ADMINISTRATIVE MESSAGE 03-2812 12/05/2003
TITLE: ABI-ACS - BTA PROCESSING
TO: ALL ABI FILERS AND INTERESTED PARTIES

ABI AVAILABILITY OF FDA BIOTERRORISM ACT (BTA) PRIOR NOTICE SOFTWARE IN ACS.

PLEASE REFER TO ADMINISTRATIVE MESSAGES 03-2540 (OCTOBER 24, 2003), 03-2619 619 (OCTOBER 27, 2003) AND 03-2625 (NOVEMBER 4, 2003).

THE BIOTERRORISM ACT OF 2002 (BTA) GOES INTO EFFECT ON FRIDAY, DECEMBER 12, 2003. CERTAIN MERCHANDISE (MOSTLY FOOD AND FOOD PRODUCTS) MARKED BY FD3 (BTA PRIOR NOTICE/FDA CLEARANCE MAY BE REQUIRED) OR FD4 (BTA PRIOR NOTICE/FDA CLEARANCE IS REQUIRED) IN THE HARMONIZED TARIFF RECORD WILL REQUIRE THAT PRIOR NOTICE DATA BE SENT IN ADDITION TO THE FDA SPECIFIC DATA ALREADY REQUIRED.

THE BTA PRIOR NOTICE SOFTWARE FOR THE CUSTOMS PORTION WILL BE LOADED INTO ACS DURING THE REGULARLY SCHEDULED DOWNTIME SATURDAY EVENING - SUNDAY MORNING, DECEMBER 6-7, 2003 AND WILL BE AVAILABLE WHEN THE SYSTEM COMES UP ON SUNDAY, DECEMBER 7, 2003. THE FDA PORTION OF THE SOFTWARE WILL BE LOADED INTO THE FDA SYSTEM ON WEDNESDAY EVENING, DECEMBER 10, 2003, OR THURSDAY EVENING DECEMBER 11, 2003. THE COMPLETE SYSTEM MAY BE AVAILABLE ON DECEMBER 11, 2003, BUT DEFINITELY WILL BE AVAILABLE ON OR AFTER DECEMBER 12, 2003

DURING THE FIRST PHASE OF THE OPERATIONAL SYSTEM, CBP WILL PERFORM BASIC EDITS AND VALIDATIONS FOR PN DATA (VALID PORT CODE, COUNTRY CODE, DATE FORMAT, ETC.) SUBMITTED THROUGH ABI USING APPLICATION IDENTIFIERS HI, HN, EI AND WP AS SPECIFIED IN THE ABOVE LISTED ADMINISTRATIVE MESSAGES. MISSING PN DATA WILL GENERATE WARNING MESSAGES THAT WILL BE SENT BACK TO THE FILER. PRIOR NOTICE DATA WILL BE SENT TO FDA WHEN IT IS RECEIVED, BUT THE ABI FILER WILL NOT RECEIVE FDA PN PN ERROR WARNING MESSAGES, PRIOR NOTICE RECEIVED MESSAGES, OR THE PRIOR NOTICE CONFIRMATION NUMBER UNTIL POSSIBLY DECEMBER 11, 2003 BUT WILL DEFINITELY RECEIVE THEM ON AFTER DECEMBER 12, 2003. BTA PRIOR NOTICE ENTRIES, IN-BOND, AND OTHER TRANSACTIONS WILL BE PROCESSED AS DIRECTED BY THE CBP OFFICE OF FIELD OPERATIONS AND THE FDA OFFICE OF REGULATORY AFFAIRS, DIVISION OF IMPORT OPERATIONS AND PROCEDURES (DIOP). PLEASE NOTE THAT THE DEFAULT DATES FOR THE DETERMINATION OF DUTY/FEE VALIDATION REMAIN THE SAME AS DESCRIBED IN THE ENTRY SUMMARY CHAPTER OF THE CUSTOMS AND TRADE AUTOMATED INTERFACE REQUIREMENTS (CATAIR).

PLEASE NOTE THERE ARE TWO AFFIRMATION OF COMPLIANCE CODES ON THE WP TRANSACTION THAT WERE NOT MENTIONED AS PART OF THE PREVIOUS ADMINISTRATIVE MESSAGE. THEY ARE:

IMN IMPORTER NUMBER
CON CONSIGNEE NUMBER

THE IMPORTER NUMBER IS A REQUIRED DATA ELEMENT FOR PRIOR NOTICE IN THE WP TRANSACTION AND MUST BE A VALID NUMBER IN THE SPECIFIED FORMAT IN THE CATAIR. THE CONSIGNEE NUMBER, IF SUBMITTED, MUST BE A VALID CONSIGNEE NUMBER IN THE SPECIFIED FORMAT IN THE CATAIR.

CUSTOMS AND FDA WILL NOTIFY THE ABI FILERS AS TO THE DATE AND TIME THE WARNING WILL BE CHANGED TO FATAL ERRORS.

IF YOU HAVE ANY QUESTIONS, PLEASE CALL YOUR ASSISNED CLIENT REPRESENTATIVE.

FOLLOWING IS A LIST OF QUESTIONS ASKED BY THE ABI FILERS AND THEIR RESPONSES:

1. WE HAVE SOME CONFLICTING INFORMATION ON WHEN PRIOR NOTICES CAN BE BE SUBMITTED.

THE "FDA PRIOR NOTICE REQUIREMENTS USING THE CURRENT CUSTOMS FDA INTERFACE DOCUMENT (FOR ENTRY) SAYS THIS ON PAGE 10: "IF FDA PN ENTRIES AGAINST AN FD0, FD1, FD2, OR NO FD MARKER IN THE TARIFF RECORD, REJECT THE THE ENTRY AND DISPLAY THE ERROR MESSAGE "FDA PRIOR NOTICE NOT REQUIRED". WE INTERPRETED THIS TO MEAN THAT WE SHOULD ONLY ALLOW USERS TO SEND PRIOR NOTICE INFORMATION TO ABI ON TARIFF NUMBERS FLAGGED WITH AN FD3 OR FD4 MARKER.

BUT, ON THE FDA WEBSITE, IN THE DOCUMENT THAT LISTS TARIFF NUMBERS FLAGGED WITH PRIOR NOTICE INDICATORS, IT SAYS THIS: "THE ABSENCE OF AN FD FLAG DOES NOT MEAN THAT PRIOR NOTICE FOR AN FDA REGULATED ARTICLE OF OF FOOD IS NOT REQUIRED". THIS WOULD INDICATE THAT USERS MIGHT NEED TO SUBMIT A PRIOR NOTICE FOR A TARIFF NUMBER NOT FLAGGED WITH FD3 OR FD4.

CAN YOU TELL US WHICH IS CORRECT?

ANSWER: IF THE BROKER HAS KNOWLEDGE OF THE USE OF A COMMODITY THAT WOULD WARRANT PN, THEY ARE REQUIRED TO SUBMIT THE INFORMATION EVEN IF THE TARRIF NUMBER IS NOT FLAGGED FD3 OR FD4. HOWEVER, CUSTOMS WOULD REJECT THIS INFORMATION IF SENT ELECTRONICALLY. CUSTOMERS SHOULD ENTER THIS INFORMATION ON THE FDA WEB SITE UNDER THIS CIRCUMSTANCE.

2. MASTER BOL (BILL OF LADING) SURFACE SHOWS AS CONDITIONAL. WHAT ARE THE CONDITIONS? WHAT MODE(S) OF TRANSPORTATION IS THIS FIELD FOR? 20,21,30,31? (10,11,12?)

ANSWER: PROVIDE THE BILL OF LADING NUMBER IF IT EXISTS. IT IS VALID FOR ALL SURFACE MODES OF TRANSPORTATION. IF THERE IS MORE THAN ONE BILL OF LADING, PROVIDE THE B/L NUMBER IN MULTIPLE AFFIRMATION OF COMPLIANCE FIELDS, ONE FOR EACH AFFIRMATION OF COMPLIANCE. THE AFFIRMATION OF COMPLIANCE CODE FOR BILL OF LADING IS BOL AIR HAS ITS OWN AFFIRMATION OF COMPLIANCE CODES FOR AIR WAYBILLS, AWB AND AWH.

3. WHEN YOU CALL CUSTOMS AND CANCEL THE ENTRY BECAUSE YOU NEED TO MAKE PN CHANGES AND WILL THIS CANCEL ALL THE PN'S FOR THAT ENTRY AT FDA?

ANSWER: IF THE FILER CALLS TO CANCEL A PN ENTRY, CBP WILL CANCEL THE ENTRY IN ACS AND CALL FDA. THE FILER MUST PROVIDE THE CORRECTED INFORMATION ON A NEW PRIOR NOTICE. THE PN PROCESS BEGINS AGAIN.

4. WHEN CANCELING THE ENTRY DO WE RECEIVE A MESSAGE VIA ABI?

ANSWER: YES. ACS WILL CONTINUE TO TRANSMIT THE
THE "ENTRY CANCELLED" MESSAGE. (REFER TO THE CARGO RELEASE
CHAPTER OF THE CATAIR, NOTE 1 AFTER THE R5 RECORD.)

5. DOES CBP/FDA ANTICIPATE BEING ABLE TO CANCEL/CORRECT PN'S VIA ABI IN FUTURE?

ANSWER: CUSTOMS IS GOING TO LOOK INTO THE POSSIBILITY OF USING THE OGA CORRECTION TRANSACTION SET TO CORRECT PN'S (DT). THERE IS NO PLAN TO ALL ALLOW ELECTRONIC CANCELLATIONS. CANCELLATION PROBABLY MEANS DELETE THE ENTRY. IN THIS CASE, A NEW ENTRY WITH THE PRIOR NOTICE INFORMATION WILL NEED TO BE CANCELLED IF APPLICABLE. IT IS NOT CLEAR WHETHER NEW PN'S WILL BE REQUIRED ON ON THE CORRECTED ENTRY.

6. CAN A PN ENTERED VIA ABI BE CANCELED/CORRECTED ON THE WEB?

ANSWER: NOT ACCORDING TO THE REGULATIONS.

7. WHEN WILL THE WEB SITE BE AVAILABLE FOR FILING THE FDA PN?

ANSWER: THE WEB SITE HAS BEEN COMPLETED AND TESTED. BUT, IT IS NOT YET AVAILABLE FOR USERS.

8. WHAT ACTIONS WILL BE TAKEN BY CUSTOMS AND FDA, STARTING ON DEC 12, IF A PRIOR NOTICE IS NOT FILED FOR AN ITEM THAT SHOULD HAVE A PN?

ANSWER: THERE IS A "PHASE IN PERIOD" OF UNDETERMINED DURATION. DURING THIS TIME, CUSTOMS WILL NOT STOP SHIPMENTS FOR FAILURE TO SUBMIT PN. THIS IS AN INITAL PERIOD OF ENFORCEMENT DISCRETION DURING WHICH SHIPMENTS WILL NOT BE REFUSED SOLELY DUE TO INADEQUATE PRIOR NOTICE OR HELD AT THE BORDER FOR LACK OF REGISTRATION BY A FOREIGN FOOD FACILITY REQUIRED TO REGISTER. FDA WILL BE ISSUING A COMPLIANCE POLICY GUIDE EXPLAINING THEIR ENFORCEMENT POLICY DURING THIS INTIAL PERIOD.

9. WHAT ACTIONS WILL BE TAKEN BY CUSTOMS AND FDA, STARTING ON DEC 12, IF PRIOR NOTICE HAS BEEN FILED LATE?

ANSWER: THERE IS AN INITIAL PERIOD OF ENFORCEMENT DISCRETION. THERE ARE NO EDITS ON THE TIMING DURING THIS PERIOD.

10. WHAT IS THE EXPECTED IMPACT IN THE PROCESSING TIME OF ENTRIES AND RELEASES BECAUSE OF THE EXTRA COMMUNICATIONS WITH FDA?

ANSWER: NO STRESS TESTING HAS BEEN DONE. SEE ABOVE UNDER "OTHER IMPORTANT INFORMATION".

11. CAN THE STATUS OF A PN, SUBMITTED VIA ACS, BE CHECKED ON THE FDA WEB

SITE?

ANSWER: NO.

12. IF WE RECEIVE A PN CONFIRMATION ON THE WEB SITE AND THEN ENTER A TARIFF LINE THAT HAS AN FD04 INDICATOR, WHAT HAPPENS IF THE CONFIRMATION NUMBER IS NOT SENT? OR, WHAT IF WE FAT FINGER THE CONFIRMATION

NUMBER AND SEND THE WRONG ONE?

ANSWER: LACK OF PN WILL CAUSE A REJECT. THERE IS NO WAY TO CHECK TO SEE IF THE CONFIRMATION NUMBER IS THE CORRECT ONE. IT MIGHT GET CAUGHT IN A POST ENTRY AUDIT.

13. AN AIRPLANE BOUND FOR SEATTLE WASHINGTON STOPS TO REFUEL IN ANCHORAGE ANCHORAGE, ALASKA. NO GOODS ARE REMOVED FROM THE PLANE UNTIL IT LANDS IN SEATTLE. WHICH IS THE THE PORT OF ARRIVAL FOR FDA PN PURPOSES, SEATTLE OR ANCHORAGE?

ANSWER: THE PORT FOR FDA PN PURPOSES IS SEATTLE.

14. IS IT ALL OR NONE FOR ACCEPT/REJECT OF PN'S FOR A SHIPMENT? OR CAN SOME PN'S ON A SHIPMENT BE ACCEPTED WHILE OTHERS ARE REJECTED?

ANSWER: ACCEPT/REJECT IS AT THE FDA LINE LEVEL.

15. THIS QUESTION CONCERNS THE BN PRIOR NOTICE RESULTS TRANSACTION. ON THE BN02 RECORD, (ONE OF WHICH IS RETURNED FOR EACH PRIOR NOTICE LINE ITEM ON THE ENTRY) YOU ARE RETURNING A 'PRIOR NOTICE LINE MESSAGE". THE DESCRIPTIION SAYS "PRIOR NOTICE LINE LEVEL MESSAGE FROM FDA, SUCH AS "PRIOR NOTICE RECEIVED" OR "PRIOR NOTICE SATISFIED". FREE FORM". WHAT IS THE DIFFERENCE BETWEEN 'RECEIVED' AND 'SATISFIED'?

ANSWER: PRIOR NOTICE RECEIVED STARTS THE CLOCK AND RETURNS THE CONFIRMATION NUMBER. THE PRIOR NOTICE "SATISFIED" MESSAGE IS NOT SENT TO THE ABI FILER.

16. WHY IS THERE NO REQUIREMENT TO REPORT BILL OF LADING INFORMATION FOR OCEAN SHIPMENTS? CURRENTLY WE ONLY REPORT BILL OF LADING INFORMATION FOR SURFACE (TRUCK AND RAIL) AND AIR.

ANSWER: WE MISREAD THE REGULATIONS. IT IS REQUIRED.

17. WHAT HAPPENS IF THE MANUFACTURER/SHIPPER DOES NOT HAVE A REGISTRATION NUMBER?

ANSWER: AFTER THE DISCRETIONARY ENFORCEMENT PERIOD, IT WILL BE REJECTED. THE MANUFACTURER/SHIPPER NEEDS TO GET ONE IF THEY ARE REQUIRED TO REGISTER, THEN NOTIFY THE BROKER.

18. WILL THE REGISTRATION NUMBER BE ADDED TO THE MID QUERY RESULTS?

IF SO, WHEN, IF NOT, HOW CAN THESE NUMBERS BE QUERIED?

ANSWER: NO. FDA TREATS THIS AS CONFIDENTIAL INFORMATION.

19. HOW ARE MULTIPLE PN CONFIRMATION NUMBERS ISSUED VIA WP RETURNED TO THE? ARE MULTIPLE PN CONFIRMATION NUMBERS IN ONE BATCH TIED TO THE ENVELOPE UMBER OR INDIVIDUALLY? HOW ARE THEY LINKED?

ANSWER: THE WP TRANSACTION IS TIED TOGETHER BY ONE OF THE FOLLOWING NUMBERS: AIR WAYBILL, ENTRY, INBOND, BILL OF LADING, FOR FOREIGN TRADE ZONE (FTZ) ADMISSION NUMBER. THE PN CONFIRMATION NUMBER IS CONTAINED IN THE BN02 RECORD. THERE MAY BE AS MANY BN02 RECORDS

FOR A GIVEN TRANSACTION AT THE FDA LINE LEVEL AS NECESSARY.

20. WHAT BN MESSAGES ARE RETURNED FOR PN INFORMATION SUBMITTED THROUGH THE WP TRANSACTION?

ANSWER: IF FDA DETECTS AN ERROR IN THE PN TRANSACTION, ONE OR MORE OF THE FOLLOWING MESSAGES WILL APPEAR:

"F" - FOREIGN CONSIGNEE, "R" - INVALID REGISTRATION, "Q" - INVALID QUANTITY, "M" - BAD MID FOR MANUFACTURER, "S" - BAD MID FOR SHIPPER, "I" - BAD ESS FOR IMPORTER, "C" - BAD ESS FOR CONSIGNEE, "Z" - INVALID STATE/ZIP FOR US MANUFACTURER, "O" - INVALID COUNTRY OF ORIGIN, "S" - INVALID COUNTRY OF SHIPPING

STATUS MESSAGES ARE AS FOLLOWS:

PRIOR NOTICE REJECT
PRIOR NOTICE RECEIVED
PN CONFIRMATION NUMBER NNNNNNNNNNNN

MAKING CHANGES TO PRIOR NOTICE DATA FOR AN ENTRY (ENTRY SUMMARY, CARGO RELEASE OR BORDER CARGO RELEASE, APPLICATIONS EI, HI AND HN RESPECTIVELY).

CUSTOMS ACS WILL PERFORM CERTAIN EDITS AND VALIDATIONS ON DATA ELEMENTS ELEMENTS FOR BOTH FDA PRIOR NOTICE AND FDA SPECIFIC DATA AS WELL AS CUSTOMS DATA ELEMENTS WHEN THE FILER TRANSMITS THE ENTRY TO ACS THROUGH ABI. IF ONE OR MORE DATA ELEMENTS FAIL TO PASS THE EDITS AND VALIDATIONS, ACS REJECTS THE ENTRY AND SENDS AN ERROR MESSAGE BACK TO THE FILER INDICATING WHICH DATA ELEMENT(S) IS/ARE IN ERROR. THE FILER CAN SUBMIT CORRECTED DATA AT ANY TIME, THE SOONER THE BETTER. CUSTOMS ACS ACCEPTS ONLY ERROR FREE ENTRIES. CUSTOMS TRANSMITS ONLY ERROR FREE ENTRIES TO FDA.

DATA, INCLUDING PRIOR NOTICE DATA, CAN BE CHANGED AT ANY TIME ON ANY ENRY NOT CERTIFIED FOR CARGO RELEASE. DATA, INCLUDING PRIOR NOTICE DATA, CAN BE CHANGED ON AN ENTRY UP TO THE TIME ACS PROCESSES THE ENTRY THROUGH CARGO RELEASE. CUSTOMS TRANSMITS

ERROR FREE FDA SPECIFIC ENTRIES, INCLUDING PRIOR NOTICE ENTRIES
TO FDA.

IF FDA FINDS (AN) ERROR(S) IN THE PRIOR NOTICE ENTRY, FDA WILL
REJECT THE ENTRY TO BACK TO CUSTOMS AT THE LINE LEVEL WITH THE
APPROPRIATE ERROR MESSAGE. CUSTOMS FORWARDS THE ERROR MESSAGE
TO THE ABI FILER FOR CORRECTION AT THE LINE LEVEL IN A NEW
APPLICAITON IDENTIFIED AS "BN". DURING THE FIRST PHASE, FDA
WILL NOT BE TRANSMITTING ERROR MESSAGES TO THE FILER.
FDA WILL KEEP TRACK OF THE ERRORS AND NOTIFY THE ABI
FILER OUTSIDE OF ACS OF CONTINUAL AND EGREGIOUS ERRORS.
FDA WILL BEGIN TO SEND ERROR MESSAGES TO CUSTOMS FOR TRANSMITTAL
TO THE FILER THROUGH ABI AT A LATER TIME.

AT THIS TIME THERE IS NO AUTOMATED MECHANISM TO MAKE
CHANGES TO A PRIOR NOTICE ENTRY ONCE ACS PERFORMS CARGO SELECTIVITY
PROCESSING IF A FILER NEEDS TO CHANGE DATA TO A PRIOR NOTICE ENTRY AFTER

ACS PERFORMS CARGO RELEASE PROCESSING, THE FILER MUST CONTACT CUSTOMS TO
CANCEL THE ENTRY. THE ABI FILER MUST RESUBMIT THE CORRECTED
DATA UNDER A NEW ENTRY NUMBER. IN THE FUTURE,
CUSTOMS AND FDA PLAN TO MODIFY THE ENTRY REJECT - CORRECTION
CAPABILITY (APPLICATIONS DT AND CP) TO PROCESS
ERRORS AT THE CBP AND FDA LINE LEVEL.

CUSTOMS AND FDA WILL CONTINUE TO PROCESS ERRORS FOR ROUTINE
FDA SPECIFIC ENTRIES USING THE CURRENT ENTRY REJECT -
CORRECTION CAPABILITY (APPLICATIONS DT AND CP).

CHANGES TO PRIOR NOTICE TRANSACTIONS OTHER THAN ENTRY.

THERE IS NO AUTOMATED MECHANISM TO PROCESS PRIOR NOTICE DATA CHANGES
PN TRANSACTIONS OTHER THAN ENTRIES (APPLICATION WP).
CONTACT FDA FOR DETAILS ON MAKING CHANGES TO PRIOR NOTICE
DATA SUBMITTED FOR TRANSACTION OTHER THAN ENTRY.

ADMINISTRATIVE MESSAGE 04-0002 URGENT 01/02/2004
TITLE: ABI-FDA BTA BN01 RECORD VALUE CHANGE POSITION 5
TO: ALL ABI FILERS, SOFTWARE VENDORS AND SERVICE BUREAUS

FROM: OFFICE OF INFORMATION AND TECHNOLOGY

SUBJECT: UPDATE TO BN01 RECORD.

ATTENTION ALL ABI FILERS, SOFTWARE VENDORS AND SERVICE BUREAUS WHO TRANSMIT FDA BTA PRIOR NOTICE DATA THROUGH APPLICATION IDENTIFER "WP" FOR ENTRY TRANSACTIONS.

PLEASE REFER TO ADMINISTRATIVE MESSAGE 03-2625 DATED NOVEMBER 4, 2003. REFER TO THE "BN" APPLICATION, RECORD IDENTIFIER BN01, POSTION 5. (LINE 257 OF THE MESSAGE).

IN ORDER TO DIFFERENTIATE BETWEEN ENTRIES SUBMITTED THROUGH APPLICATION IDENTIFIER "WP" FROM ENTRIES SUBMITTED THROUGH APPLICATION IDENTIFIERS "HN, HI AND EI", ACS WILL TRANSMIT THE HEADER VALUE OF "N" INSTEAD OF THE HEADER VALUE "E" IN THE "BN" APPLICATION RECORD BN01, POSITION 5. THUS, ACS WILL SEND AN "N" IF THE BN OUTPUT MESSAGE IS IN RESPONSE TO A "WP" INPUT TRANSACTION FROM THE FILER AND WILL SEND AN "E" IF THE BN OUTPUT MESSAGE IS IN RESPONSE TO AN INPUT TRANSACTION OF "HN, HI, OR EI."

THIS IS EFFECTIVE IMMEDIATELY.

WE REGRET ANY INCONVENIENCE THIS MAY CAUSE.

IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT YOUR CLIENT REPRESENTATIVE.

ADMINISTRATIVE MESSAGE 04-1240 05/12/2004
TITLE: OGA-FDA BTA PHASE III PRIOR NOTICE CHANGES
ATTN: ALL ABI FILERS ESPECIALLY SOFTWARE VENDORS AND SELF PROGRAMMERS:

ABI EDITS FOR PHASE 3 OF THE BTA WILL NOT BE TURNED ON UNTIL MAY 19TH, 2004.

CERTAIN FDA BTA EDITS AND VALIDATIONS THAT GENERATED WARNING MESSAGES IN PHASES I AND II WILL GENERATE FATAL ERRORS IN PHASE III. THE CHANGE FROM WARNING MESSAGES TO FATAL MESSAGES APPLIES ONLY TO PRIOR NOTICE DATA SUBMITTED WITH ENTRIES (PROGRAM APPLICATIONS HN, HI, AND EI). IT DOES NOT APPLY TO INDEPENDENT PRIOR NOTICE TRANSACTIONS SUBMITTED THROUGH APPLICATION WP. IT IS THE RESPONSIBILITY OF THE ABI FILER TO CORRECT ALL ERRORS IN THE BTA TRANSACTION AND RETRANSMIT THE CORRECTED ENTRY FOR FDA PN AND ADMISSIBILITY PROCESSING.

FDA ENTRIES WITH LINES SUBJECT TO PN MUST FOLLOW THE SAME EDITS AND VALIDATIONS OF THE CURRENT FDA ENTRIES IN THE CUSTOMS FDA INTERFACE. IN ADDITION THE FDA PN ENTRY RECORDS MUST CONTAIN THE FOLLOWING DATA:

1) FD01 AND FD05 AFFIRMATION OF COMPLIANCE CODES AND QUALIFIERS AS DESCRIBED BELOW:
   THE FIRST PRIOR NOTICE AFFIRMATION OF COMPLIANCE MUST APPEAR IN THE FD01 RECORD.
   IF THE FILER SUBMITS A PREVIOUSLY RECEIVED PRIOR NOTICE CONFIRMATION NUMBER (PNC) IN LIEU OF PN DATA, THE PNC MUST APPEAR IN THE FD01 RECORD. IF THE PNC IS SENT IN THE FD01 RECORD, DO NOT TRANSMIT ADDITIONAL PRIOR NOTICE AFFIRMATIONS OF COMPLIANCE IN THE FD05 RECORDS.
2) FD02. THE FIRST QUANTITY AND UNIT OF MEASURE (POSITIONS 5-14 AND 15-18). A MINIMUM OF ONE QUANTITY AND UNIT OF MEASURE MUST BE PRESENT
3) FD04.THE CONTACT NAME AND TELEPHONE NUNUMBER (POSITIONS 19-28, 29-38) THE CONTACT NAME (BOTH FIRST AND LAST) AND TELEPHONE MUST BE PRESENT.

AS A REMINDER, ACS GENERATED WARNING MESSAGES IF ANY OF THE ABOVE DATA ELEMENTS WERE MISSING DURING PHASES I & II OF THE FDA BTA PRIOR NOTICE. EFFECTIVE MAY 13, 2004, THE ABI FILER IS RESPONSIBLE FOR THE CORRECTION AND RETRANSMISSION OF ANY PN ENTRY THAT GENERATES A FATAL ERROR BECAUSE ANY OF THE ABOVE ELEMENTS IS NOT TRANSMITTED.

ABI ALSO GENERATED A WARNING MESSAGE IF ANY OF THE MANDATORY AFFIRMATION OF COMPLIANCE CODES WERE ABSENT DURING BTA PHASES I & II. EFFECTIVE MAY 13, 2004, THE FOLLOWING 17 AFFIRMATIONS OF COMPLIANCE WILL GENERATE A FATAL MESSAGE IF THEY ARE MISSING FROM THE BTA PRIOR NOTICE TRANSACTION:

SUBMITTER:

SLN	SUBMITTER LAST NAME	IF SLN & QUALIFIER NOT PRESENT ACS WILL REJECT
SFN	SUBMITTER FIRST NAME	IF SFN & QUALIFIER NOT PRESENT ACS WILL REJECT
SPN	SUBMTR PHONE NUMBER	IF SPN & QUALIFIER NOT PRESENT ACS WILL REJECT
SFX	SUBMITTER FAX NO	IF SFX & QUALIFIER NOT PRESENT ACS WILL REJECT
SEM	SUBMITTER EMAIL	IF SEM & QUALIFIER NOT PRESENT ACS WILL REJECT
SCN	SUBMITTER FIRM NAME	IF SCN & QUALIFIER NOT PRESENT ACS WILL REJECT
SA1	SBMTR ADDRESS LINE 1	IF SA1 & QUALIFIER NOT PRESENT ACS WILL REJECT

SAC SUBMITTER CITY IF SAC & QUALIFIER NOT PRESENT ACS WILL REJECT
SAS SBMTR STATE/PROVINCE IF SAS & QUALIFIER NOT PRESENT ACS WILL REJECT
SCZ SBMTR ZIP/MAIL CODE IF SCZ & QUALIFIER NOT PRESENT ACS WILL REJECT
SCC SBMTR ISO CNTRY CODE IF SCC & QUALIFIER NOT PRESENT ACS WILL REJECT
SFT SUBMITTER FIRM TYPE IF SFT & QUALIFIER NOT PRESENT ACS WILL REJECT

ANTICIPATED ARRIVAL INFORMATION:

APA ANTICIP PORT ARRIVAL IF APA & QUALIFIER NOT PRESENT ACS WILL REJECT
ADA ANTICIP DATE ARRIVAL IF ADA & QUALIFIER NOT PRESENT ACS WILL REJECT
ATA ANTICIP TIME ARRIVAL IF ATA & QUALIFIER NOT PRESENT ACS WILL REJECT

OWNER:

OFT OWNER FIRM TYPE IF OFT & QUALIFIER NOT PRESENT ACS WILL REJECT

COUNTRY OF SHIPPING

CSH COUNTRY OF SHIPPING IF CSH & QUALIFIER NOT PRESENT ACS WILL REJECT

PLEASE REFER TO ADMINISTRATIVE MESSAGE 03-2619 TRANSMITTED NOVEMBER 4, 2003 FOR SPECIAL EDITS.

FOLLOWING ARE WARNING MESSAGES THAT WILL BE CHANGED TO FATAL ERRORS IN BTA PRIOR NOTICE PHASE III MAY 13, 2004:

FDP-REQ'D PRIOR NOTICE NOT SUBMITTED CHANGE FROM WARNING TO FATAL ERROR
FGF-CONTACT NAME REQ'D FOR FDA PN CHANGE FROM WARNING TO FATAL ERROR
FGG-FDA PN MANDATORY FLD MISSING CHANGE FROM WARNING TO FATAL ERROR
FDH-FD-AOC INVALID CONTACT PHONE NO CHANGE FROM WARNING TO FATAL ERROR
FGI-"PNC" MUST BE IN THE FD-01 RECORD CHANGE FROM WARNING TO FATAL ERROR
FGJ-QTY 1 REQ'D FOR FDA PRIOR NOTICE CHANGE FROM WARNING TO FATAL ERROR
FGM-FD04 CONTACT NME,TELE REQD FDA PN CHANGE FROM WARNING TO FATAL ERROR

PHASE I AND II WARNING MESSAGES THAT WILL CONTINUE AS IS OR BE CHANGED TO FATAL ERRORS IN BTA PRIOR NOTICE PHASE III MAY 13, 2004:

FGA-INVALID PRIV.OWNED VEH STATE CDE CONTINUES AS FATAL ERROR
FGB-INVALID PRIV.OWNED VEH PROV CDE CONTINUES AS FATAL ERROR
FGC-INV PRIV.OWNED VEH CNTRY OF REG CONTINUES AS FATAL ERROR
FGD-INVALID RAIL CAR NUMBER CONTINUES AS FATAL ERROR
FGE-PRIOR NOTICE DATA NOT ALLOWED FATAL ERROR: FD0 TARIFFS ONLY
FGF-CONTACT NAME REQ'D FOR FDA PN CHANGE FROM WARNING TO FATAL ERROR
FGG-FDA PN MANDATORY FLD MISSING CHANGE FROM WARNING TO FATAL ERROR
FGH-FD-AOC INVALID CONTACT PHONE CONTINUES AS FATAL ERROR
FGI-"PNC" MUST BE IN THE FD-01 RECORD CHANGE FROM WARNING TO FATAL ERROR
FGJ-QTY 1 REQ'D FOR FDA PRIOR NOTICE CHANGE FROM WARNING TO FATAL ERROR
FGK-FD-AOC: INVALID ZIP/MAIL CODE CONTINUES AS FATAL ERROR
FGL-'PFR' INV MANUF. REGIST. EXEMPT CONTINUES AS FATAL ERROR
FG0-INVALID PRIVT OWNED VEH LICENSE # CONTINUES AS FATAL ERROR
FG1-INVALID MANF/PROC REGISTRATION NO CONTINUES AS FATAL ERROR
FG2-INVALID PRODUCER FIRM TYPE CONTINUES AS FATAL ERROR
FG3-INVALID MFR REGIST. EXEMPTION IND CONTINUES AS FATAL ERROR
FG4-INVALID SHIPPER REGISTRATION NBR CONTINUES AS FATAL ERROR

FG5-INVALID SUBMITTER FIRM TYPE	CONTINUES AS FATAL ERROR
FG6-INVALID COUNTRY OF SHIPPING	CONTINUES AS FATAL ERROR
FG7-INVALID OWNER FIRM TYPE	CONTINUES AS FATAL ERROR
FG8-INVALID PACKAGE/CAN CODES	CONTINUES AS FATAL ERROR
FG9-INVLD PRIOR NTCE CONFRM NBR	CONT. AS FATAL ERROR (FORMAT ONLY)

IN SUMMARY, EFFECTIVE MAY 13, 2004, IF EITHER A PNC OR PND IS NOT TRANSMITTED, LACK OF THE FOLLOWING ADDITIONAL INFORMATION WILL CAUSE AN ENTRY TO BE REJECTED:
QUANTITY
CONTACT NAME AND CONTACT TELEPHONE NUMBER
SUBMITTER (12 AFFIRMATIONS OF COMPLIANCE)
ANTICIPATED ARRIVAL INFORMATION (TO INCLUDE PORT, DATE, TIME)
OWNER FIRM TYPE
COUNTRY OF SHIPPING

THE ABOVE APPLIES ONLY TO ENTRIES SUBMITTED IN APPLICATIONS HN, HI, EI.

PLEASE NOTE ABI EDITS FOR PHASE 3 OF THE BTA WILL NOT BE TURNED ON UNTIL MAY 19, 2004

IF YOU HAVE ANY QUESTIONS PLEASE CALL YOUR CLIENT REPRESENTATIVE.

ADMINISTRATIVE MESSAGE 04-1667 07/20/2004
TITLE: OGA-FDA BTA PN FOOD FACILITY REGISTRATION EXEMPTION REASONS
ATTN ALL ABI FILERS, BROKERS, AND SOFTWARE VENDORS.

THE PRIOR NOTICE INTERIM FINAL RULE REQUIRES SUBMISSION OF A REGISTRATION NUMBER FOR THE PRODUCER OF THE ARICLE OF FOOD UNLESS THE FACILITY IS EXEMPT FROM REGISTRATION OR IF THE ARTICLE OF FOOD WAS IMPORTED FOR "TRANSHIPMENT OR OTHER EXPORT". IF THE FACILITY IS EXEMPT, THE "FME" (FOOD FACILITY REGISTRATION EXEMPTION) AFFIRMATION OF COMPLIANCE CODE AND QUALIFIER SHOULD BE TRANSMITTED.

THE FOOD AND DRUG ADMINISTRATION IS MODIFYING THE QUALIFIERS FOR "FME" TO INDICATE THE REASON FOR EXEMPTION. FILERS CAN BEGIN TO TRANSMIT THE NEW QUALIFIERS BEGINNING AUGUST 13, 2004. TRANSMISSION OF THE EXISTING "Y" QUALIFIER CAN CONTINUE UNTIL FILERS HAVE BEEN NOTIFIED OF AN END-DATE. FILERS MAY WANT TO PROGRAM FOR TRANSMITSSION OF ANY ONE-DIGIT ALPHA CHARACTER TO ACCOMMODATE ADDITIONAL EXEMPTION REASONS.

QUALIFIER	QUALIFIER DESCRIPTION
A	FACILITY IS OUT OF BUSINESS
B	FACILITY IS PRIVATE RESIDENCE (21 CFR 1.227(B)(2))
C	FACILITY IS A RESTAURANT (21 CFR 1.226(D); 1.227(B)(10))
D	FACILITY IS RETAIL FOOD ESTABLISHMENT (21 CFR 1.226(C); 1.227(B) (11))
E	FACILITY IS NON-PROCESSING FISHING VESSEL (21 CFR 1.226(F)
F	FACILITY IS NON-BOTTLED DRINKING WATER COLLECTION AND DISTRIBUTION ESTABLISHMENT (21 CFR 1.227(B)(2))
G	INDIVIDUAL GIFT - LABEL NAME/ADDRESS IN LIEU OF REGISTRATION NUMBER (21 CFR 1.281(A)(6),(B)(5) AND (C)(6))
H	GROWER - SATISFIES FARM EXEMPTION (21 CFR 1.226(B); 1.227(B) (3))

CONTACT YOUR CLIENT REPRESENTATIVE IF YOU HAVE QUESTIONS.

ADMINISTRATIVE MESSAGE 04-2171 10/07/2004
TITLE: OGA-BTA PRIOR NOTICE REJECT INFORMATION
TO: ALL ABI FILERS OF PRIOR NOTICE DATA

FROM: THE FOOD & DRUG ADMINISTRATION

IN AUGUST FDA IMPLEMENTED ADDITIONAL PRIOR NOTICE EDITS AND FILERS ARE EXPERIENCING AN INCREASED NUMBER OF REJECTS. THE LEADING CAUSE OF REJECTS IS FAILURE TO SUBMIT PRIOR NOTICE (PN) DATA WHEN REQUIRED. THE SECOND LEADING CAUSE IS INAPPROPRIATE DISCLAIM OF PRIOR NOTICE WHEN THE FOOD PRODUCT REQUIRES PRIOR NOTICE.

PRIOR NOTICE CAN BE SUBMITTED IN ONE OF THE FOLLOWING WAYS:

FILERS CAN SUBMIT THE ADDITIONAL PN DATA ELEMENTS FOR EACH LINE WITHIN A CONSUMPTION ENTRY THAT IS SUBJECT TO PRIOR NOTICE.

FILERS CAN SUBMIT IN-BOND ENTRIES VIA CBP'S ABI "WP" TRANSACTION. THEY WILL RECEIVE A PRIOR NOTICE CONFIRMATION NUMBER AND THAT NUMBER CAN THEN BE TRANSMITTED AS AN AFFIRMATION OF COMPLIANCE CODE WHEN SUBMITTING A CONSUMPTION ENTRY FOR THE FOOD PRODUCT.

ANYONE CAN FILE PRIOR NOTICE VIA FDA'S WEB-BASED PRIOR NOTICE SYSTEM INTERFACE (PNSI) AND THEY WILL RECEIVE A PRIOR NOTICE CONFIRMATION NUMBER. THAT NUMBER CAN THEN BE TRANSMITTED AS AN AFFIRMATION OF COMPLIANCE CODE WHEN SUBMITTING A CONSUMPTION ENTRY FOR THE ARTICLES OF FOOD.

CBP (ABI/ACS) DETERMINES IF PRIOR NOTICE DATA IS REQUIRED BASED ON THE OTHER GOVERNMENT AGENCY (OGA) FLAG ON THE HTS (HARMONIZED TARIFF SCHEDULE). THE RULES ARE AS FOLLOWS:

FD4 PRIOR NOTICE (PN) DATA IS REQUIRED, FDA ADMISSIBILITY DATA (801(A)) IS REQUIRED.

FD3 PN MAY BE REQUIRED OR DISCLAIMED, 801(A) MAY BE REQUIRED OR DISCLAIMED.

FD2 PN MAY BE REQUIRED , 801(A) IS REQUIRED.

FD1 PN MAY BE REQUIRED, 801(A) MAY BE REQUIRED OR DISCLAIMED.

FD0 NO 801(A) OR PN DATA ACCEPTED.

NO FLAG SHOULD SUBMIT 801(A) AND/OR PN IF APPROPRIATE.

SINCE THERE IS NOT ALWAYS A SIMPLE RELATIONSHIP BETWEEN PRODUCT CODES AND HTS CODES, FDA'S OASIS SYSTEM IS PROGRAMMED TO EDIT FOR PRIOR NOTICE REQUIREMENTS BASED ON THE PRODUCT CODE SUBMITTED. AS A RESULT WE HAVE A NUMBER OF SITUATIONS WHERE FILERS ARE SUBMITTING AN ENTRY AND ARE NOT PROVIDING PRIOR NOTICE DATA OR ARE TRANSMITTING A DISCLAIM "PND" AFFIRMATION OF COMPLIANCE CODE BUT THE PRODUCT CODE REQUIRES PRIOR NOTICE. IN THOSE CASES, FDA IS SENDING A REJECT BACK TO ABI AND ULTIMATELY THE FILER RECEIVES A LINE LEVEL REJECT WITH A REASON CODE. MOST PRODUCT CODES ARE STRAIGHTFORWARD HOWEVER THERE ARE SOME INDUSTRY

CODES WHERE CERTAIN PRODUCT CODES REQUIRE PN (AND WILL CAUSE A REJECT IF NOT SENT) AND OTHERS DO NOT.

IN THE CASE OF INDUSTRY 50 THE PRIOR NOTICE REQUIREMENTS ARE ONLY APPLICABLE TO TWO PRODUCT CODES:

50A--01 COLOR FOR FOODS, DRUGS AND COSMETICS (FD&C) (CERTIFIED)
50B--01 COLOR FOR FOOD (NOT CERTIFIED)

IN THE CASE OF INDUSTRY 54, THE PRIOR NOTICE REQUIREMENT IS DETERMINED BY THE PRODUCT CODE SUBCLASS. THE FOLLOWING SUBCLASSES REQUIRE PN:

A ENRICHED HUMAN FOODS
B HUMAN FOOD DIETARY SUPPLEMENT 1 INGREDIENT
C HUMAN FOOD DIETARY SUPPLEMENT MULTI INGREDIENTS
L ENRICHED ANIMAL FOODS
M ANIMAL DIET SUPPLEMENTS
Y NOT ELSEWHERE CLASSIFIED (NEC)

THE FOLLOWING DO NOT REQUIRE PN:

D HUMAN N/RX 1 INGREDIENT
E HUMAN N/RX COMBINED INGREDIENT
F HUMAN RX 1 INGREDIENT
G HUMAN RX COMBINED INGREDIENT
I INVESTIGATIONAL
N ANIMAL N/RX DRUG
R ANIMAL RX DRUG

WE HAVE ALSO SEEN MANY REJECTS FOR NO PRIOR NOTICE SUBMITTED FOR ARTICLES OF FOOD WITH U.S. GOODS RETURNED TARIFF CLASSIFICATIONS. PLEASE REFER TO ABI ADMINISTRATIVE MESSAGE 04-2093, SEPTEMBER 27, 2004 FOR INFORMATION ON HTS 9801001097 (OTHER AMERICAN GOODS RETURNED). IF PRODUCTS WHICH FALL UNDER THIS HTS ARE NOT SUBJECT TO PRIOR NOTICE, THIS CODE REQUIRES A "PND" DISCLAIMER. IF THE PRODUCT REQUIRES PRIOR NOTICE THE FDA COUNTRY OF PRODUCTION (US) DOES NOT CHANGE THIS REQUIREMENT. FAILURE TO SEND PRIOR NOTICE DATA WILL RESULT IN A FDA REJECT.

ANOTHER CAUSE OF FDA REJECTS IS THE USE OF AN EXPIRED OR CANCELLED PRIOR NOTICE CONFIRMATION NUMBER (PNC). IF YOU RECEIVE THIS REJECT, THE FILER MUST CONTACT THE SUBMITTER OF THE PRIOR NOTICE TO DETERMINE WHY IT WAS EXPIRED OR CANCELLED. IN EITHER CASE NEW PRIOR NOTICE MUST BE FILED. THE ENTRY THEN WOULD HAVE TO BE CORRECTED USING THE ABI OTHER GOVERNMENT AGENCY CORRECTION (CP) TRANSACTION WITH THE CORRECT, CURRENT PRIOR NOTICE CONFIRMATION NUMBERS.

THE FOOD & DRUG ADMINISTRATION