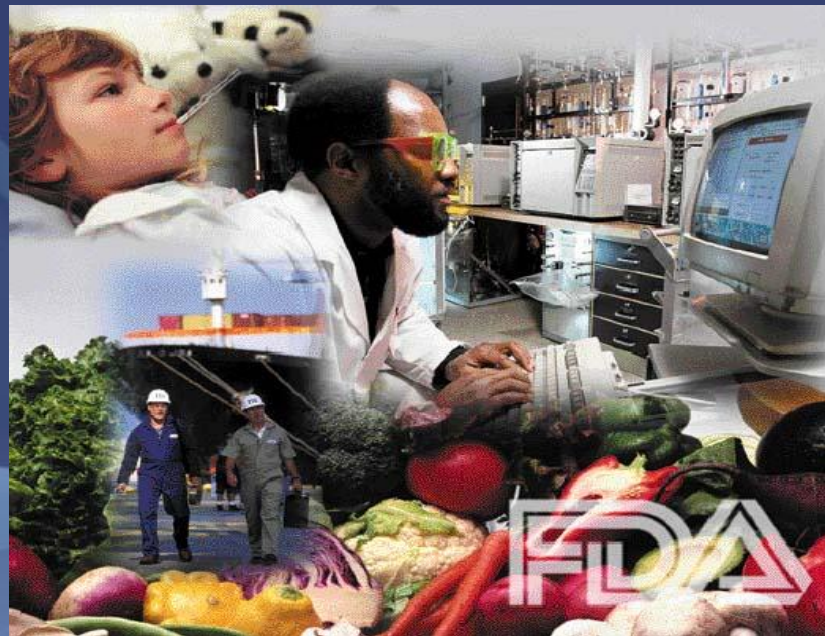


Food and Drug Administration (FDA) –
What you should know before exporting food products to the US



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US FOOD AND DRUG ADMINISTRATION-FDA

The FDA is the administrative agency responsible for ensuring the safety and effectiveness of drugs, medical supplies and food products in the United States.

The FDA's duty: to implement the Federal Food, Drug and Cosmetic Act and other laws aimed at protecting consumer health and security.

- The laws applicable to domestic food products are equally applied to imported food products.
- No certificates are provided to indicate that foreign products comply with US food standards; instead, they are inspected in the same manner as domestic food products.
- The inspection is performed in the nearest FDA District Office or at Customs Office at the port of entry.
- If the product or the labeling affixed to it are not suitable to the FDA standards, it may reject these products.

PRODUCTS THAT ARE SUBJECT TO FDA INSPECTION (1)

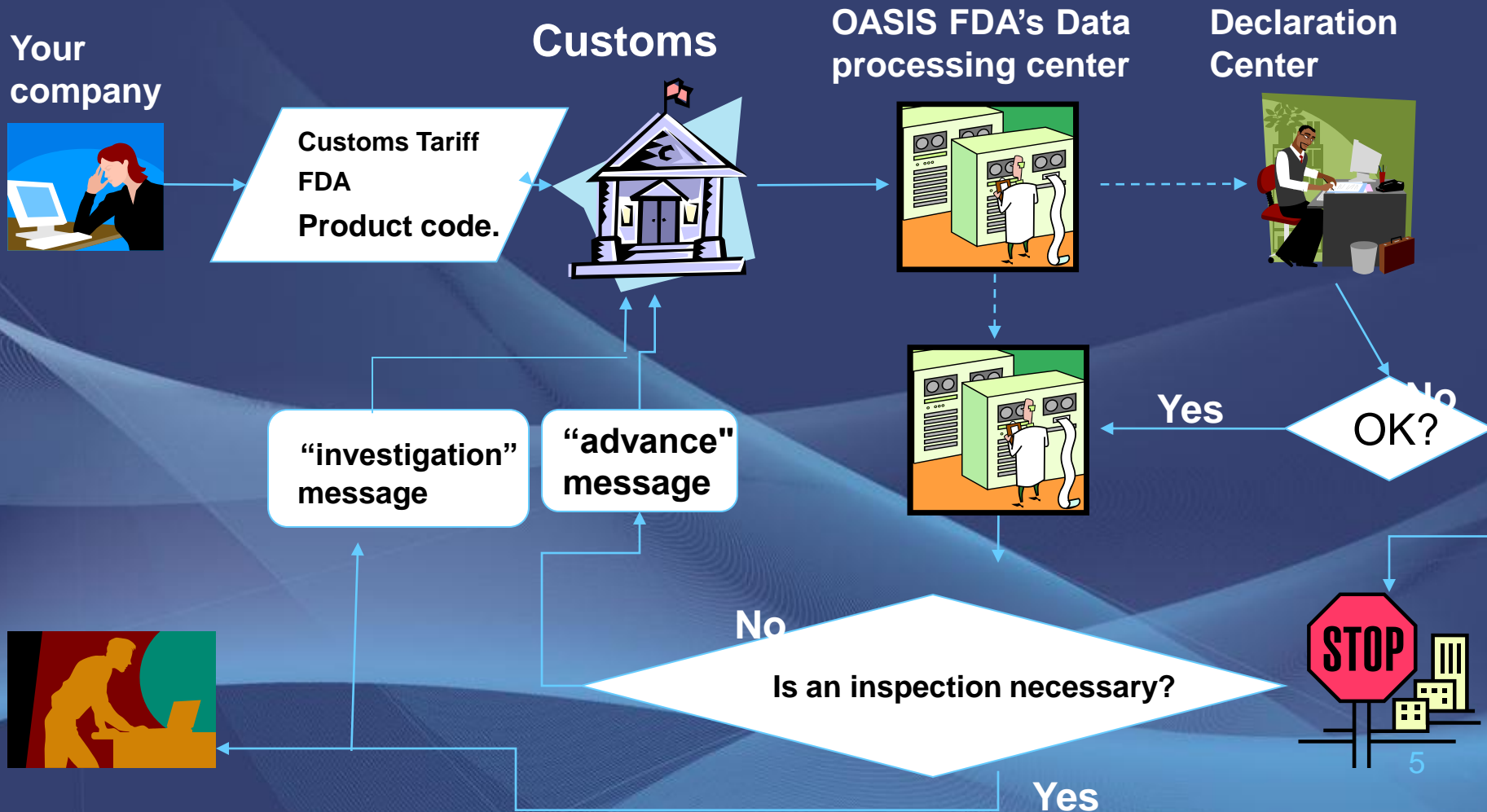
- All food products other than meat and poultry;
- Medicine sold with or without prescription;
- Medical products that contain blood;
- Vaccines;
- Tissue used for transplants;
- All medical materials;
- All tools, machines and equipment that emit radiation (microwave ovens included);
- Food and medication for animals;
- Cosmetic products;



FOOD PRODUCTS THAT ARE SUBJECT TO FDA INSPECTION (2)

- Diet products and all food products that contain diet products;
 - Baby formula;
 - Beverages (including alcoholic drinks and bottled water);
 - Fruits and vegetables;
 - Fish and seafood;
 - Canned and frozen food products;
 - Bakery products, snacks, and products containing sugar (including gum);
 - Raw agricultural products in the form of food or food additives.
- ❖ Meat, poultry and egg products are subject to USDA inspection and are exempt from FDA inspection.

Electronic transactions in connection with the import of food products



THE BIO-TERRORISM ACT (2002)

- Companies that wish to export foodstuffs to USA:
 1. Have to be registered in the FDA Registry
 2. Have to appoint an agent in the US
 3. Have to notify the FDA before each shipment

<http://www.fda.gov/oc/bioterrorism/bioact.html>



REGISTERING WITH THE FDA

Registration is mandatory for all companies that are involved with food products to be consumed in the US, including:

- All domestic and foreign producers and manufacturers;
- Companies engaged in packaging, warehousing and distribution of food products;
- Registration is required only once for each company and it can be done at:
<http://www.cfsan.fda.gov/~furls/ovffreg.html>



REGISTERING WITH THE FDA - 2

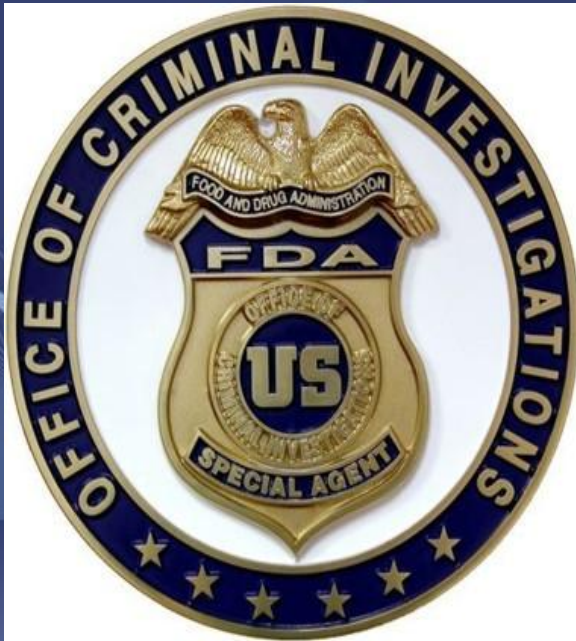
- If any of the registration information provided to the FDA changes at a later point of time, it should be reported within 60 days.
- The FDA's registration number given to the company only signifies that the company is in compliance with the 2002 Bio-Terrorism Act; however, it does not indicate that the FDA has found the company in compliance with the respective FDA standards for the goods exported.



REGISTRATION WITH THE FDA - 3

- Farms and restaurants are exempt from the registration requirement if the foreign farm exports the products directly to the US itself.
- However, if the farm sends the products to another company for processing, packaging or warehousing before sending them to the US, that company has to be registered in the FDA registry.
- When the product is produced, processed and packaged at the same location, that facility has to be registered with the FDA.
- If the products are being stored in a warehouse or cold storage before they are shipped to the US, the warehouse or storage facility has to be registered with the FDA.

Possible consequences from insufficient registration



- Failure to comply is considered to be a prohibited act under the Federal Food, Drug and Cosmetic Act.
- If the company has insufficiently registered, the FDA may keep the products at the port of entry (or in a FDA designated location upon entry) at the expense of the owner, purchaser, importer or consignee, until the completion of the missing registration.

DESIGNATION OF THE AGENT

- According to the Bioterrorism Act, foreign companies that wish to export food products into the United States must designate a US Agent for FDA communications.
- Agents are not required to be companies or organizations. An Agent may be an individual who has a residence or a place of business in the US and is physically present in this country.
- Each entity may only have one single agent for purposes of FDA registration. But there may be more than one agent for sales, etc.
- If the exporting company ships the goods without designating an agent in the US, the FDA will not allow these goods to clear Customs and enter the US. They cannot be delivered to the importer or to the consignee and they will be detained at the port of entry.

DESIGNATION OF THE AGENT – 2

- The agent establishes contact between the exporter and the FDA, and provides a signed document to the FDA attesting the veracity of the exporter's information.
- As a rule, the agent will not be held liable for any wrongdoing on the part of the exporter.
- Exceptions: in certain circumstances, the FDA can hold the agent responsible
 1. If the agent knowingly gives false information to the FDA;
 2. If the agent is the same legal entity as the food exporter.

WRITTEN NOTICE TO THE FDA (PRIOR NOTICE)

Information required in the Notice:

- Submitter (name, address, phone, fax, e-mail).
- Transmitter*, if different from submitter (name, address, phone, fax, e-mail).
- CBP entry type and if available, the CBP entry identifier.
- The identification of the articles of food, including complete FDA product code, the common or usual name or market name, the estimated quantity (from largest to smallest container size), and the lot or code numbers (if required under the FDA Act or Regulations).
- Name and address of importer*.
- Name and address of owner (if different than importer or ultimate consignee)*.
- Name and address of ultimate consignee*.

WRITTEN NOTICE TO THE FDA - 2

- A declaration stating the veracity of the information given to the FDA, and signed by the US Agent.
- For food no longer in its natural state, manufacturer name and address* (unless being sent by an individual as a personal gift).
- For food in its natural state, grower if known, or name and address of consolidator.
- FDA country of production.
- Shipper name and address*.
- Country from which the article is shipped.
- Anticipated arrival information (port of arrival and border crossing, date of arrival, time of arrival).
- Prior Notice can be submitted by any person knowledgeable of the required information.
- FDA requires Notices for each imported food entry, even if they are being sent in the same shipment.

WRITTEN NOTICE TO THE FDA - 3

- Mode of transportation.
- Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) Code.
- HTS (Harmonized Tariff Schedule) Code.
- Planned shipment information, where applicable :
 - All airway bill number, or bill of lading and container number, if containerized cargo;
 - Vessel name and voyage number;
 - Air flight number;
 - Road trip number;
 - Rail car number;
 - Private vehicle license plate number and state/province.

** Indicates that if registration number is provided, then only city and country are required instead of the full address. And/or not required for an article of food imported or offered for import for transshipment, storage and export, or further manipulation and export.*

WRITTEN NOTICE TO THE FDA - 4

- Except for the individual's name, as well as the name of the company and the street name where the company is located, all information must be submitted in English.
- The Notice to the FDA may be made electronically through one (1) of the two (2) systems:
 1. Automatic system of Customs and Border Protection:
(Automated Broker Interface of the Automated Commercial System - ABI/ACS)
<http://www.cbp.gov/xp/cgov/home.xml>
 2. FDA's early warning system:
(FDA's Prior Notice System Interface - PNSI)
<http://www.cfsan.fda.gov/~pn/pnoview.html>
- FDA will give the exporting company a confirmation number indicating that its Notice was appropriate and timely. The shipping company must have the FDA's confirmation number ready when the products arrive in the US.
<http://www.access.fda.gov>

Which food products are subject to FDA's Notice Requirement?

- Unless exempted, all food for human or animal consumption that is imported or offered for import into the US for use, storage or distribution in the US, is subject to prior notice. This also includes:
 - Food for gifts and trade;
 - Quality assurance/quality control samples;
 - Food for future export;
 - Food for transshipment through the US to another country (unless it does not leave the port of entry prior to being re-exported);
 - Food for use in a US Foreign Trade Zone;
 - Food sent by mail; and
 - Food sent by express couriers.

Products exempt from FDA's Mandatory Notice Requirement



- Food carried by or otherwise accompanying an individual entering the United States, if the food is for personal use and not commercial sale;
- Homemade food sent as a non-commercial gift to an individual in the US; and
- Meat, poultry or egg products that are exclusively regulated by the US Department of Agriculture at the time of importation.

TIME LIMITS FOR FDA NOTICE

- Time of **earliest** possible Notice
Except for food arriving by international mail*, Prior Notice cannot be submitted more than 5 days before the products' arrival to the US.
- Time of **latest** possible Notice
 1. By land or road transportation, a minimum of 2 hours before arrival.
 2. By air or rail transportation, a minimum of 4 hours before arrival.
 3. By marine transportation, a minimum of 8 hours before arrival.
 4. For mail shipments*, prior notice must be submitted before the food is mailed.

Acceptance of Notice by the FDA



- Upon receipt of the Notice, the FDA sends the exporting company a confirmation message and number indicating that the Notice was received and that it is being processed.
- However, the confirmation receipt is not indicative of whether the Notice sent was correct and/or timely.

A Subsequent Change in Information

- If there is any change in the initial information given to the FDA, it should be reported to the FDA in writing as soon as possible.
- If the estimated quantity, anticipated arrival information, planned shipment information or estimated date of mailing change after prior notice has been submitted, no action is required.
- All other changes will result in the need to resubmit Prior Notice and the timeframe will restart.
- If the shipment of food is cancelled, and the food will no longer be offered for import or imported into the US, then the previously submitted Prior Notices must be cancelled.

What happens to the products that have not been reported?

- FDA will not allow that company's products to clear Customs and enter the US unless the notification is made. They cannot be delivered to the importer or the consigned party and the products will be detained at the port of entry.
- If the food article is to be exported to another country and it does not leave the port of entry prior to being re-exported, there will be no need to have it detained for not being reported.
- Section 306 of the Bio-Terrorism Act, authorizes the FDA to forbid non-reporting persons or companies from exporting food products to the US.
- If, the delay notwithstanding, the FDA has examined and responded to the application, then the products are allowed to enter the US.

FDA Product Code

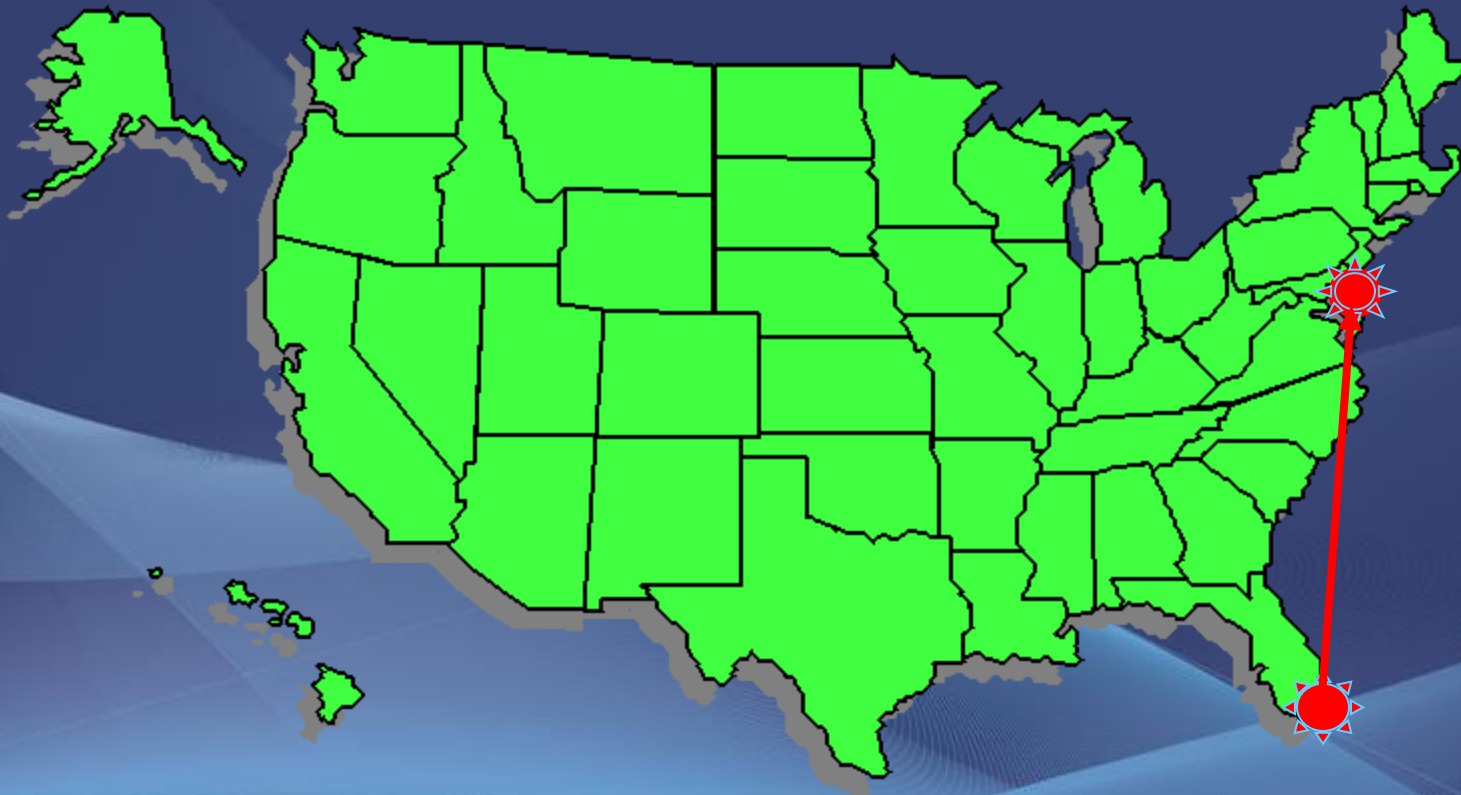
You can find the code number for the product you are going to export, from the FDA web page at the following addresses:

- 1. <http://www.accessdata.fda.gov/SCRIPTS/ORA/PCB/PCB.HTM>
- 2. <http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.cfm>
- Examples:
 - Soft Drink / Water – 29
 - Spices, Flavors and Salt – 28
 - Vegetable Oils – 26
 - Cosmetics – 53

Country of Production vs. Country of Origin (CBP)

- The term “Country of Origin”, which is found in the Customs Law is different from the term “Country of Production”, which can be found in the FDA Regulations.
- For **food products in their natural state**, Country of Origin and Country of Production are the same. The country where the produce is grown and gathered (including making it ready for shipment) is the Country of Production.
- For **processed food products**, Country of Origin and Country of Production may be different.
Example: Beans that were grown and dried in Turkey, and then processed and canned in another country (i.e.: Bulgaria).
- According to US Customs Law, Country of Origin is the country where they were grown, in this case, Turkey. But, when it comes to the written Notice to the FDA, they are considered as canned beans. Therefore, according to FDA’s regulations, the Country of Production is the country where the dried beans are processed and canned, that is in this case, Bulgaria.

Port of Entry vs. Port of Arrival



Port of Entry vs. Port of Arrival

- **Port of Arrival:** Whether goods arrive by air, sea or land transportation, it is the physical point where the food products arrive for the first time on US soil.
- **Port of Entry:** Where the goods make their entry for Customs purposes.
- In the Notice to the FDA, the port of arrival must be indicated. Note that **the port of arrival may be different from the port of entry** – where the goods actually clear US Customs inspection.
- The Notice must include the correct port of arrival. Wherever the point of arrival is, the FDA District Office of that state will be dealing with all FDA related matters.

US Food Products Import Procedure

- Every shipment is inspected for appearance and condition; conformity is checked for labeling and certificates. In addition, they are checked for the need of product investigation and laboratory analysis.
- If the products cannot pass these tests, their entry in the US is denied. Within 90 days of rejection the products must either be destroyed or exported to another country. If this is not done, products are sent back to the exporter and the cost is deducted from the security deposit.

Inspection of the Samples

- If the FDA has collected samples from the products, the Importer may not distribute them until they have been inspected and the FDA has rendered a decision.
- Generally, the testing of the samples takes 10 days. For products that have a shelf life of 7 days or less, the sample inspection and report are done before 5:00 pm of the following day the samples were collected.



FDA Control Procedure - 1

- Import operation starts when the importer sends product entry documents to Customs and Border Protection (CBP).
- Through OASIS, CBP will send the documents received from the importer or the Customs broker, to the applicable FDA District Office. CBP notifies the FDA's District Office of all product entries.
- Upon examining the entry information, the FDA will decide whether to: Allow the products to enter without investigation; collect samples and analyze; or subject the products to Automatic Detention.
- If the products are not required to be inspected, the District Office issues the "May Proceed Notice", which allows the products to enter. In 80% of electronic applications, the "May Proceed Notice" is obtained a few minutes after the FDA analyzes the data through OASIS.
- If the products do not need to be investigated, District Office issues a "Permission Notice" allowing their entry.

FDA Inspection Procedure - 2

- Import Alerts will be issued to identify those products or shippers that have met the criteria for automatic detention. It indicates a mandatory inspection for that class of products.
- If the study of the sample reveals that the product is in compliance with the applicable standards, the District Office issues a "Product Release Notice" and allows the import. In that case, the FDA will pay the cost of the sample products to the importer and/or owner of the products.
- If the inspection, sampling or label inspection performed at the port, or another evidence indicate that the products violate the applicable standards, District Office prepares a release Notice adding its interpretation. If the violation is serious, it may decide, as a precaution, to confiscate the products and to schedule a Hearing/Meeting with the importer or owner.
-
- Confiscation Notice clearly indicates the nature of the violation, and also indicates a date for an unofficial meeting within ten (10) days.
- FDA also issues a list of weekly confiscations.

FDA's Authority

- **The right to detain the products**
 - If the products entered the US without written Notice, registration and/or appointment of an US agent, the FDA has the right to detain the products until these conditions are satisfied.
- **The right to seize the products**
 - If the food products can create a danger for human health and FDA has sufficient evidence to prove this, the Harbor Master can decide to seize the products.
 - If you are, or are importing with the assistance of, an importer who has been previously convicted of a crime related to importing a health hazard.
- **The right to enjoin an importer**
 - It is possible for the FDA to enjoin an importing company which has imported products that do not conform with FDA standards.
 - After their conformity with the standards are proven, the goods seized by the FDA are turned over to an importer with no prohibition.

FDA's Authority – 2

- **The right to impose monetary penalty**
 - FDA may impose monetary penalty according to The Food Quality Protection Act (21 U.S.C 333(f)) without a court order.
 - General Application: FDA first sends a warning letter, then applies the monetary penalty. But, in case of a very severe violation, the money penalty may be imposed without the warning letter.
- **The right to seize the products – 2**
 - In case of a violation of standards (adulteration).
 - If false or misleading labeling is used.
 - If there is a health hazard or a fraudulent situation.
 - If there is something contrary to Federal Food, Drug, and Cosmetic Act.
- **The right to go to court**
 - FDA, after seizing the products, may go to court and ask for an injunction against the importing and distributing company.

Situations that violate Standards

- Adulteration: When the food product contains part or whole piece that belongs to a sick animal.
- Added Bulk: When a foreign material is added to a product to increase its weight, or reduce its quality or to improve its appearance.
- Alcohol: The amount of alcohol that is used to enhance taste to be more than 1% or ½ its volume.
- Allergen: When labeling on the product does not indicate the allergens it contains.
- Bacteria: Contains Bacteria.
- Calibrating: Using different weight measurement units than the ones used in the US; misinformation.
- Food Additive: containing food additives.
- Misbranding: i.e. product containing a component considered a health hazard if used in the indicated amount on the label; or any other kind of labeling irregularity.
- Having something poisonous or contagious in the container in which the product was shipped.
- The facilities in which the food product is produced and the method by which it is produced being different than usual. Having minimal control in Production, manufacturing and packaging.

Security - 1

- While waiting for the FDA's decision, of the owner or the importer may post a security deposit, receive the products, change the labeling or make corrections – this is called “30 day Conditional Release”.
- During this Conditional Release period, the owner/importer must keep the merchandise ready for the FDA to take samples and perform inspections; and if FDA rejects the merchandise, it should be returned to Customs.
- Amount of security deposit is: Price of products + Customs tariff + taxes.
- If asked to do so, the importer must return the products to the port of entry at the end of this 30 day conditional release. The merchandise is kept until the "May Proceed" Notice or “Release” Notice is received from the FDA.
- FDA may ask Customs to return the merchandise to owner/importer under these circumstances:
 - If the sampled merchandise could not be preserved until the FDA's Proceed or Release Notice is issued; or
 - If the entry of the merchandise is rejected.
- In the event of returning the merchandise to the owner or the importer, the security deposit is kept and until the FDA gives permission, the merchandise cannot be sold.

Security – 2

- The penalty for not returning the merchandise ranges from the face-value amount in the security deposit, to three (3) times the invoice price.
- If the importer does not return to Customs the merchandise found in violation of standards, it may sue the company, confiscate the security deposit and get as much as three(3) times its value.
- In opposition, if the merchandise was not returned to Customs because of an unforeseen reason without any foul intention, the company may sue Customs, offer to pay a smaller amount of restitution and request to have its responsibility for security to be terminated.
- If the products are not returned, and instead are sent to the market for sale, FDA may seek a Court injunction to stop the merchandise from being sold.

Product Admittance

- Execution of Notice and registration pre-conditions do not guarantee admittance of the products.
- Notwithstanding compliance with mandatory FDA registration and Notification, FDA may still refuse entry on the grounds that the products are in violation of the applicable standards.
- FDA notifies the importer/owner in case of the products being rejected, as well as admitted.



Approval or Denial

- If the products are found appropriate and approval is given for their import, they are immediately sent away from the port of entry for sale or distribution.
- If the goods are rejected, they will be kept in the port of entry. The specific location where the goods are kept (warehouse or container) must be reported to the FDA.
- FDA or US Customs are not responsible for transportation to another place or warehousing of the goods, as well as any expenses arising therefrom.
- Rejected products will never clear Customs and enter USA. However, importer/owner may still re-apply after making the necessary alterations, so the products can be in compliance with the applicable standards.
- Rejected food products may be removed to another location by making a security deposit.

Port shopping



- If a product, once rejected to enter the US, applies for import in the same manner at a later date, it is automatically considered in violation of standards. However, it is possible to re-apply after making the product comply with the standards.

Detention

- Detention may not exceed 20 days.
- However, if there is a situation that may cause a health hazard and that may require the FDA to seize the products or stop their distribution, then detention may be of 30 days.
- If the FDA's decision is just based on a possible violation of applicable standards, it may be overturned by a court if it can be proved to have been an arbitrary decision and lacking foundation.
- If FDA, after investigation decides to reject the products (and they do not have to be destroyed), they will be labeled "UNITED STATES: REFUSED ENTRY". This labeling is done at owner's expense.
- If upon information or evidence that the products may create a serious health hazard, the products are kept for an additional 24 hours at the port of entry for testing and evaluation.

Upon FDA's decision to Detain the products



- Importers can generally do one of the following:
 - Decline the costs and try to support their position by proving that the products are not in violation of applicable standards. This can be done in the form of special investigation reports, additional documents, etc.
 - Offer to bring their products into conformity.
 - Demand a document to be prepared immediately indicating rejection of the products.
 - Not reply.

Detention of Products without physical inspection (Automatic Detention)

- If the products are sanctioned without physical inspection but on a suspicion, in view of Import Alerts and previous records, a detention Notice and a meeting date are given to the importer to discuss the subject. The products are kept until the Importer, producer or the shipping company proves that they comply with FDA standards and directions.
- FDA sends a written Notice to inform about the results of automatic detentions, product inspections and investigations.
- If 25% or more of the inspected products are found non-compliant to the standards within a 6 month period; or if the product assortment is detained 3 or more times, FDA may reject same kind of products that come from that country or that producer, automatically, without inspection. If there is serious risk of health hazard, again , there may be an automatic detention.

Automatic Detention – 2

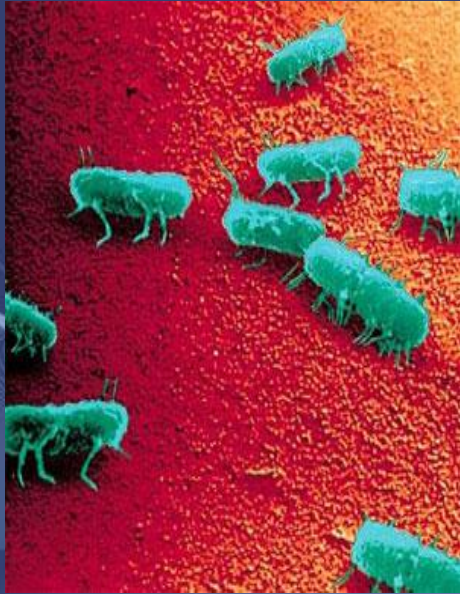
- If a company faces automatic detention by the FDA, it may file with the FDA a petition requesting cancellation of detention.
- In this situation, the FDA inquires as to whether the circumstances that led to the detention have been corrected.
- To achieve this, a report is requested from an independent laboratory, indicating that the products meet all applicable standards.
- FDA may later check the test results of this laboratory by comparing those results with previous ones from the same product group.
- A couple of court decisions indicate that FDA may impose automatic detention subsequent to sending a Notice explaining the relevant procedures.

Automatic Detention – 3

Products that have automatic detention:

- In 1994, canned tomatoes shipped from Italy were rejected on the grounds that they contained mold, and all shipments from that company and that exporter were rejected.
- In 1989, canned mushrooms that came from China.
- Canned tuna that came from various countries.
- Dried Raisins from Turkey were rejected without inspection, on the grounds that they contained unacceptable levels of lead and that they were hazardous to health. These decisions included the exporter's name. 15 samples out of a total of 22 were found containing unacceptable lead levels; therefore the FDA decided to reject all Turkish raisins.
- Detention based on a company name is very difficult because raisins can be bought in open market; therefore the FDA decided to reject all Turkish raisins without inspection.
- In 1996, Turkish pistachios were in the list of products to be detained without inspection. Furthermore, all food products that contain Turkish pistachios like halvah, were rejected because they contain the chemical Aflatoxin.

Products that are considered Dangerous



- 1985 – Salmonella typhimurium – improperly pasteurized milk – 200,000+ cases
- 1989 – Chilean grapes contaminated with cyanide
- 1993 – Jack-in-the-Box hamburgers, *E. coli*
- 1994 – Salmonella enteritidis – ice cream – 200,000+ cases
- 1996 – E. coli, bean sprouts, 7,000 cases
- 2002 – MDR *Salmonella* Newport (multi-state)
- 2002 – Multi-state *Listeria* outbreak

Example



Between 1997 and 1998, the largest seafood importer of Florida attempted to import 10.800 kilograms and \$4.443.000 worth of frozen lobsters from Mexico and Jamaica.

But the test results showed that the seafood had *Salmonella* bacteria. FDA rejected 10 shipments and ordered the importer to either destroy the products or export them to another country.

Penalty: 5 years prohibition, 3 years incarceration and \$500.000 restitution.

FDA's Import Alerts



- FDA's import operations and planning section prepares import alerts and issues them to 21 District Offices.
- FDA prepares those warnings if it has reason to believe that there is a pattern of violations in food product shipments received from certain countries, producers and shipping companies.
- At the present time, there are 330 alerts in effect. Accordingly, an automatic hold sanction is applied on almost 100% of products that are inspected.

Objection

- If FDA made a detention decision based on the product's appearance:
 1. You may request an unofficial hearing with the FDA District Office, at which you may be represented by counsel. You may argue that the products are not in violation of standards or that they may be re-labeled or transformed to meet the standards. The FDA will hold such meeting within 10 days from the request.
 2. You may submit test results from an independent laboratory.
 3. You may submit evidence indicating that the FDA's lab test results are unreliable and demand that your products be re-tested.
 4. Backed by scientific evidence or encapsulated in your Expert's Report, you may attempt to show your products do not violate the applicable standards.

Objection – 2

- Time is of the essence when importing food products. Therefore, even though a Court may overturn an FDA decision if proven arbitrary, the amount of time involved renders it impractical.
- At the hearing before the FDA District Office, you may be able to argue that your products do not violate the applicable standards and that the FDA misinterpreted the rules and standards. The FDA hearing between the importer, the manufacturer and the District Office may also be held by telephone conference. This hearing is in fact an opportunity given to the company to defend itself and generally the FDA is allowed to negotiate with the company. But the burden of proof is with the importer or the owner of the product.

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Shipment has arrived in the US

Registration of entry documents (within 5 days)

Customs Inspection

**If the products
are withdrawn**

**Customs will send the entry
documents to the FDA**

FDA will not conduct
a sample study

Notice of advancement

Products may be released

FDA will conduct
a sample study

Study in FDA Laboratory

Sample study results are announced
to Customs and the importers

**If the products could not be
withdrawn from Customs**

Objection to the harbormaster

Investigation

Court

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Study in FDA laboratory

Your Products conform
with the standards

Products will be released

Your Products are in violation
of the applicable standards

Importer will answer

Hearing at the FDA

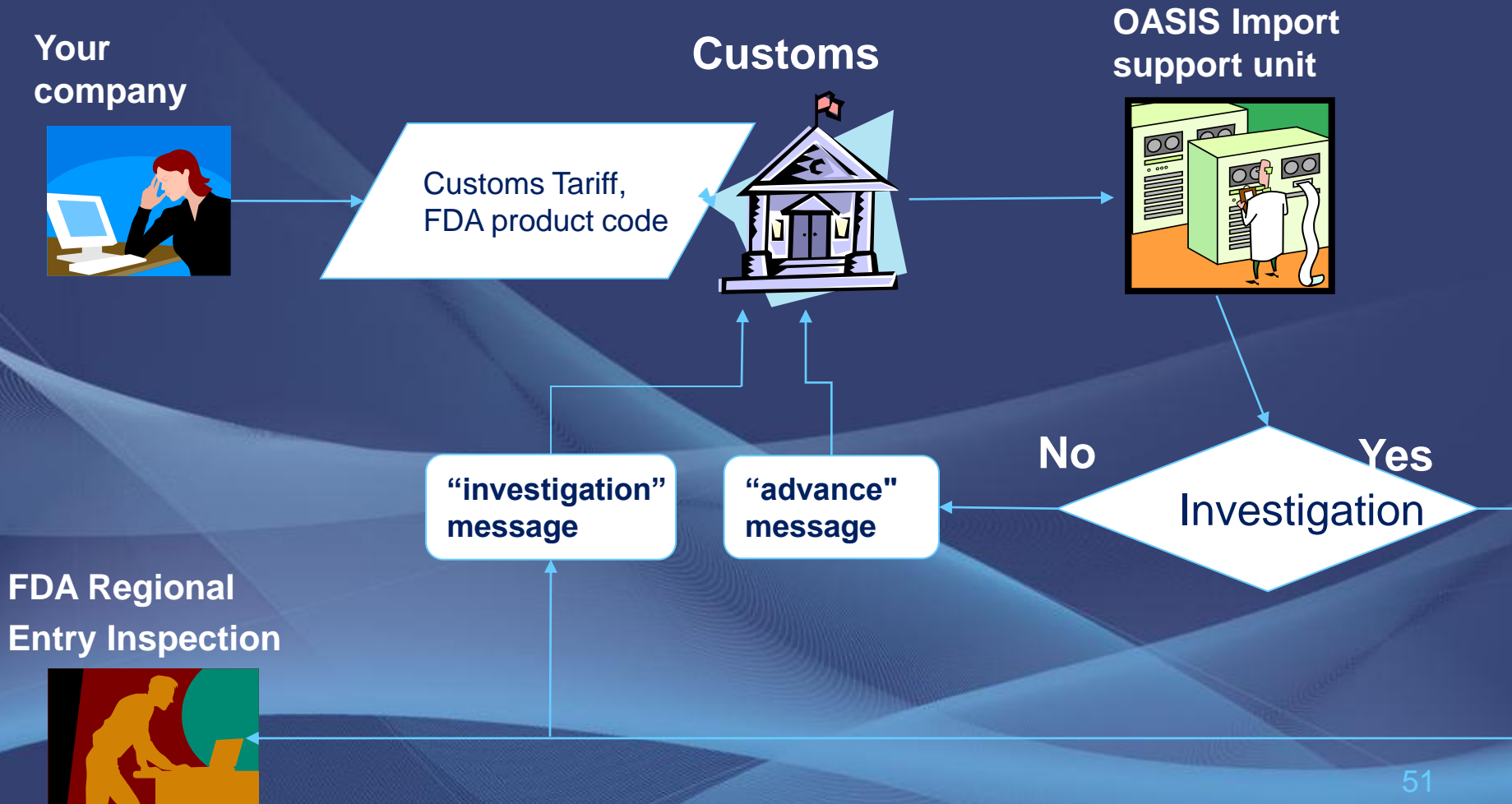
Evidence of conformity
will be submitted

Time demanded from
the FDA to make the products
conform with the standards

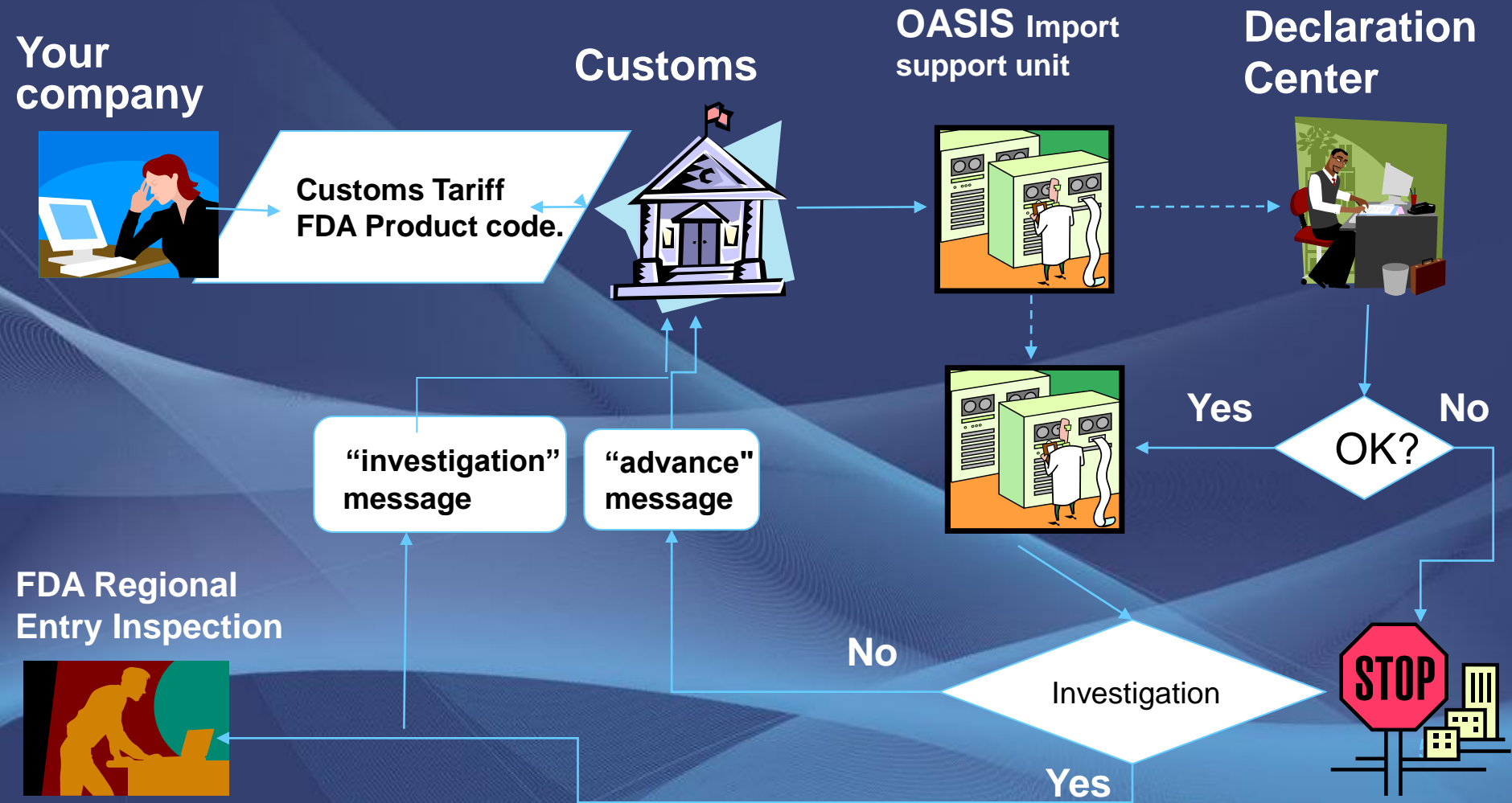
Importer will not answer

Notice of rejection

Electronic transactions for importing non food products.



Electronic transactions done when importing food products



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- FDA receives electronic information about entries from Customs (CBP) through CBP's ABI/ACS to OASIS.
- After information is transmitted from ABI/ACS, OASIS performs additional validations on the data. If no corrections from the importer's part are needed, it screens the entry information against FDA admissibility criteria. If the FDA electronic review determines that further evaluation is not necessary, the system transmits a message back through the FDA/CBP interface that it "may proceed without FDA examination". If further evaluation is necessary, FDA staff will review the entry information and may request additional information necessary to make an admissibility determination or may examine/sample the product.
- Finally, if the FDA determines that the product "appears, by examination or otherwise" to be subject to refusal of admission, the FDA will evaluate the entry information, take appropriate action and notify the importer and agent/customs broker.

Re-labeling and Changing – 1



- It is necessary for the importing company/owner to file an application to the FDA District Office requesting permission for re-packaging, re-labeling or any corrections, as a reply to the Notice of Detention and Hearing. The FDA attaches the correction report at the back of the application form.
- If the FDA District Office approves the correction, it issues a Notice “Detained and Released” for the products' release.
- The expenses related to storage of products during the detention and release procedure, are paid by the importer or owner of the products. This payment is made to Customs and is part of the security cancellation procedure.

Re-labeling and Changing – 2

- An application may be submitted for correction and change a second time. However, if the products cannot be made to comply with the standards after this, the District Office issues a “Rejection Notice”.
- If the District Office is convinced that the non-compliance cannot be corrected, it may issue the “Rejection Notice” in the beginning. If they think that the importer cannot correct the violation even though it is technically possible to correct it, they may reject the entry of those products and recommend Customs to order the destruction of the products. Generally, judicial objections to that kind of decisions are rejected.
- It is necessary to either destroy the products or export them to another country within 90 days.

Special Arrangements Used For Some Food Products

Cheese, Milk and Milk Products:

- Import permit is necessary;
- Quotas are in effect;
- Can only be imported by license holder.

Fruits, Vegetable and Snacks:

- Fresh or dried fruits, vegetables and snacks should be in compliance with the implementation of US grade regarding quantity and weight.
- These products are inspected by the Food Safety and Inspection Service of The Department of Agriculture, and a certificate is issued regarding the inspection.



General Implementation

- Generally, importing companies are working together with Customs brokers to enable their products entry.
- Applications and Notices are sent electronically to Customs and Border Protection (CBP) and later, the relevant information is transferred to the FDA electronically, for investigation.
- It is imperative that the information is correct and coherent. OASIS investigation depends entirely on the correct product code input.
- Evaluation of the registration Officer is used for control of coherence by the FDA.

General Recommendations

- All the information required for the Customs should be included in your invoice.
- Prepare your invoices carefully and legibly.
- Mark and number each package and make sure those numbers are clearly indicated in your invoice.
- Indicate the products in each package and list them in your invoice one by one.
- Mark your products indicating the country of origin and obey the labeling and marking rules used in the US.
- Always pay attention to the particular arrangements necessary for exporting products that require such treatment, like food and beverages.

General Recommendations – 2

- Follow the instructions given by your client regarding invoicing, packaging, marking and labeling.
- Pay attention to US Customs standards.
- Protect your facility by an alarm system to avoid any involvement with narcotics.
- Ship your products with shippers who use Automatic manifesting system.
- If you plan to work with a Customs broker, use a company who participates in the Automatic Broker Interface System.

CONCLUSION

Every participant in this chain needs the support in:

- Labeling of products;
- Registration and certificate operations;
- Registering the facility where the products are produced and processed;
- To make Notices on time;
- To keep records straight;
- For negotiations, in preparation of Agreements, Invoices and Bills of Lading;
- Every Exporter needs: A knowledgeable, accessible and trustworthy Customs broker.