Form Approval: OMB No.0910-0502

Expiration date: 08/31/2016

See OMB Statement at end of form

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please Note:

The system will automatically time out if there is no activity for 30 minutes and you will need to re-do your work from the beginning.

| Date: 01/13/20 | 15 15:49:30 | | | | | | | |
|---------------------|-----------------------------------------------------------------------------|-------------------------------------------------------|-----------------------|-----------|--|--|--|--|
| Are you a man No | afacturer, processer, or packer of food for human or animal consump | ition in the United States or do you hold such produc | S? Yes | | | | | |
| SECTI | ON 1 TYPE OF REGISTRATION | | | | | | | |
| 1a. FOI | FOREIGN REGISTRATION | | | | | | | |
| 1b. INI | INITIAL REGISTRATION: Registration number will be generated upon submission | | | | | | | |
| ARE YOU T | HE NEW OWNER OF A PREVIOUSLY REGISTERED FACII | LITY? Yes No | | | | | | |
| 1c. PRI | VIOUS OWNER'S TITLE : PREVIOUS OWNER'S NAME : | PREVIOUS OWNER'S REGISTRATION NUMBE | R: | | | | | |
| SECTI | ON 2 FACILITY NAME / ADDRESS I | NFORMATION | | | | | | |
| FACILITY N | AME: STEFANAKIS EMMANOUIL | | | | | | | |
| FACILITY N | AME SUFFIX: Manufacturing | F | ACILITY NAME SUFFIX O | R: | | | | |
| FACILITY S | TREET ADDRESS, Line 1: 09 , BELIBASAKI STR | | | | | | | |
| FACILITY S | FREET ADDRESS, Line 2: | | | | | | | |
| CITY: ARK | LOCHORI | S | TATE/PROVINCE/TERRITO | Irakleion | | | | |
| ZIP CODE (F | OSTAL CODE): 70300 | , | | | | | | |
| COUNTRY/A | REA: GREECE | | | | | | | |
| PHONE NUM | MBER (Include Area/Country Code): 030 28910 29066 | | | | | | | |
| | | | | | | | | |
| FAX NUMB | ER (Optional; Include Area/Country Code): 030 28910 29066 | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| E-MAIL ADI | DRESS: meligyris@gmail.com | | | | | | | |
| SECTI | ON 3 PREFERRED MAILING ADDRE | SS INFORMATION (Optional) | | | | | | |
| Complet | e this section if different from Section 2 | Facility Name/Address Information | tion (OPTIONAL) | | | | | |
| | _ | | 1 | | | | | |
| If informatio | n is the same as section 2, check the box: | | | | | | | |
| NAME: STEI | ANAKIS EMMANOUIL Manufacturing | | | | | | | |
| ADDRESS, I | ine 1: 09 , BELIBASAKI STR | | | | | | | |
| | · · · 2· | | | | | | | |
| ADDRESS, I | ine 2: | | | | | | | |
| CITY: ARK | | STATE/PROVINCE/TERRITORY: | Irakleion | | | | | |

| PHONE NUMBER (Include Area/Country Code): 030 28910 29066 | | |
|-----------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| FAX NUMBER (Optional; Include Area/Country Code): 030 28910 29066 | | |
| | | |
| E-MAIL ADDRESS (Optional): meligyris@gmail.com | | |
| SECTION 4 PARENT COMPANY NAME/ADDRESS INFORMAT | TION | |
| (If applicable and if different from sections 2 and 3). If information i | s the same as another section, | ck which section: |
| | | |
| Section 2 - Facility Address Information | | |
| Section 3 - Preferred Mailing Address Information | | |
| None of the above | | |
| NAME OF PARENT COMPANY: STEFANAKIS EMMANOUIL | | |
| PARENT COMPANY SUFFIX: Manufacturing | PARENT COMPANY SUFFIX | HER: |
| STREET ADDRESS OF PARENT COMPANY, Line 1: 09 , BELIBASAKI STR | | |
| STREET ADDRESS OF PARENT COMPANY, Line 2: | | |
| CUTY, ADVALOCHODI | CT A TE/NDOVINGE /FEDDINA | Tarblein |
| CITY: ARKALOCHORI ZIP CODE (POSTAL CODE): 70300 | STATE/PROVINCE/TERRIT(| Irakleion |
| COUNTRY/AREA: GREECE | | |
| PHONE OF INDIVIDUAL AT PARENT COMPANY (Include Area/Country Code): 030 28910 29066 | | |
| FAX # OF INDIVIDUAL AT PARENT COMPANY (Optional; Include Area/Country Code): 030 28910 29066 | | |
| E-MAIL ADDRESS OF INDIVIDUAL AT PARENT COMPANY (Optional): meligyris@gmail.com | | |
| (If this facility uses trade names other than that listed in section 2 about "Also doing business as," "Facility also known as"): | ove, list them below (e.g., | |
| ALTERNATE TRADE NAME #1: | | |
| SECTION 5 FACILITY EMERGENCY CONTACT INFORMATION | ON | |
| INDIVIDUALS TITLE (Optional): INDIVIDUALS TITLE OTHER: | | |
| INDIVIDUALS NAME (Optional): MELINA'S GOURMET FOODS Inc | | |
| INDIVIDUALS MIDDLE NAME (Optional): | | |
| INDIVIDUALS LAST NAME (Optional): | | |
| TITLE (Optional): | | |
| EMERGENCY CONTACT PHONE (Include Area/Country Code): 001 408 5406916 | | |
| E-MAIL ADDRESS (Optional): kosta@melinas.com | | |
| SECTION 6 TRADE NAMES | | |
| In the electronic version of FDA Form 3537, Section 6 (Trade Name | es) has been merged with Section | 1 (Parent Company Na |
| SECTION 7 UNITED STATES AGENT | | |
| (To be completed by facilities located outside any state or territory o | f the United States, District Of | lumbia, or The Comn |
| NAME OF U.S. AGENT: MELINA'S GOURMET FOODS Inc | | |
| ADDRESS, Line 1: 1822 Stone Avenue , San Jose CA | | |
| ADDRESS, Line 2: | | |
| CITY: San Jose | STATE: California | |
| | | |

| ZIP CODE (POSTAL CO | DE): 95125 | | | | | | | | COUN | TRY/AREA: UN | ITED STA | | |
|----------------------------------------------------|----------------------------|-------------|--------------------------------|----------------------------|-----------------|------------|------------|-----------------|------------|-----------------------------|-------------|-------------|---------------|
| PHONE NUMBER (Inclu | ide Area/Countr | y Code): 4 | 108 5406916 | 5 | | | | | | | | | |
| EMERGENCY CONTAC | T PHONE NU | MBER (In | clude Area | Code): 408 540 | 06916 | | | | | | | | |
| | | | | | | | | | | | | | |
| FAX NUMBER (Optiona | l; Include Area | Code): | | | | | | | | | | | |
| EMAIL ADDRESS: kosta | a@melinas.com | | | | | | | | | | | | |
| SECTION 8 | SEAS | ONAL | FACIL | ITY DAT | ES OF | OPER | ATION | (Optio | nal) | | | | |
| Optional - Give | the appro | oximat | te dates | that you | r facilit | y is op | en for | business | , if its | operations | are cn | seasonal b | oasis. |
| For Harvest 1 | | | | | | | | | | | | | |
| Start Month: | | | | | | | | | | End Month: | | | |
| For Harvest 2 | | | | | | | | | | | | | |
| Start Month: | | | | | | | | | | End Month: | | | |
| SECTION 9 | TYPE | OF ST | ORAGE | (FOR FA | ACILITIES | THAT | ARE P | RIMARIL | / HOLE | DERS) (OPT | TONAL | | |
| Ambien | t (neithe | er fro | zen no | ır refrio | erated |) Stor | age. | | | | | | |
| | ` | | ZCII IIC | n iciiig | Cratea |) 5101 | uge | | | | | | |
| Refriger | rated Sto | orage | | | | | | | | | | | |
| Frozen S | Storage | | | | | | | | | | | | |
| SECTION 10 | | AL PI | RODUC | T CATE | GORIES | – HUN | AAN/A | NIMAL/B | ютн | | | | |
| ⊽ | | | | | | | | | | | | | |
| Food for Human | Consumption | F | ood for Ani | mal Consump | otion | | | | | | | | |
| | | | | | | | | | | | | | |
| SECTION 10a | _ | | | | | | | HUMAN | CONS | UMPTION | and | PE OF AC | TIVITY |
| | CONDU | JC I EL | AI II | IE FACIL | .111 (01 | PIION | AL) | | | | | | |
| | TYPE OF AC | TIVITY C | ONDUCTE | D AT THE FAC | CILITY (Opt | tional) | | | | | | | |
| | Check all type food. | s of operat | tions that ar | e performed at | this facility r | egarding t | he manufac | turing/processi | ng, packin | g or holding of | | | |
| To be completed by all food facilities. Please see | , moranig | | | | | | | | | | | | |
| instructions for further examples. | (e.g. storage | ow Acid | Interstate Conveyance | | Ci | Contract | Labeler / | Manufacturer | Repacker | Salvage | | | |
| examples. | including F | ood | Caterer / Catering Point | Shellfish Establishment | Commissary | Sterilizer | | / Processor | / Packer | Operator (Reconditioner) | | | |
| | tanks, grain elevators) | | 1 Ollit | | | | | | | | | | |
| 6. CANDY WITHOUT | | | | | | | | | | | | | |
| CHOCOLATE, CANDY | | | | | | _ | _ | | _ | | | | |
| SPECIALTIES AND CHEWING | | | | | | | | ✓ | | | | | |
| GUM [21 CFR 170.3 (n) (6), | | | | | | | | | | | | | |
| [(9), (25), (38)] SECTION 11 | OMBLE | n And | EDA TAI | R, OR AG | ENT IN | CHAI | D.CE IN | CODMAI | LION | | | _ | |
| _ | _ | | | | | | | | | I.C.: | 41 | | |
| Provide the foll section: | owing ini | ormai | 10n, 11 C | imerent . | irom an | otner | section | is on the | IOIM. | 11 informa | tion is | same as | another secti |
| | | | | | | | | | | | | | |
| Section 2 - Facilit | ty Address Infor | mation | | | | | | | | | | | |
| Section 3 - Prefer | red Mailing Add | dress Info | rmation | | | | | | | | | | |
| Section 4 - Parent Company Address Information | | | | | | | | | | | | | |
| Section 4 - Parent | Company Addi | iess infort | пацоп | | | | | | | | | | |
| Section 7 - US A | - | | THE OWNER | D ODED ATO | D OD ACE | IT IN CIT | ADCE, em | EEANIAVIO D | MMANOT | Ш | | | |
| NAME OF ENTITY OR I | | | | K, OPERATOI | K, OK AGE | NI IN CH | ARGE: ST | EFANAKIS E | WMANOU | JIL | | | |
| STREET ADDRESS, Lin | | | | | | | | | | | | | |
| CITY: ARKALOCHORI | | | | | | | | S | ΓATE/PRO | OVINCE/TERRIT | ORY: Irak | 1 | |

| ZIP CODE (POSTAL CODE): 70300 | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| COUNTRY/AREA: GREECE | |
| PHONE NUMBER (Include Area/Country Code): 030 28910 29066 | |
| FAX NUMBER (Optional; Include Area/Country Code): 030 28910 29066 | |
| E-MAIL ADDRESS (Optional): meligyris@gmail.com | - |
| SECTION 12 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 13 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 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 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 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 penaltic | rm. By submitting this form to FDA, -in-charge of the facility) who submit or agent-in-charge must below identif |
| NAME OF PERSON SUBMITTING THIS REGISTRATION FORM: STEFANAKIS EMMANOUIL | |
| CHECK ONE BOX | |
| A. OWNER, OPERATOR, OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED) | |
| B. INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION | |
| IF YOU CHECKED BOX B ABOVE, INDICATE WHO AUTHORIZED YOU TO SUBMIT THE REGISTRATION: | |
| OWNER, OPERATOR, OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED) | |
| NAME OF INDIVIDUAL WHO AUTHORIZED REGISTRATION ON BEHALF OF OWNER, OPERATOR, OR AGENT IN CHARGE (FILL IN ADL'R | BELOW): -N/A- |
| ADDRESS INFORMATION FOR THE AUTHORIZING INDIVIDUAL: -N/A- | |
| AUTHORIZING INDIVIDUAL STREET ADDRESS, Line 1: -N/A- | |
| AUTHORIZING INDIVIDUAL STREET ADDRESS, Line 2: -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 (Optional): -N/A- | |
| | >> Submit |