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 REC	GISTRATION NUMBER:
Section 2 Facility Name/Address Information	
FACILITY NAME: Elan Impex	
FACILITY NAME SUFFIX: Manufacturing	
FACILITY STREET ADDRESS, Line1: 312 Vikas Kunj, Vikas Puri	<del></del>
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	
<del>-</del>	ddroes Information)
(Complete this section only if different from Section 2, Facility Name/Ad	uuress miiumalium)
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: De	elhi
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	e same as another section, check which section.
( approado ana n'amoron nom occión o 2 ana o), n'importante an	
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	<del></del>
STREET ADDRESS OF PARENT COMPANY, Line2:	
CITY New Polisi	CTATE (DDOVINGE TERRITORY, DAIL)
CITY: New Delhi ZIP CODE (POSTAL CODE): 110018	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
	oontage amega you oncode to designate a dinerent contact nere.
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:

file:///C:/Users/DELL/Downloads/13016435758\_registration.html

INDIVIDUAL'S NAME:	
INDIVIDUAL'S MIDDLE NAME:	
INDIVIDUAL'S LAST NAME:	
TITLE:	
EMERGENCY CONTACT PHONE (Include Area/Country Code): 91 866 9269	638
E-MAIL ADDRESS: contact@elanimpex.in	
Section 6 Trade Names	
(If this facility uses trade names other than that listed i	n 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	
•	e or territory of the United States, District Of Columbia, or The Commenwealth 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 38973	14
FAX NUMBER (Include Area/Country Code):	
EMAIL ADDRESS: fda@itbhdg.com	
Section 8 Seasonal Facility Dates of Operation	1
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 - HUMA	N/ANIMAL/BOTH
Food for Human Consumption Food for An	imal Consumption

## **Section 9a Food for Human Consumption**

		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.													
food	ne completed by all I facilities. Please instructions for ner examples.	Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Warehouse / Holding Facility (e.g., storage	Frozen Food Storage Warehouse / Holding	Acidified Food Processor	Low Acid Food Processor	Interstate Conveyance Caterer / Catering Point	Contract		Manufacturer / Processor	Repacker / Packer	Salvage Operator (Reconditioner)	Farm Mixed- Type Facility	Other Activity Conducted (Please Specify Below Row 37)	
	1. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]														
	2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula														
	3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]														
	4. BEVERAGE BASES [21 CFR 170.3 (n) (3), (35)]														
	5. CANDY WITHOUT CHOCOLATE, CANDY SPECIALTIES AND CHEWING GUM [21 CFR 170.3 (n) (6), (9), (25), (38)]														
	6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING /														

2112	020			FDA -	FOOD FAC	JILITY RI	EGISTRA	IION		
	INSTANT CEREALS [21 CFR 170.3 (n) (4)]									
	7. CHEESE AND CHEESE PRODUCT CATEGORIES [21 CFR 170.3 (n) (5)]									
	a. Soft, Ripened Cheese									
	b. Semi-Soft Cheese									
	c. Hard Cheese									
	d. Other Cheeses and Cheese Products									
	8. CHOCOLATE AND COCOA PRODUCTS [21 CFR 170.3 (n) (3), (9), (38), (43)]									
	9. COFFEE AND TEA [21 CFR 170.3 (n) (3), (7)]									
	10. COLOR ADDITIVES FOR FOODS [21 CFR 170.3 (o) (4)]									
	11. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (Includes Medical Foods) [21 CFR 170.3 (n) (31)]									
	12. DIETARY SUPPLEMENT CATEGORIES									
	a. Proteins, Amino Acids, Fats and Lipid Substances [21 CFR 170.3(o) (20)]									
	b. Vitamins and Minerals									
	c. Animal By- Products and Extracts									
	d. Herbals and Botanicals									
	13. DRESSING AND CONDIMENTS [21 CFR 170.3 (n) (8), (12)]									
	14. FISHERY / SEAFOOD PRODUCT CATEGORIES [21 CFR 170.3 (n) (13), (15), (39), (40)]									
	a. Fin Fish, Whole or Filet									
	b. Molluscan Shellfish									
	c. Other Shellfish									
	d. Ready to Eat (RTE) Fishery Products									
	e. Processed and Other Fishery Products									
	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),									

/27/2	27/2020 FDA - FOOD FACILITY REGISTRATION												
	(12), (13), (14), (15), (16), (17), (18), (19), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32)]												
	16. FOOD SWEETENERS (NUTRITIVE) [21 CFR 170.3 (n) (9) (41), 21 CFR 170.3 (o) (21)]												
	17. FRUIT AND FRUIT PRODUCTS [21 CFR 170.3 (n) (16), (27), (28), (35), (43)]												
	a. Fresh Cut Produce												
	b. Raw Agricultural Commodities												
	c. Other Fruit and Fruit Products												
	18. FRUIT OR VEGETABLE JUICE, PULP OR CONCENTRATE PRODUCTS [21 CFR 170.3 (n) (3), (16), (35)]												
	19. GELATIN, RENNET, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)]												
	20. ICE CREAM AND RELATED PRODUCTS [21 CFR 170.3 (n) (20), (21)]												
	21. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)]												
	22. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)]												
	23. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]												
	24. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)]												
	25. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11) (14), (17), (18), (23), (24), (29), (34), (40)]												
	26. NUTS AND EDIBLE SEED PRODUCT CATEGORIES [21 CFR 170.3 (n) (26), (32)]												
	a. Nut and Nut Products												
	b. Edible Seed and Edible Seed Products												
	27. PREPARED SALAD PRODUCTS [21 CFR 170.3 (n)												

	(11), (17), (18), (22), (29), (34), (35)]													
	28. SHELL EGG AND EGG PRODUCT CATEGORIES [21 CFR 170.3 (n) (11), (14)]													
	a. Chicken Egg and Egg Products													
	b. Other Eggs and Egg Products													
	29. SNACK FOOD ITEMS (FLOUR, MEAL OR VEGETABLE BASE) [21 CFR 170.3 (n) (37)]													
	30. SPICES, FLAVORS, AND SALTS [21 CFR 170.3 (n) (26)]													
	31. SOUPS [21 CFR 170.3 (n) (39), (40)]													
	32. SOFT DRINKS AND WATERS [21 CFR 170.3 (n) (3), (35)]													
	33. VEGETABLE AND VEGETABLE PRODUCT CATEGORIES [21 CFR 170.3 (n) (19), (36)]													
	a. Fresh Cut Products													
	b. Raw Agricultural Commodities													
	c. Other Vegetable and Vegetable Products													
•	34. VEGETABLE OILS (INCLUDES OLIVE OIL) [21 CFR 170.3 (n) (12)]									•				
	35. VEGETABLE PROTEIN PRODUCTS (SIMULATED MEATS) [21 CFR 170.3 (n) (33)]													
	36. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS), OR STARCH [21 CFR 170.3 (n) (1), (23)]													
<b>✓</b>	37. NONE OF THE ABOVE FOOD CATEGORIES									•				
	e food categories I ENTIAL OILS AND			y, then prin	t the applic	able food	category or	categorie	s.					
	ESSENTIAL OILS AND MINT PRODUCTS  Other Activity Conducted													

## Section 10 - Owner, Operator or Agent in Charge Information

Provide the following information, If different from all other sections on the form. If information is the same as another section of the form, Check which section:

- Section 2 Facility Address Information
- Section 3 Preferred Mailing Address Information
- Section 4 Parent Company Address Information
- Section 7 US Agent Address Information

NAME OF ENTITY OR INDIVIDUAL WHO IS THE OWNER, OPERATOR, OR AGENT IN CHARGE: Vivek

STREET ADDRESS, Line 1: 312 Vikas Kunj, Vikas Puri

STREET ADDRESS, Line 2:

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-