NAME: _____
 TITLE: _____
 EMERGENCY CONTACT PHONE (Include Area/Country Code): 91 866 9269638
 E-MAIL ADDRESS: contact@elanimpex.in

Section 6 Trade Names

(If this facility uses trade names other than that listed in section 2 above, list them below (E.G., "also doing business as," "facility also known as")):

ALTERNATE TRADE NAME #1: _____

Section 7 United States Agent

(To be completed by facilities located outside any state or territory of the United States, District Of Columbia, or The Commonwealth of Puerto Rico)

NAME OF U.S. AGENT: ITB HOLDINGS LLC
 ADDRESS, Line 1: 390 N Orange Ave Ste 2300
 ADDRESS, Line 2: _____
 CITY: Orlando STATE: Florida
 ZIP CODE (POSTAL CODE): 32801 COUNTRY/AREA: UNITED STATES
 PHONE NUMBER (Include Area/Country Code): 855 3897344 1
 EMERGENCY CONTACT PHONE NUMBER (Include Area Code): 855 3897344
 FAX NUMBER (Include Area/Country Code): _____
 EMAIL ADDRESS: fda@itbhdg.com

Section 8 Seasonal Facility Dates of Operation

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

For Harvest 1
 Start Month: _____ End Month: _____
For Harvest 2
 Start Month: _____ End Month: _____

Section 9 General Product Categories - HUMAN/ANIMAL/BOTH

Food for Human Consumption Food for Animal Consumption

Section 9a Food for Human Consumption

To be completed by all food facilities. Please see instructions for further examples.	TYPE OF ACTIVITY CONDUCTED AT THE FACILITY (Optional) Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.												
	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 Processor	Low Acid Food Processor	Interstate Conveyance Caterer / Catering Point	Contract Sterilizer	Labeler / Relabeler	Manufacturer / Processor	Repacker / Packer	Salvage Operator (Reconditioner)	Farm Mixed-Type Facility	Other Activity Conducted (Please Specify Below Row 37)
<input type="checkbox"/> 1. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 4. BEVERAGE BASES [21 CFR 170.3 (n) (3), (35)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 5. CANDY WITHOUT CHOCOLATE, CANDY SPECIALTIES AND CHEWING GUM [21 CFR 170.3 (n) (6), (9), (25), (38)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> 6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING /	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CITY: New Delhi

STATE/PROVINCE/TERRITORY: Delhi

ZIP CODE (POSTAL CODE): 110018

COUNTRY/AREA: INDIA

PHONE NUMBER (Include Area/Country Code): 91 866 9269638

FAX NUMBER (OPTIONAL; Include Area/Country Code):

E-MAIL ADDRESS (Required unless FDA has granted a waiver under 21 CFR 1.245): contact@elanimpex.in

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 the Submitter: Vivek

CHECK ONE BOX

A.OWNER, OPERATOR, OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)

B.INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION

ADDRESS INFORMATION FOR THE AUTHORIZING INDIVIDUAL: -N/A-

AUTHORIZING INDIVIDUAL STREET ADDRESS, Line1: -N/A-

AUTHORIZING INDIVIDUAL STREET ADDRESS, Line2: -N/A-

CITY: -N/A-

STATE/PROVINCE/TERRITORY: -N/A-

ZIP CODE (POSTAL CODE): -N/A-

COUNTRY/AREA: -N/A-

PHONE NUMBER (Include Area/Country Code): -N/A-

FAX NUMBER (Optional; Include Area/Country Code): -N/A-

E-MAIL ADDRESS (Required unless FDA has granted a waiver under 21 CFR 1.245): -N/A-