CONTINUED COMPLIANCE

with

FDA FSVP AGENCY PROGRAM

- Confidential -

OVERVIEW *of* FSVP AGENCY

As your company's properly designated and qualified FDA FSVP Agent and FSVP Importer, United Safety Agents', *(USA)*, FDA-mandated responsibility is to verify that the physical, chemical, and biological hazards associated with all of your company's imported products have been – or will be – appropriately controlled prior to public consumption. Your company's Letter of Consent contains an exhaustive list of products for which USA has agreed to act as the FSVP Agent. The Letter of Consent, and the information that it contains, should only be provided when filing entry with U.S. Customs and Border Protection *(CBP)* during the importation of previously verified and approved products. If your company would like to import products that are not listed on your Letter of Consent, please notify USA immediately so that we may perform all required actions and ensure that any new products satisfy all FDA standards.

*REPORTING *of* ENTRIES*

To safeguard your company against fraudulent entries and maintain an accurate account of USA's Data Universal Numbering System *(DUNS)* number usage, we respectfully request that you submit record of all entries made under FSVP Agency. Please visit USA's **Register of Entries Portal** located at ***unitedsafetyagents.com/shipmentregister***. For each entry/line, we ask that you provide: A) the Date of Entry; B) the Entry/Line no.; C) the Name of the entered Product and its respective Supplier; and D) any other applicable data. You may submit this information either at the time of each entry or in bulk prior to the fifth day before the end of each month. In the event your company has not filed any entries within a given month, no action shall be necessary. *(see "fig. I")*

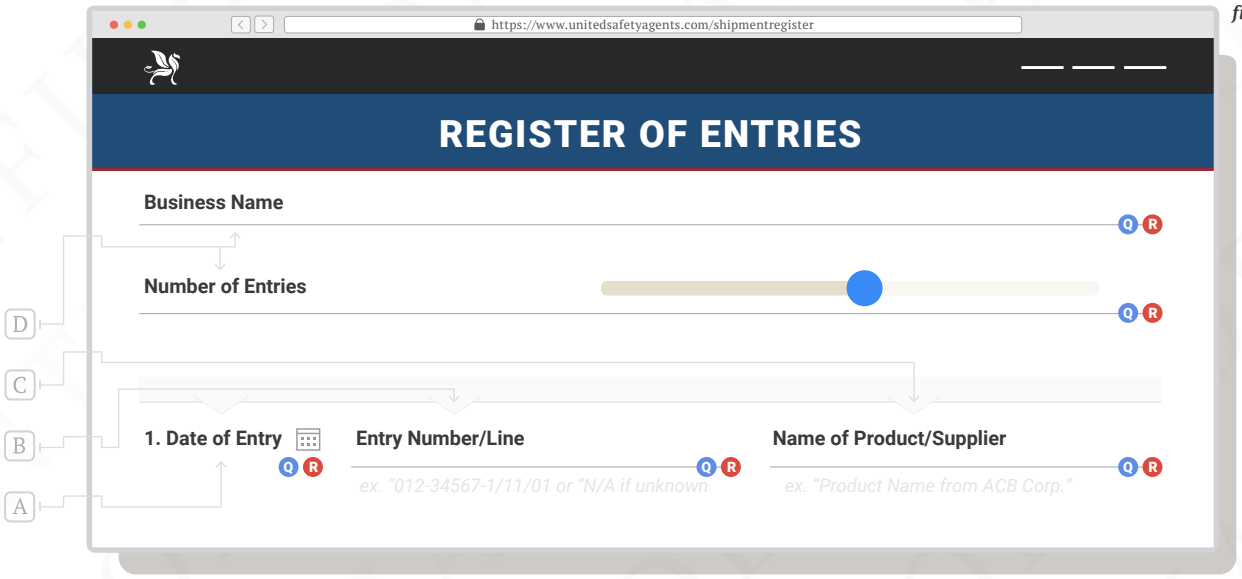

fig. I

Note: reported entry lines will be used for validation purposes only. FDA record will be used as a basis for shipment surcharges

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GUIDANCE *for* CUSTOMS FILER

Your Custom Broker / filer should always be provided with, and maintain on file, the most recent version of your company's Letter of Consent, in its full form. You shall not transcribe the information contained within the Letter of Consent onto a separate document. If your Customs Broker / filer requests that a separate "FSVP Importer" form be filled, please provide USA with a copy of said request so that we may complete and return it.

Additionally, we suggest the filer adhere to the following guidance: When a product under FDA oversight is offered for entry into the U.S., CBP's Automated Commercial Environment *(ACE system)* will prompt the filer to transmit a code. When prompted, **FSV** should be entered as the **Entity Role Code**. This code will send a signal to the ACE system indicating that the entry is subject to FSVP and will trigger a request for the details listed on the Letter of Consent.

DATA ELEMENT	CODE	CONDITION
Entity Role Code	FSV	IF GOVT Agency program code is FOO and processing code is NSF, PRO, ADD, DSU, FEE, THEN the following FSVP-related details will be mandatory for all FDA FOO lines unless Industry Codes 16 or 32 are present in **PG02**: **1.** DUNS#, Firm Name, Firm Address 1 are required in **PG19**; **2.** All the elements, except Apt#, are required in **PG20** AND **3.** Qualifier Code = FSV and eMail address are required in **PG21**; individual's name and tel# are optional in **PG21**. If line item is a food and the above items are not transmitted as above, the entry **will be rejected by CBP**. *Visit **unitedsafetyagents.com/filing** to learn more.*

Source: FDA Guidance for ACE/ITDA. Version 2.5.1. April 10, 2018. Pg 162

Please do not hesitate to place your company's Customs Broker / filer in contact with USA. We stand ready to answer any questions that they may have.

+1 (888) 551-7403 or *Schedule a Call*
info@unitedsafetyagents.com
8:00am - 7:00pm, Mon-Fri. *(Eastern, GMT -5/GMT-4)*

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ONGOING REQUEST *for* UPDATED DOCUMENTS

21 CFR part 1, subpart L requires that all FSVP records be updated and maintained. USA ensures that there will not be an FSVP-related issue during the entry process by continually monitoring each product's complianc with the relevant regulatory guidelinese. Depending on our determination and review of your company's specific product(s) and hazard profile(s), we request that the following documents be provided consistent with the marked intervals.

FACILITY FOOD SAFETY PLAN

- ☐ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☑ *refer to your company's manual*

HACCP PLAN / HARPC PLAN

- ☐ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☑ *refer to your company's manual*

ON-SITE AUDIT RESULTS

- ☐ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☑ *refer to your company's manual*

LABORATORY TESTING RESULTS

- ☐ if positive results are returned
- ☐ if recall or import refusal occurs
- ☐ if FDA inspection occurs
- ☐ on an annual basis
- ☐ on a quarterly basis
- ☐ on a per-batch basis
- ☐ prior to every shipment
- ☐ Chemical ☐ Biological
- ☑ *refer to your company's manual*

FACILITY LICENSE

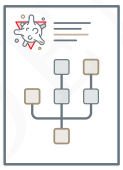
- ☐ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☑ *refer to your company's manual*

QUALIFICATIONS

- ☐ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☑ *refer to your company's manual*

PRODUCT LABEL

- ☐ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☑ *refer to your company's manual*



RECALL PLAN

- ☐ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☑ *refer to your company's manual*

IMPLEMENTATION RECORDS

- ☐ if recall or import refusal occurs
- ☐ if FDA inspection occurs
- ☐ on an annual basis
- ☐ on a quarterly basis
- ☐ on a per-batch basis
- ☐ prior to every shipment
- ☑ *refer to your company's manual*

FSVP QUESTIONNAIRE

- ☐ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☑ *refer to your company's manual*
  - *download copy*

MORE INFORMATION

Visit *unitedsafetyagents.com/documents*

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ANNUAL RECERTIFICATION

FSVP Agency coverage is annual for each registered product. All products must be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis, or sooner if any change occurs. To ensure that your company does not experience any issues at entry caused by a lapse in coverage, you can expect to receive a notification via email thirty (30) days prior to the end of each product's coverage term. To ensure receipt, please add *info@unitedsafetyagents.com* to your email client's safe senders list, address book, or contact list.

USEFUL LINKS

United Safety Agents' Website	***Website***
Register *of* Entries Portal	***Portal***
New: **FDA Registration** & **U.S. Agent** Portal	***Portal***
FDA Foreign Supplier Verification Program	***Website***
List *of* Food Safety Documents *for* FSVP	***Website***
List *of* Common Food Safety Hazards	***Website***
FSVP Supplier Questionnaire	***Document***
Additional Useful Information & Links	***Website***

CONFIDENTIALITY

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CONTACT

If you have any questions or require additional information, please contact United Safety Agents LLC directly via Email: info@unitedsafetyagents.com; Phone: +1 (888) 551-7403; Fax: +1 (888) 557-2649; UnitedSafetyAgents.com, or via Mail: 715 West Park Avenue, No. 222, Oakhurst, New Jersey 07755-9998, United States of America.

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The Foreign Supplier Verification Program *(FSVP)* compliance is mandatory. FSVP requires all imported food, beverage, and/or dietary supplement products to have been produced in compliance with processes and procedures that provide at least the same level of public health protection as those required domestically, among other requirements. Additionally, a properly designated and qualified United States *(U.S.)* representative *(also refered to as an FSVP Importer/Agent)* must verify that each imported product's physical, chemical, and biological hazards have been – or will be – controlled in an appropriate manner prior to public consumption. As provided by Title 21 of the Code of Federal Regulations, and elsewhere; the U.S. Food and Drug Administration *(FDA)* requires that an FSVP Importer/Agent be physically located within the U.S. and accept responsibility for FSVP compliance at entry.

PENALTIES *for* NON-COMPLIANCE

The importation or offering for importation into the United States of an article of food without the importer having an FSVP that meets the requirements of section 805 of the FD&C Act, including the requirements of this subpart, is prohibited under section 301(zz) of the FD&C Act. As provided by §1.514, FDA can impose a wide range of penalties when firms choose to operate outside of FSVP. FDA has confirmed their intentions to ensure compliance with FSVP.

Import Refusal An article of food is subject to refusal of admission under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act if it appears that the importer of that food fails to comply with FSVP.

Import Alert An Import Alert for FSVP noncompliance is applicable to any human/animal food subject to FSVP regulation, and allows FDA to detain imported foods at the port of entry under the protocol for Detention Without Physical Examination *(DWPE)*. **Import Alert 99-41**: An importer may be added to the Red List of this import alert because it appears that the importer is not in compliance with FSVP requirements for one or more foods.

Red List The specific food or foods from a specific foreign supplier may be included on the Red List to identify the food or foods that are subject to DWPE when imported or offered for import by the identified importer. In some cases, an importer may be subject to DWPE for all food that the importer imports if it appears that the importer is in violation of FSVP requirements for all such foods.

IMPORTANT

DO NOT import a food item bound under FSVP if: 01) the item has not successfully undergone FSVP verification and is currently approved for importation, or 02) your company's FSVP compliance coverage has expired.

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