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TO : Brokers, Importers, ABI Filers and Other Interested Parties

FROM : Port Director,
Port Huron, Michigan

SUBJECT : PHASE V Implementation of the Bio-Terrorism Act, November 1, 2004

**BIOTERRORISM ACT (BTA) INTERIM PROCEDURES
FOR TRADE PARTNERS**

(UPDATED OCTOBER, 2004)

I. CBP PROCEDURES FOR BTA PROCESSING

Purpose: The purpose of this document is to provide guidance to trade partners engaged in the entry and release of imported food products, which are subject to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BTA), which was implemented on December 12, 2003.

Background: The BTA is intended to protect the health and safety of the people of the United States from an intended or actual terrorist attack on the nation's food supply. Under the Prior Notice (PN) requirements of the BTA, the Food and Drug Administration (FDA) must receive prior notice (electronically) for all food imported or offered for import into the United States. Any imported food products that are not in compliance with the PN requirements of the BTA, must be held at either the port of arrival or a secure facility until such time that they are either brought into compliance with the BTA or are exported from the United States with CBP approval.

Food: Under the BTA, "food" is defined as any of the following:

- Articles of food or drink used for man or other animals (human and animal food including dietary supplements)

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- Chewing gum
- Articles used as components of any such article, except for food contact substances and pesticides

BTA-Regulated Importations: The PN requirements of the BTA apply to all of the following regardless of value:

- All food imported or offered for import into the United States
- Imported food, which is stored or distributed in the United States
- Imported food and trade items
- Imported food transshipped through the United States to another country
- Food imported into the United States for future export
- Imported food admitted into a U.S. Foreign Trade Zone (FTZ)

BTA PN Exemptions: At this time, the FDA has exempted (or authorized enforcement discretion upon) the following classes of food products from the PN reporting requirements of the BTA:

- Meat, poultry and egg products subject to the exclusive jurisdiction of the United States Department of Agriculture (USDA).
- Homemade goods shipped as gifts
- Personal use food accompanying a traveler
- Food that is immediately exported (IE, in-bond type 63)
- Food contained in household goods
- Samples of food for non-consumption
- Food (as a gift) from an individual to an individual

Required PN Data: PN must include the following data elements:

- Product (by FDA Product Code)
- Manufacturer/Shipper/Grower
- Registration or Exemption Claim
- Country of Origin
- Country from which the product is shipped
- Anticipated port of arrival
- Anticipated date of arrival
- ACS entry type and date
- Bill of Lading/Air Waybill and/or in-bond number as appropriate

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Required PN Timeframes: For all imported shipments of BTA-regulated food products, PN must be provided to FDA within the following timeframes:

- **Land Border:** PN must be submitted 2 hours prior to arrival for shipments arriving at the border by commercial or passenger vehicles and pedestrians including permit ports, and 4 hours prior to arrival if arriving at the border by rail. Shipments arriving by ferry, contained in another conveyance (ex: truck, rail car, etc.), must meet land border reporting requirements for mode of travel.
- **Air:** PN must be submitted 4 hours prior to arrival for shipments arriving by air
- **Vessel:** PN must be submitted 8 hours prior to arrival for shipments arriving by vessel
- **International Mail:** PN must be submitted at the time of mailing in the foreign country

PN Submission: Any person or entity possessing the required knowledge can make the submission of PN data to FDA. However, the PN submission must be complete and filed within the required timeframes to satisfy the PN reporting requirements of the BTA. PN data can either be submitted via:

- ACS at the time of entry via the Automated Broker Interface (ABI) – This method uses the current FDA OASIS interface and adds data elements for PN submission. This is designed to work with ABI entries filed by ABI filers.
- ACS/ABI independent PN (via the WP transmission) – This is an interface with FDA that allows ABI filers to submit PN data independent of any entry data. For PN submissions made via the ABI independent interface, the submitter will receive a confirmation number from FDA, which must be provided with the entry documentation by the entry filer. Any ABI filer (including in-bond only filers) may use this interface to submit a PN for use with in-bond shipments, informal entries, Foreign Trade Zone (FTZ) admissions and any other entry type that is not fully automated.
- FDA Prior Notice System Interface (PNSI) – This is FDA's Internet based system that allows anyone to supply PN information directly to FDA. For PN submissions made through PNSI, the submitter will receive a confirmation number from FDA, which must be provided with the entry documentation by the entry filer. This may be used for informal entries filed by non-automated importers (walk-up entries), in-bond shipments, FTZ admissions, carnets, Section 321 releases and any other type of non-automated entry or release.

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PN Enforcement Guidelines for November 1, 2004 and thereafter: Failure to provide Prior Notice will result in refusal of shipment and/or penalty. FDA determination that Prior Notice data is inadequate will also result in refusal of merchandise.

All shipments of imported food that violate the PN reporting requirements will be either held at the port of arrival or sent to a secure facility until they can be brought into full compliance or are exported from the United States with CBP approval. In addition, penalties may be issued for egregious violators.

Determining PN Compliance: For all entry types that are processed through ACS Cargo Selectivity using a CBP 3461 or CBP 3461 ALT, CBP Officers will be able to review any necessary PN compliance information in ACS. For all entry types that are not processed through ACS Cargo Selectivity, the entry filer must provide a copy of the FDA confirmation number from either the FDA Prior Notice System Interface (PNSI) or ABI with the entry. This may be a screen print of the ABI (WP) Transmission or the FDA PNSI screen or the number may be written or printed on the entry or release documents. CBP Officers shall query this number in the ACS prior notice database using new function codes. These databases will contain a status field that will provide the current status of the prior notice.

- **Border Release Advanced Screening & Selectivity (BRASS):** Effective December 12, 2003, BRASS and Rail AMS Line Release processing was no longer allowed for the entry and release of imported food products that are subject to the PN reporting requirements of the BTA. All BTA-affected BRASS C-4 codes were revoked by that date. Any subsequent shipments will be required to be processed through ACS Cargo Selectivity using either a CBP 3461 or CBP 3461 Alt (including PAPS).
- **Permit Ports:** As of December 12, 2003, BTA-regulated merchandise was no longer allowed to be released strictly under a permit with subsequent release processing via the ACS BREL function code.

Importers holding a current valid permit for shipments of imported food will still be allowed entry and release at Northern Border permit ports after December 12, 2003, but they must also be processed through ACS Cargo Selectivity using either a CBP 3461 or CBP 3461 ALT and complete the PN process. In addition, importers of food products entered at a Northern Border permit port must continue to maintain a valid permit on file with the appropriate Port Director. This is not to be construed as an expansion of the use of these ports to include merchandise not covered by the current permits. The only requirement of this change is that food products covered by the BTA must file entry using Cargo Selectivity. CBP will attempt to

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accommodate any permit holder who wishes to use Selectivity for any entry at permit ports on a case-by-case basis.

Facsimile transmissions of CBP 3461 or CBP 3461 ALT documents will be accepted by CBP Officers at permit ports as long as the shipment is accompanied by a manifest and invoice. Port Directors are authorized to determine other methods of communicating CBP 3461 information to CBP Officers at permit ports.

Most permit ports do not have the equipment or space to perform examinations of imported merchandise, and lack secure facilities in which imported merchandise can be held until it can be brought into compliance with the BTA. In the case of a shipment, which is under a “BTA Hold”, CBP Officers will hold the shipment at the permit port of arrival and arrange for examination. If necessary the merchandise will remain at the permit port of arrival until the examination can be completed. Depending on the nature of required examinations, some of these may be performed at a permit port. However, if this is not possible, the shipment should be sent under a CBP bond (including in-bond) to the nearest port of entry with adequate equipment and facilities with which to perform the examination.

In addition, most permit ports do not have sufficient secure storage facilities located in close proximity to the port, which can be used to hold BTA-regulated merchandise until it can be brought into compliance with the BTA. In instances when BTA-regulated merchandise must be held at a secure facility and no such facility is available, the merchandise must be sent under a CBP bond (including in-bond) to the nearest port with an available secure facility or exported (see secure facility section). Shipments of BTA-regulated merchandise cannot be held at the importer’s premises, which also include any storage facilities owned or operated by the importer.

ACS Functionality and Messaging:

- **BTA Holds:** A “BTA Hold” can be placed on an entry or it can be placed on a bill of lading or air waybill in ACS. In either case, when a “BTA Hold” is placed on a shipment, it removes an existing release date, or prevents ACS from establishing a release date. However, “BTA Holds” do not cause an entry to be designated as “Intensive” by ACS Cargo Selectivity.
- **Downtime Policy:** CBP and FDA have jointly published a Contingency Plan for System Outages that describes various scenarios for continuation of operations when CBP and/or FDA systems fail. This is available at the FDA web site at: <http://www.CBPsan.fda.gov/~pn/pndguid.html>.

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- **“Pen & Ink Changes”:** For entries transmitted to CBP through the Automated Broker Interface (ABI), changes to the ABI entry data, also known as “Pen & Ink Changes”, will not be permitted if there is a “BTA Hold” associated to the shipment. Limited changes will be allowed to bill of lading and non-BTA entry lines if the shipment is not on hold. If disallowed changes are necessary, CBP must **CANCEL** the original entry and the filer must submit a new entry with the corrected entry data. It will be permissible for CBP users to add a line(s) if the tariff number does not have a BTA indicator in the harmonized file.
- **ABI LN Bill of Lading Corrections:** For entries transmitted to CBP via ABI that have a “BTA Hold” or a “BTA Hold Unset”, changes to bill of lading data cannot be made with the “ABI LN Bill of Lading Correction” capability. However, such changes can be made on entries with BTA-regulated merchandise that does not have a “BTA Hold or a “BTA Hold Unset.”
- **“On Screen Changes”:** If the entry has a “BTA Hold” or a “BTA Hold Unset”, field personnel will not be allowed to use the ACS onscreen change function to make any changes to header, line level, or to bill of lading or air waybill data.

II. ENTRY PROCESSING PROCEDURES

BTA-Regulated Merchandise Processing Procedures: The following paragraphs contain specific procedures for processing BTA merchandise with specific types of entries.

Verifying PN Status: As stated earlier, for all entry types that are processed through ACS Cargo Selectivity using a CBP 3461 or CBP 3461 ALT, CBP Officers will be able to review any necessary PN compliance information in ACS. Most in-bond entries will provide automated results as well (see in-bond section). For all non-automated entries or fully paper entry or release processes, the FDA confirmation number (and/or envelope number) must be provided with the entry. This may be a screen print of the ABI (WP) Transmission or the FDA PNSI screen or the number may be written or printed on the entry or release documents.

The shipments may be held at the port of arrival, moved to a secure facility or exported with CBP concurrence if a confirmation number is not provided at the time of movement. If the confirmation number is provided, the CBP officer will query the number using ACS to determine the PN status. If the status is “not satisfied”, the shipment may not be

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released and may be held at the port of arrival, moved to a secure facility or exported with CBP concurrence.

CBP 3461 & CBP 3461 ALT:

ABI

For all entry types that are transmitted through ABI and processed through ACS Cargo Selectivity using a CBP 3461 or CBP 3461 ALT, CBP Officers must determine if there is a “BTA Hold” on the shipment. If there is a “BTA Hold” on the shipment, CBP Officers must arrange to hold and examine the shipment. If the prior notice is inadequate the processing will not be completed.

Non-ABI

For any entries that utilize a CBP 3461 or CBP 3461 ALT not transmitted via ABI, the entry filer must provide the FDA confirmation number with the entry. This may be a screen print of the ABI (WP) Transmission or the FDA PNSI screen or the number may be written or printed on the entry or release documents. If the confirmation number is provided, CBP Officers shall query the number in the ACS prior notice database. If there is a “BTA Hold” on the shipment, CBP Officers will arrange to hold and examine the shipment. If the number is not provided or the status is “Not Satisfied” the shipment should not be released (see PN inadequate section).

CBP 7501: When an ABI transmitted CBP 7501 is used to simultaneously file the entry and entry summary for a shipment, CBP Officers must determine if there is a “BTA Hold” on the shipment. If there is a “BTA Hold” on the shipment, CBP Officers must arrange to hold and examine the shipment. If the prior notice is inadequate the processing will not be completed.

Non-ABI Informal Entries: For all informal entries (CBP 368, CBP 3299, CBP 3311, etc) that are not processed through ACS Cargo Selectivity, CBP Officers must first determine if the merchandise is subject to the BTA and whether it qualifies for any listed exemption to the PN reporting requirements of the BTA. After having accomplished this, CBP Officers should check that the FDA confirmation number is provided with the entry. This may be a screen print of the ABI (WP) Transmission or the FDA PNSI screen or the number may be written or printed on the entry or release documents. If the confirmation number is provided, CBP Officers will query the number in the ACS prior notice database. If there is a “BTA Hold” on the shipment, CBP Officers must arrange to hold and examine the shipment. If the number is not provided or the status is “Not Satisfied” the shipment will not be released (see PN inadequate section).

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Carnets: Since carnets are used for the temporary importation of merchandise that will be re-exported in the same form as when it was originally imported, food products are not generally imported under the cover of a carnet. To the extent that carnets are used to temporarily import BTA-regulated merchandise, the carnet should be accompanied by the FDA confirmation number showing that PN has been submitted for the shipment. This may be a screen print of the ABI (WP) Transmission or the FDA PNSI screen or the number may be written or printed on the entry or release documents. If the confirmation number is provided, CBP Officers shall query the number in the ACS prior notice database. If there is a "BTA Hold" on the shipment, CBP Officers must arrange to hold and examine the shipment. If the number is not provided or the status is "Not Satisfied" the shipment will not be released (see PN inadequate section).

FTZ & Warehouse Withdrawal Entries: Foreign Trade Zone entries (06) and warehouse withdrawals and rewarehouse entries (22) are not performed at the time of arrival and are exempt from the PN reporting requirements of the BTA. PN must be satisfied before the admission to the FTZ (or movement in-bond) or prior to filing a warehouse entry (Type 21) - Also see FTZ Procedures Section.

FAST/NCAP Shipments: Due to NCAP rules that do not allow shipments subject to other government agency requirements, there should be no FAST/NCAP shipments subject to PN.

FAST/PAPS Shipments: PAPS is a release process that accesses ACS Selectivity through a manifest number. The processing steps for CBP 3461 and CBP 3461 ALT apply to FAST/PAPS shipments as well. All BTA PN requirements apply.

Section 321 Releases: Section 321 releases from the manifest are allowed for BTA-regulated merchandise, but each line item requiring PN must be accompanied by the PN confirmation number issued by ABI or the FDA PNSI. This may be a screen print of the ABI (WP) Transmission or the FDA PNSI screen or the number may be written or printed on the entry or release documents. If the confirmation number is provided, CBP Officers shall query the number in the ACS prior notice database. If there is a "BTA Hold" on the shipment, CBP Officers must arrange to hold and examine the shipment. If the number is not provided or the status is "Not Satisfied" the shipment will not be released (see PN inadequate section).

Monthly Manifest: There should be no Monthly Master Manifest shipments subject to PN.

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III. FDA/BTA EXPRESS CONSIGNMENT PROCEDURES

General Processing Information

The prior notice provision of the Act covers food and beverages for human or animal consumption. This includes all express consignment shipments, for both commercial and personal use, **regardless of value**, unless exempt.

All shipments for which PN is inadequate will be refused admission and penalties may be issued for egregious violators. Shipments that are determined by targeting to pose a risk to the food supply will be held as they are identified.

Processing Procedures:

CBP processing in express consignment facilities will change as follows:

- There is no *de minimus* for merchandise subject to BTA, therefore, all shipments regardless of value, must meet the Prior Notice (PN) requirement. ABI transactions will be automatically validated in ACS during entry processing. In the case of Non-ABI shipments, CBP Officers will be required to validate PN submissions for these entries in the ACS system. CBP Officers will be required to validate each PN in ACS. PN confirmation numbers should be provided for each shipment where they are available. This may be a screen print of the ABI (WP) Transmission or the FDA PNSI screen or the number may be written or printed on the entry or release documents. The large express consignment operators have assured CBP and FDA that they will provide the prior notice confirmation numbers on the paper manifest or in their proprietary electronic systems used by CBP Officers.
- CBP Officers assigned to manifest or entry review will ensure that a Prior Notice Confirmation Number (PNCN) is listed on the manifest or other entry documentation for all applicable food shipments.
- All applicable food shipments found to have an inadequate PN, at the time of entry or manifest review, will be refused admission under Section 801(m)(1) of the Act (21 U.S.C. 381(m)(1) and held by the carrier at the Port of Entry (express consignment facility), other secure storage location or exported immediately.
- CBP will notify the carrier of each shipment refused under the auspices of the BTA.

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- A refused shipment may not be released to the importer, owner or consignee until FDA has notified CBP that the refusal is rescinded. If the express consignment carrier is the importer of record for release purposes they will not be considered as the importer or ultimate consignee for release or for storage issues.
- If an article of food that is refused is part of a shipment that contains other articles that are admissible, the refused articles may be segregated from the rest of the shipment under FDA or CBP supervision.
- Any article of food that has been refused under Section 801(m)(1) shall immediately be considered general order merchandise as described in Section 490 of the Tariff Act of 1930, as amended. Follow the Inadequate PN section of this publication for more information.
- The carrier, when instructed, will be responsible for holding specifically identified shipment(s) for BTA enforcement purposes.

IV. FDA/BTA IN-BOND PROCEDURES

General Processing Information

Immediate Export (IE) movements are exempt from prior notice (PN) reporting requirements of the Bioterrorism Act (BTA). Immediate Transportation (IT) movements are required to provide prior notice but may be allowed to move to the port where entry will be filed if there are no security concerns requiring examination or refusal.

For all Transportation and Exportation (T&E) in-bond movements, regardless of mode or method of transmission, the carrier should provide an indicator that the shipment contains "merchandise subject to FDA/BTA". In the automated environment, AMS, ABI (QP) and CAFES have been modified to accept a Y or N field labeled BTA. The party preparing the in-bond document will be responsible to provide notice with the CBP 7512 that merchandise on the shipment is subject to the prior notice requirements of the BTA. Someone (shipper, importer, broker etc) will file prior notice (PN) using ABI or FDA Prior Notice System Interface (PNSI) that references the in-bond number, bill of lading, air waybill or other unique identifier. No messages will be sent authorizing movement of the in-bond until prior notice is satisfied. In most cases ACS/AMS will query an ACS PN database to find PN information on file and return a status message to the CBP Officer, AMS and the trade.

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No shipments moving under a T&E in-bond will be allowed to move from the port of arrival without submitting prior notice. If the PN is inadequate, T&E movements will be held at the port of arrival until the prior notice is satisfied.

Fully Automated T&E Movements

Sea/Rail/Truck: The indicator that the shipment contains merchandise subject to the FDA/BTA should be set to “yes” by the carrier. AMS (and QP) will query the ACS prior notice database by in-bond number and bill of lading. If the in-bond number/BOL (T&E) is not in the database or the PN is inadequate:

- No movement authorization will be granted and the shipment will be held until the PN is satisfied. When the PN is satisfied, the movement authorization message will be sent. If the in-bond record is in the database the status of the prior notice will be checked.
- If the status is “PN Satisfied”, a movement authorization message will be generated and the shipment will be allowed to move.

If the status is “PN Not Satisfied” (within time frames):

- No movement authorization will be granted and the shipment will be held at the port of arrival until the PN is satisfied. When the PN is satisfied, the movement authorization message will be sent to the carrier.

If the status is “BTA Hold”:

- A hold will be sent to the carrier. CBP or FDA (or both) will coordinate to examine or sample the merchandise. If the merchandise is rejected or not allowed to move, the in-bond transaction will be cancelled.

Air: The indicator that the shipment contains merchandise subject to the FDA/BTA should be set to “yes” by the carrier. AMS will query the ACS prior notice database by in-bond number and air waybill. If the in-bond number/AWB (T&E) is not in the database or the PN is inadequate:

- No movement authorization will be granted and the shipment will be held until the PN is satisfied. When the PN is satisfied, the movement authorization message will be sent to the carrier.

If the in-bond record is in the database the status of the prior notice will be checked.

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- If the status is “PN Satisfied”, a movement authorization message will be generated and the shipment will be allowed to move.

If the status is “BTA Hold”:

- A hold will be sent to the carrier. CBP or FDA (or both) will coordinate to examine or sample the merchandise. If the merchandise is rejected or not allowed to move, the in-bond transaction will be cancelled.

Paper CBP 7512: The carrier or CBP 7512 preparer has three options for notifying CBP of the presence on an in-bond document of merchandise subject to the BTA:

- They may print or stamp the following statement at the bottom of the description block; “This Shipment Contains Merchandise Subject to The FDA/BTA”.
- They may put the above statement on a sticker affixed to the in-bond documents or on a cover page attached to the in-bond document.
- They may attach a copy of the FDA Prior Notice System Interface or ABI printout as a cover page for the in-bond documents.

When ACS processes the in-bond it will query the prior notice database by in-bond number and bill of lading or air waybill. If the in-bond number/BOL or AWB (IT or T&E) is not in the database:

- A “PN not satisfied” will be created. The information will also be displayed in public remarks if the AWB or BOL has been electronically transmitted. No movement authorization will be granted and the shipment will be held until the PN is satisfied. When the PN is satisfied, the movement authorization message will be sent to the carrier.

If the in-bond record is in the database the status of the prior notice will be checked.

- If the status is “PN Satisfied”, a movement authorization message will be generated and the shipment will be allowed to move.

If the status is “BTA Hold”:

- A “BTA Hold” will be displayed to the CBP Officer. The information will also be displayed in the public remarks and a hold will be sent to the carrier if the BOL or AWB was transmitted electronically. CBP or FDA (or both) will coordinate to

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examine or sample the merchandise. If the merchandise is rejected or not allowed to move, the in-bond transaction will be cancelled.

CBP 7512B (U.S./Canada Intransit Manifest): The CBP 7512B is used at land border locations on the northern border. Based on agreements between the two governments and codified in 19 CBPR Part 123, it establishes simplified procedures for bonded movement through contiguous countries. The same form is used by both governments and allows a single document to control movement through and into both countries. It is affected by the BTA as follows:

- Canadian Merchandise Intransit through the United States – Current processing treats this movement as a Transportation and Exportation (T&E) movement. All rules for land border T&E movements (see above) apply.
- U.S. Origin Merchandise Intransit through Canada – Since this movement into Canada does not meet the definition of exportation, arrival at the U.S. port of destination does not constitute an importation. As a result, PN is not required for this merchandise.

V. FDA/BTA INTERNATIONAL MAIL PROCEDURES

General Procedures:

The Bioterrorism Act requires that the Food and Drug Administration (FDA) receive prior notice of food imported or offered for import into the United States after December 12, 2003. The purpose of this requirement is to provide FDA personnel with time to review, evaluate, and assess information before a food product arrives, thus allowing for better targeting and interception of contaminated food products.

The prior notice provision of the Act covers food and beverages for human or animal consumption, including all international mail, except where the item is specifically exempt from the reporting requirements. For the latest items that are exempt from the Act, please consult the latest version of the FDA "Compliance Policy Guide" (CPG) on the FDA website.

Processing Procedures

When PN confirmation numbers are available they should be provided for each mail shipment on the Customs Declaration, CN 22 or CN 23, affixed to the mail package.

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CBP and FDA will continue to exercise enforcement discretion until further notice. See www.fda.gov for information on the current CPG.

VI. FDA/BTA FTZ PROCEDURES

General Processing Information:

All merchandise destined to a foreign-trade zone (FTZ) must meet all PN requirements before admission into the Zone. If an in-bond movement is required to move the goods to the zone, then the procedures outlined in the FDA/BTA IN-BOND PROCEDURES must be followed.

Merchandise that has been granted direct delivery arriving at a zone must meet PN requirements before admission into the zone.

Processing Procedures:

Operators must assure that a prior notice (PN) has been submitted to FDA and present proof of the prior notification to CBP prior to moving the merchandise from the place of arrival to the zone. PN should be filed referencing the arriving bill of lading, air waybill or truck pro-bill number.

Operators will prepare a CBP 6043/dray ticket for the merchandise. Somewhere on the CBP 6043 the operator must indicate "Merchandise Subject to FDA/BTA." PN must be submitted via ABI or the FDA Prior Notice System Interface (PNSI). Once the confirmation number is obtained the operator must present the CBP 6043 and the FDA confirmation number to CBP. This may be a screen print of the ABI (WP) Transmission or the FDA PNSI screen or the number may be written or printed on the CBP 6043.

The CBP Officer will query the FDA confirmation number in ACS. If the status of the confirmation is "PN satisfied" CBP will sign the CBP 6043 and the operator may proceed to move the merchandise from the place of arrival to the zone with the normal filing of a CBP 214.

If the PN status is Inadequate:

- CBP will not allow the movement of the merchandise to the zone. The prior notice must be satisfied prior to admission and the merchandise may not proceed to the importer's premises but must be held at the port of entry, at a secure facility or exported with CBP concurrence.

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If the status is “BTA Hold”:

- CBP or FDA (or both) will coordinate to examine or sample the merchandise in accordance with procedures. If the hold is released after examination CBP will sign the CBP 6043 for movement of the merchandise to the zone. Normal CBP 214 filing procedures must then be followed.

VII. INSTRUCTIONS FOR INADEQUATE PRIOR NOTICE

General

There are three ways that the PN could be deemed to be inadequate:

- The PN is not submitted for shipment where it is required
- The PN is submitted but is inaccurate as to one or more required data elements
- The PN is submitted and is accurate, but is submitted prior to the expiration of the regulatory time frames (2, 4, or 8 hours prior to arrival or at the time of foreign mailing)

If merchandise arrives at a U.S. port of arrival and the PN is inadequate, the importer/carrier has three regulatory options:

- Hold the shipment at the Port of Entry if the port director determines there is sufficient room to hold the shipment.
- Immediately export the shipment without entry into the United States.
- Send the merchandise to a secure facility (at the importers own risk and expense) pending satisfactory PN. **Please note:** all facilities that hold merchandise subject to the BTA must register with the FDA under the registration requirements of the BTA regardless if they will be utilized as secure facilities.

Once it has been established that PN is inadequate the shipment (for CBP purposes) becomes General Order (G.O.) merchandise under 19 CBPR 127.1(c).

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Shipment Retained Within the Port of Arrival

In the air and sea environment, the merchandise may be retained at the terminal facility of the carrier. This is considered to be within the Port of Arrival. For land border shipments, the CBP facility at the point of arrival (CBP Port of Entry or equivalent) is the port of arrival. If the land border carrier (bonded) has a terminal facility within the port limits, the merchandise may be held there pending satisfactory PN. The merchandise does not have to be transported to a G.O. warehouse. If the carrier does not have a terminal facility or is unable to hold the type of commodity due to special handling requirements (perishable, frozen commodity), the shipment will be sent to a suitable secure facility as directed by the port director. Additionally, merchandise may be transported to a G.O. warehouse at the request of the consignee, carrier, or if directed by the port director.

Movement to a Secure Facility Within Port Limits

If the carrier does not have a terminal facility within the port of arrival, merchandise with inadequate PN will be sent to a secure facility pending satisfaction of PN.

The choice of a secure facility normally rests with the carrier/importer. If the shipment must be moved for examination by either agency, CBP or FDA will decide where or if the merchandise will be moved. The movement must be performed under a CBP bond, and will be accomplished on a CBP 6043 or an electronic equivalent. The move may be performed by a bonded cartman, bonded carrier or anyone who falls under the guidelines of 19 CBPR 112.2(b) (bonded facility operator picking up and transporting merchandise to their facility).

Movement to a Secure Facility Outside Port Limits

If a shipment cannot be held within the port limits, the shipment will be sent to the nearest suitable facility outside the port. The movement will be performed on a CBP 7512. For tracking purposes, no automated CBP 7512s will be allowed for these movements. Additionally, all of these in-bond shipments must be input into the automated system by the initiating port, and the port must verify that the merchandise arrived within 48 hours of initiation of the in-bond movement. Any shipment for which PN is inadequate and that is moving in-bond to the nearest suitable facility outside the port must have the statement below in the description field of the CBP 7512:

Vigilance ★ *Service* ★ *Integrity*

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“This shipment is not currently admissible due to failure to satisfy the prior notice requirements of the BTA and must be delivered within 48 hours with seals intact to the port and facility designated. Failure to comply could lead to criminal and/or civil charges.”

It will be the responsibility of the port receiving the in-bond shipment to track the shipment and ensure prior notice is satisfied prior to entry.

Requirements for a Secure Facility

All facilities that hold merchandise subject to the BTA must register with the FDA under the registration requirements of the BTA. However, all registered facilities cannot be utilized as secure facilities. Bonded warehouses (other than General Order warehouses) and foreign trade zones cannot be used as secure facilities because admission of the merchandise into those facilities requires PN. Secure facilities will be used to hold merchandise pending satisfactory PN. The FDA has three criteria for a secure facility:

- The building must be bonded
- Registered with the FDA
- The importer/consignee of the merchandise may not also own the facility holding their shipment.

Some examples of qualifying facilities include:

- General Order Warehouses (G.O.)
- Container Freight Stations (CBPS)
- Centralized Examination Stations (CES)
- Bonded carrier terminal facilities and other facilities covered by a Type 2 (custodial) or Type 3 (International Carrier) bond

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Verification of Facility Status

For any move to a secure facility, the following information must be included with the transfer document (CBP 6043 or 7512):

- Registration number of facility (if known or available)
- Name of the facility
- Physical address of the facility where the merchandise will be held
- Phone number of the facility
- Related entry number and/or name of the importer of record

CBP will confirm with the FDA that the facility is registered. If the facility is not registered, the importer will need to choose another facility. CBP is prohibited from disclosing to the Trade Community if a facility is registered with the FDA.

Monitoring Shipments Sent to Secure Facilities

If the merchandise stays at the carrier's facility or is sent to a facility that does not have G.O. status, it will be held under constructive G.O. Constructive G.O. procedures allow merchandise to be held by a carrier or other appropriate party under the same requirements as a G.O. warehouse.

Procedures to Release Shipments in Secure Facility

A facility proprietor may release merchandise from their possession once a CBP release has been granted. Any entry (consumption, transportation) requires that PN be satisfied prior to processing of the entry. Once PN is satisfied, CBP will be able to process the entry.

If entry is not made on the merchandise, it will be disposed of along G.O. guidelines. The G.O. time period expires six months from date of importation. The port will determine if the merchandise is saleable (for export only). If not, the merchandise will be destroyed.

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Perishable merchandise in secure storage will follow the guidelines of 19 CBPR 127.28(c). This allows for expedited processing due to the nature of the merchandise.

If merchandise is still in the carriers' possession and CBP orders the merchandise to be destroyed, the carrier may export the merchandise in lieu of destruction. Destruction costs will be borne by the facility holding the merchandise (including the carrier's facility).

Rail Shipments without PN

Any rail shipment for which PN has not been satisfied will be allowed to proceed to the nearest practicable location where it may be held and will be held there until PN is satisfied. The shipment will be tracked using Rail AMS. Additionally, rail carriers will notify the port director of the intended location where the freight will be retained pending satisfaction of PN. Rail carriers should be encouraged to identify these locations to Port Directors as soon as possible.

Commingled Merchandise

The BTA allows for segregation of shipments where commingled commodities within the shipment do not require submission of PN. CBP does not consider this a manipulation and it may be performed in any location the Port Director feels is suitable to accomplish the task (import lot, secure facility). The Port Director may allow the segregation of the shipment to allow the entry or movement of the merchandise not subject to PN. A CBP 3499 will be submitted requesting the segregation. A new entry for the segregated merchandise will be required and the BTA merchandise will remain at the port or in a secure facility until PN is satisfied.

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Robert O. Prause
Port Director