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Seafood Safety and Compliance with FDA and CBP Regulations

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Boston Seafood Show

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Recognized as one of the “Best Lawyers in America” in the area of **FDA law** for years:

- 2009
- 2010
- 2011
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Do you have questions about importing/exporting?

http://www.grcustomslaw.com

Agenda

- FDA Import Process
- FDA Laws/Regulations
- FDA Detention and Refusal Process
- Import Alerts
- Detention Without Physical Examination
- Typical U.S. Customs Liquidated Damages Process

Federal Food, Drug and Cosmetic Act

- Imported products must fully comply with the Federal Food, Drug and Cosmetic Act before merchandise is released by U.S. Customs and FDA.

- 21 U.S.C. 301

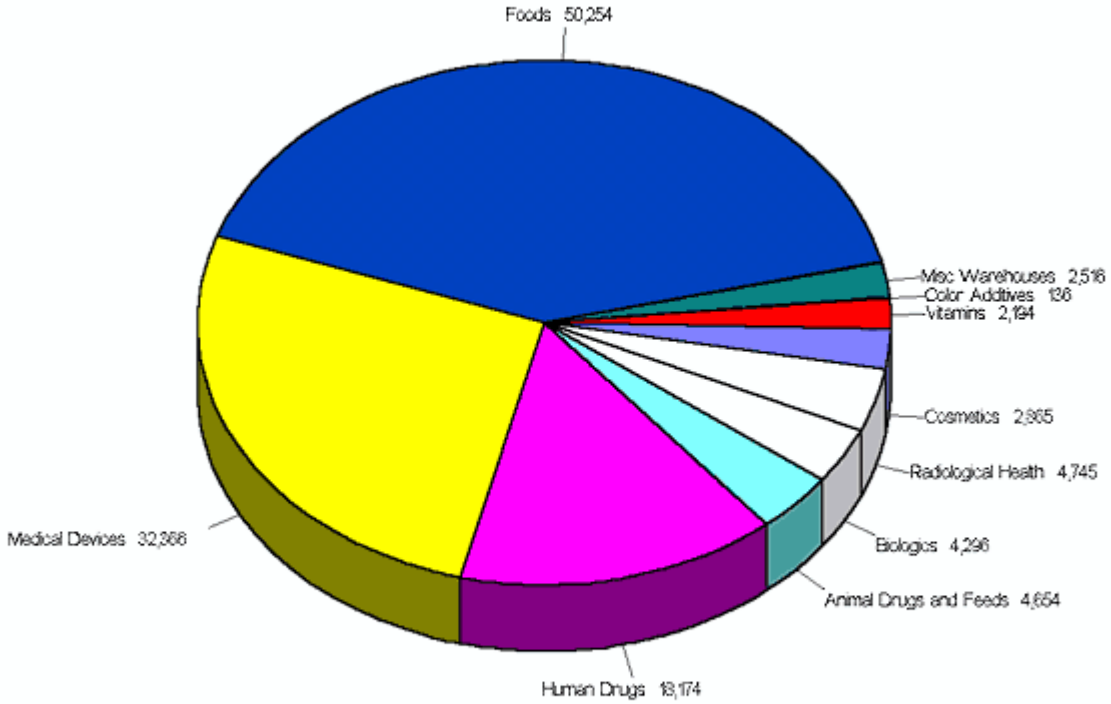
FDA Law

– 21 U.S.C. 381 – Imports and Exports

- Imports, list of registered foreign establishments
- Disposition of refused articles
- Reimportation
- Exports
- Temporary holds at ports of entry
- Warning notice
- Prior notice

FDA Inspection Responsibilities

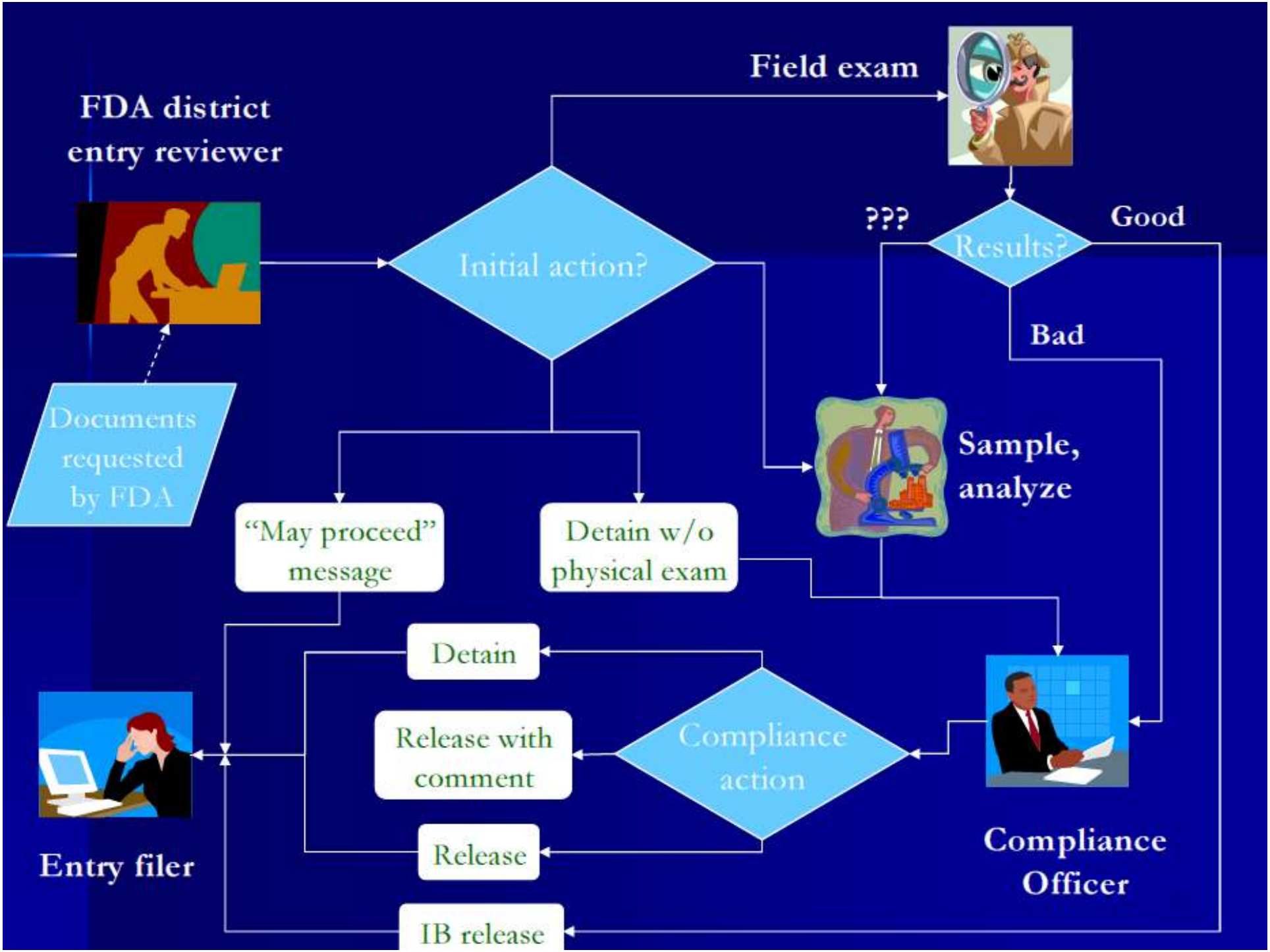
Total Establishments* 113,170



*FDA defines establishments as a business or other facility under one ownership and at one geographic location or address that processes, manufacturers, labels, repacks, stores, distributes, tests, or otherwise manipulates products under the jurisdiction of FDA. In addition, certain individuals or goups of individuals whose activities fall under the jurisdiction of FDA are also establishments. The sum of all categories is greater than the total because some establishments do business in more than one category.

Detention without Physical Examination (DWPE)

- DWPE is appropriate when there exists a
  - **history of the importation of violative products**,
  - or **products that may appear violative**,
  - or when **other information indicates that future entries may appear violative**
- Detention without physical examination properly places the responsibility for ensuring compliance with the law on the importer.


Field exam
FDA district entry reviewer
Initial action?
???
Results?
Good
Bad
Documents requested by FDA
Sample, analyze
"May proceed" message
Detain w/o physical exam
Detain
Release with comment
Compliance action
Release
IB release
Entry filer
Compliance Officer

Adulterated

- A food shall be deemed to be adulterated:

(1) if it bears or contains any poisonous or deleterious substance which may render it

- Injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if it the quantity of such substance in such food does not ordinarily render it injurious to health; or

(2) If it bears or contains any added poisonous or added deleterious substance

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance

Misbranded

- A food shall be deemed misbranded if:
  - (1) its **labeling** is false or misleading in any particular way; or
  - (2) its **advertising** is false or misleading in a material respect
    - If it is offered for sale under the name of another food
    - If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word “imitation” and, immediately thereafter, the name of the food imitated
    - If its container is so made, formed or filled as to be misleading.

Warning Letters

- Recent Warning Letters
  - Gorton's Fish Fillets
  - Nestle
  - Beech-nut
  - Dryers Grand Ice Cream, Inc.
  - Spectrum Organic Products, Inc.

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District
One Montvale Avenue
Stoneham, Massachusetts
02180
(781) 587-7500
FAX: (781) 587-7556

Warning Letter

CMS 266316

UNITED PARCEL SERVICE
OVERNIGHT DELIVERY

January 13, 2012

Mr. F. Nelson Blount
President
Blount Seafood Corporation
630 Currant Road
Fall River, MA 02720

Dear Mr. Blount

We inspected your seafood processing facility, located at 630 Currant Road, Fall River, MA on November 17-18, 2011, November 21, 2011, November 28, 2011 and December 6, 2011. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123, and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR 123 & 110). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your retail and bulk, refrigerated modified atmosphere seafood soups are adulterated, in that they been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov[1].

We have reviewed your firm's response of December 27, 2011 and note that it lacks sufficient corrective actions.

Your significant violations were as follows:

Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

FEB 22 2010

WARNING LETTER

VIA OVERNIGHT MAIL

Judson Reis, President & CEO
Gorton's, Inc.
128 Rogers Street
Gloucester, Massachusetts 01930

Re: CFSAN-OC-10-03

Dear Mr. Reis:

The Food and Drug Administration (FDA) has reviewed the label for your "Gorton's Beer Batter Crispy Battered Fish Fillets" product. Based on our review, we have concluded that this product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, **Code of Federal Regulations**, Part 101 (21 CFR 101). Your "Gorton's Beer Batter Crispy Battered Fish Fillets" product is misbranded within the meaning of section 403(r)(1)(A) of the Act [21 USC § 343(r)(1)(A)] because the product label bears a nutrient content claim but does not meet the requirements to make the claim. You can find copies of the Act and these regulations through links in FDA's home page at http://www.fda.gov.

Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (or by delegation, FDA) authorizing the use of such a claim. Characterizing the level of a nutrient in food labeling of a product without complying with the specific requirements pertaining to nutrient content claims for that nutrient misbrands

Import Alert Example #1

- Import Alert: #16-81
- Published Date: May 13, 2010
- Type: DWPE (detention without physical examination)
- Import Alert Name:
  - **“Detention Without Physical Examination of Seafood Products Due to Presence of Salmonella”**
  - Reason for Alert:
    - Division of Import Operations and Policy has received recommendations from districts for detention without physical examination of seafood products due to Salmonella contamination from specific manufacturers/shippers. This import alert has been developed for seafood products from firms/countries which do not readily fit into previously existing import alerts.

Import Alert Example #2

- Import Alert # 16-120
- Published Date: January 25, 2013
- Type: DWPE Import Alert Name:
  - **"Detention Without Physical Examination of Fish/Fishery Products from Foreign Processors (Mfrs.) Not in Compliance with Seafood HACCP"**
  - Reason for Alert:
    - On December 18, 1997, 21 CFR Part 123 became effective. Under this regulation, all fish and fishery products, whether foreign or domestic in origin, are required to be prepared, packed and held in facilities operating under mandatory HACCP requirements. Foreign processors who fail to meet these requirements may have entries subject to detention without physical examination until such time as such documentation demonstrating compliance is provided, as described in "GUIDANCE" section of this import alert.
    - FDA might determine the foreign processor's compliance through inspection of the foreign processor, inspection of an importer, review of import entry records, or through review of an importer's seafood product reconditioning proposal.

Removal from Import Alert List

- FDA's Regulatory Procedures Manual
  - Chapter 9 – Import Operations and Actions
  - **9-6 – Detention without Physical Examination (DWPE)**
    - *Available at*
    - http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179271.htm

Removal from Import Alert List

- FDA's Regulatory Procedures Manual provides guidance to those who wish to get off the Import Alert list:
- Generally, one would need:
  - A minimum of **five consecutive non-violative commercial shipments** must enter the U.S.,
  - At least **one of the five non-violative entries should be audited by the FDA** to ensure compliance,
  - The five shipments must be **over a reasonable time period**, not one day
  - A Petition must be filed with the FDA requesting that the importer be removed from the automatic detention list

FDA Notice of Sampling

- TITLE 21 – FOOD AND DRUGS
- FOOD AND DRUG ADMINISTRATION

- <u>GENERAL ENFORCEMENT REGULATIONS</u>
  - Sec. 1.90 – Notice of Sampling
    - When a sample of an article offered for import has been requested by the district director, the collector of customs having jurisdiction over the article shall give to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the district director or the collector of customs of the results of examination of the sample.

Lab Prospective on Sampling

- What importers should do from laboratory prospective when goods are tested/sampled by FDA

Prize Time Question

Which of the following is ***incorrect***?

A. FDA may detain products that "appear" to be in violation of FDA regulations

B. An example of "misbranded" labeling would be "100% juice" when there is really 75% juice

C. An example of "adulterated" labeling would be "100% juice" when there is really 75% juice

D. An example of an "adulterated" food would be one found to contain salmonella.

Detention Process Notice of FDA Action

- The Food, Drug and Cosmetic Act authorizes FDA to detain a regulated product that ***appears*** to be out of compliance.

- The FDA District Office will then issue a “Notice of FDA Action” specifying the nature of the violation to the owner or importer.

FDA Notice of Action

- Redelivery for FDA Examination Requested

Line	Product Description	Quantity
001	Food	85,000 lbs.

- A request has been made to CBP to order redelivery for all the above product(s) which were conditionally released to you under the terms of the entry bond.

Notice of FDA Action

- Products that appear (from examination or otherwise) to be violative may be detained and ultimately refused entry into the U.S.

- The standard for detention and refusal is extremely low – detention is permissible without actual observation of a product or its labeling.

FDA Notice of Action #1

- You have the right to provide oral or written testimony to the FDA, regarding the admissibility of the article or the manner in which the article can be brought into compliance

- Request extension from the FDA **NOW!**

Informal Hearing

- The owner or importer is entitled to an informal hearing in order to provide testimony regarding the admissibility of the product.

- "You have the right to provide oral or written testimony to the FDA, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance"

Private Lab

- FDA has the obligation of evaluating the analytical data submitted by private laboratories to determine whether import entries comply with the Act and can be released for sale.

- FDA is to be assured that the scientific data presented is technically valid, has been obtained using sound methods of sampling and analysis, and has recognized quality assurance measures applied.

- While the guidance is written in reference to private laboratories, it is really the importer that is ultimately responsible for the entry's compliance with applicable laws and regulations.

- If a private laboratory does not provide acceptable evidence and documentation to support the credibility of its analysis, the importer bears the responsibility and consequences of the inadequacy.

Private Lab (cont.)

- It should be noted that because circumstances vary among district offices and laboratories, there is no single set of procedures that can be prescribed for the entire field.

- For this reason, there is a guidance document that recommends suggested procedures. Districts and field laboratories may adapt them to their needs.

- The agency can make decisions on a lot-by-lot basis regarding the entries submitted for importation. The acceptability of the work performed by the private laboratory is an important element in this decision.

Top Food Product Refusals – February 2013

Industry	Number of Refusals
16 – Fishery/Seafood Prod	161
03 – Bakery Prod/Dough/Mix/Icing	113
02 – Whole Grain/Milled Grain Prod/Starch	103
24 – Vegetables/Vegetable Products	100
28 – Spices, Flavors and Salts	98
12 – Cheese/Cheese Prod	77
21 – Fruit/Fruit Product	74

[1] *Available at:* http://www.accessdata.fda.gov/scripts/importrefusals/ir_byProduct.cfm?DYear=2013&DMonth=2

Microbiology and Chemistry

Common lab analyses for detained products

- Nutritional Labeling
- Filth and Decomposition
- Pesticide Residues
- Salmonella
- E. Coli
- Methyl Mercury
- Nitrofurans
- Melamine
- Malachite Green
- Chloramphenicol
- Lea/Cadmium
- Flouroquinolones
- Aflatoxin
- Sulfites
- Mold
- Heavy Metals
- Listeria
- Gentian Violet

Hazard Analysis and Critical Control Point (HACCP)

- Many out-of-country manufacturers are unsure of the requirements or testing involved to enter the export stream or resolve issues, we can provide proactive knowledge and documentation to put in place the corrective actions required to prevent future detentions.

- As certified HACCP consultants, as well as microbiological experts, we are called upon frequently to troubleshoot such items as:
  - Contamination issues
  - HACCP Plan Publication and SOP Generation
  - GMP and SOP Audits
  - Developing microbiological and chemical sampling regimes to support governmental regulations and HACCP guidelines/SQF/Internal company food quality guidelines

- Specifically, what we can do for import/export clients is to evaluate their products, records and HACCP plans to ensure that their testing requirements and CoA's are in line with the FDA/USDA regulations on their specific products.

Conditional Release

- 19 C.F.R. 141.113. Food, Drugs, Devices and Cosmetics:
  - For purposes of determining the admissibility of any food, drug, device, or cosmetic, the release from CBP custody of any such product will be deemed conditional.
  - The conditional release period will terminate upon the earliest occurring of the following events:
    - 1) the date that FDA issues a notice of refusal of admission;
    - 2) the date that FDA issues a notice that the merchandise may proceed; OR
    - 3) Upon the end of the 30-day period following the date of release.

Second Notice of FDA Action

- If the owner fails to submit evidence that the product is in compliance or fails to submit a plan to bring the product into compliance, FDA will issue a ***second*** "Notice of FDA Action" refusing admission of the product.

Final Notice – FDA Action

- Subject: NO LOCATION RECEIVED

"You have been previously notified that this shipment is to be held intact for FDA examination and/or sampling. You have not advised us of the status or location of the lot represented by the referenced entry number. A written release from FDA is required before moving your goods in domestic commerce."

Notice of Refusal

- The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act in that they appear to be adulterated, misbranded or otherwise in violation.

Notice to Redeliver

"A request has been made to Customs to order redelivery for all the above product(s), in accordance with 19 C.F.R. 141.113, which were conditionally released to you under terms of the entry bond. Failure to redeliver into Customs custody will result in a claim for liquidated damages under the provisions of the entry bond."

Entry Bond – Agreement to Redeliver Merchandise

- Sec. 113.62 Basic Importation and Entry Bond Conditions
  - A bond for basic importation and entry shall contain the conditions listed in this section and may be either a single entry or a continuous bond.

- (d) Agreement to Redeliver Merchandise.
  - If merchandise is released conditionally from Customs custody to the principal before all required evidence is produced, before its quantity and value are determined, or before its right of admission into the United States is determined, the principal agrees to redeliver timely, on demand by Customs, the merchandise released if it:
    - (1) fails to comply with the laws or regulations governing admission into the United States;
    - (2) must be examined, inspected, or appraised as required by 19 U.S.C. 1499; OR
    - (3) must be marked with the country of origin as required by law or regulation. It is understood that any demand for redelivery will be made no later than 30 days after the date that the merchandise was released or 30 days after the end of the conditional release period (whichever is later). (See §§ 141.113(b), 12.73(b)(2),and 12.80 of this chapter.

Refusal

- The product then has to be exported or destroyed (in accordance with CBP Bulletin) within 90 days otherwise subject to Liquidated Damages.

- Failure to do so may result in destruction of the products. Distribution of the products may result in their seizure and/or injunction or criminal prosecution of persons responsible for their distribution.

Liquidated Damages Claim

- In accordance with 19 C.F.R. 141.113
- Redelivery Notice (date)
- Redelivery Required (date)
- “Described merchandise not redelivered into Customs custody after refused admission by the FDA”
- “Failure to comply with a demand for redelivery . . . Will result in the assessment of liquidated damages equal to three times the value of the merchandise . . .”

FP&F Petition Process

- Claim from CBP
- 60 Days to Respond
- Mitigating Factors

The Imported Seafood Safety Program

- FDA is responsible for the safety of all fish and fishery products entering the United States. The agency uses every available tool to identify immediate or potential threats as well as the best course of action to protect public health and safety. As part of the FDA's import safety effort, the agency provides as much available information and guidance as possible to consumers, industry, and government about seafood safety at www.fda.gov including:
  - HACCP
  - Foreign Inspections and Global Presence
  - PREDICT
  - Foreign Country Assessments
  - Food Safety Modernization Act
  - Integrated Food Safety System
  - National Residue Monitoring Program
  - Consumer Information

FDA's Fish and Fisheries Products Hazards and Controls Guidance

- FDA operates a mandatory safety program for all fish and fishery products under the provisions of the Federal Food, Drug and Cosmetic (FD&C) Act, the Public Health Service Act, and related regulations. The FDA program includes research, inspection, compliance, enforcement, outreach, and the development of regulations and guidance.
- As a cornerstone of that program, FDA publishes the *Fish and Fisheries Products Hazards and Controls Guidance*, an extensive compilation of the most up-to-date science and policy on the hazards that affect fish and fishery products and effective controls to prevent their occurrence. The fourth edition of this guidance document, which has become the foundation of fish and fishery product regulatory programs around the world, is now available at http://www.fda.gov.

QUESTIONS??

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