

04-1779 OGA-CBP FDA ADDITIONAL EDITS AND VALIDATIONS AUGUST 13 2004

ADMINISTRATIVE MESSAGE 04-1779 08/10/2004

TITLE: OGA-CBP FDA ADDITIONAL EDITS AND VALIDATIONS AUGUST 13 2004
ATTENTION ALL ABI BROKERS, SOFTWARE VENDORS, AND SELF PROGRAMMERS:

EFFECTIVE AUGUST 13, 2004, CUSTOMS AND BORDER PROTECTION (CBP) AND THE FOOD AND DRUG ADMINISTRATION (FDA) WILL ENHANCE THE EDITS AND VALIDATIONS FOR THE BIOTERRORISM ACT OF 2002 (BTA). IN ADDITION TO THE CURRENT EDITS AND VALIDATIONS, ABI FILERS SHOULD CONCERN THEMSELVES WITH THE FOLLOWING DATA ELEMENTS:

1) PRIOR NOTICE CONFIRMATION (PNC) NUMBERS. FILERS SHOULD ENSURE IF A PNC NUMBER IS SUBMITTED WITH AN ENTRY, THAT IT IS VALID, CURRENT, AND NOT CANCELLED, AND THAT THE CONFIRMATION NUMBER IS TRANSMITTED AS THE FIRST AFFIRMATION OF COMPLIANCE IN THE FD01 RECORD. IF INVALID, EXPIRED, CANCELLED, OR NOT IN THE FD01 RECORD, FDA WILL REJECT.

2) IF SUBMITTING FDA SPECIFIC DATA FOR MERCHANDISE MARKED AS FD3 (PRIOR NOTICE MAY BE REQUIRED) IN THE TARIFF RECORD AND PRIOR NOTICE IS NOT REQUIRED, TRANSMIT THE "PND" DISCLAIMER AS THE FIRST AFFIRMATION OF COMPLIANCE IN THE FD01 RECORD ALONG WITH THE FDA SPECIFIC INFORMATION FOR FDA ADMISSIBILITY. FDA WILL NOTIFY THE ABI FILER WITH A REJECT MESSAGE IF PRIOR NOTICE IS REQUIRED BASED ON THE PRODUCT CODE. THE FILER MUST THEN RESUBMIT THE ENTRY WITH THE PRIOR NOTICE INFORMATION. IF THE MERCHANDISE MARKED AS FD3 IN THE TARIFF RECORD DOES NOT REQUIRE FDA REVIEW FOR EITHER PRIOR NOTICE OR FDA ADMISSIBILITY, DISCLAIM THE MERCHANDISE USING THE FD0 MARKER IN THE OA RECORD AS IS DONE NOW.

IF THE FILER SUBMITS AN FDA PRODUCT CODE THAT REQUIRES PRIOR NOTICE FOR MERCHANDISE MARKED AS FD2 (FDA CLEARANCE REQUIRED) OR FD1 (FDA CLEARANCE MAY BE REQUIRED) IN THE TARIFF RECORD, AND DOES NOT SUBMIT THE PRIOR NOTICE DATA, FDA WILL REJECT THE TRANSACTION AND REQUEST THAT THE FILER SUBMIT PRIOR NOTICE DATA. IF THE FILER SUBMITS PN DATA WITH A PRODUCT CODE THAT DOES NOT REQUIRE PN, FDA WILL SEND THE FILER THE MESSAGE "WARNING - PN NOT REQUIRED". IF THE FILER FEELS THAT PN IS REQUIRED, PLEASE VALIDATE THE PRODUCT CODE FOR USE IN FUTURE SUBMISSIONS.

3) CBP WILL EDIT FOR THE PRESENCE OF THE FOOD FACILITY REGISTRATION NUMBER (AFFIRMATION OF COMPLIANCE "PFR") OR A FOOD FACILITY (FDA PN MFR) REGISTRATION EXEMPTION INDICATOR (AFFIRMATION OF COMPLIANCE "FME". IF ONE OR THE OTHER IS NOT PRESENT, CBP WILL REJECT THE ENTRY. FDA WILL VALIDATE THE EXEMPTION REASON. IF INVALID, FDA WILL REJECT THE ENTRY, AND TRANSMIT THE CODE "E" IN POSITION 77 OF THE BN02 RECORD IN THE BN APPLICATION. VALID CODES ARE LISTED IN ADMINISTRATIVE MESSAGE 04-1667.

PLEASE NOTE THE FOLLOWING REMINDERS:

4) WHEN SUBMITTING A CONSOLIDATED CONSIGNEE WITH THE ENTRY, THE FILER MUST REPORT THE FOOD AND DRUG ESTABLISHMENT INDICATOR (FEI) AT THE FDA LINE

LEVEL IN POSITIONS 15-26 OF THE FD03 RECORD.

5) PRIOR NOTICE REQUIRES A MINIMUM OF ONE UNIT OF MEASURE WITH THE APPROPRIATE QUANTITY BEGINNING IN POSITIONS 5-14 AND 15-18 IN THE FD02 RECORD. LACK OF A QUANTITY AND UNIT OF MEASURE FOR A PRIOR NOTICE GENERATES A CBP REJECT.

6) FILERS SHOULD SUBMIT THE BILL OF LADING (BOL) OR AIR WAYBILL (AWB) NUMBER AS AN AFFIRMATION OF COMPLIANCE IN THE FD05 RECORD IN ORDER TO ALIGN THE BILL OF LADING - AIR WAYBILL WITH THE APPROPRIATE FDA LINE FOR PURPOSES OF FILING PRIOR NOTICE. BOL, AWB, DATA MUST BE IN THE STANDARD FORMAT. BILL OF LADING OR AIR WAYBILL INFORMATION DECLARED AT THE ENTRY LEVEL IS NOT TRANSLATED TO THE FDA LINE.

FDA REJECT REASON CODES:

THE FOOD AND DRUG ADMINISTRATION IS EXPANDING THE REJECT REASON CODES USED TO INDICATE EDIT FAILURES. FDA WILL BEGIN TO USE THE EXPANDED VERSION OF THESE CODES ON AUGUST 13, 2004. THE CODES APPEAR IN THE BN APPLICATION FD02 RECORD FROM POSITIONS 64 THROUGH 78. NOTE THAT A CODE FOR A GIVEN POSITION MAY VARY AS SHOWN BELOW:

POS. CODE DESCRIPTION

64	F	FOREIGN CONSIGNEE
65	R,F,M	INVALID REGISTRATION: R-MISSING REGISTRATION R - MISSING REGISTRATION F - REGISTRATION NOT ON FILE M - MISMATCH IN REGISTRATION
66	Q	INVALID QUANTITY
67	M	INVALID MID FOR MANUFACTURER
68	S	INVALID MID FOR SHIPPER
69	I	INVALID IMPORTER FOR FDA
70	C,U	INVALID CONSIGNEE FOR FDA C - INVALID CONSIGNEE U - UNKNOWN/CONSOLIDATED CONSIGNEE
71	Z	INVALID STATE/ZIP FOR US MANUFACTURER
72	O	INVALID COUNTRY OF ORIGIN
73	S	INVALID COUNTRY OF SHIPPING
74	N	OTHER REJECT REASON - CALL FDA
75	P	PN DATA REQUIRED (APPLIES TO ENTRY FILERS ONLY) USE CP APPLICATION TO INPUT PN DATA
76	W	WARNING PN DATA NOT REQUIRED (FILER WILL NOT RECEIVE A CONFIRMATION NUMBER)
77	E	INVALID EXEMPTION (FME) QUALIFIER
78	C,E,X	PN CONFIRMATION NUMBER (PNC) INVALID C - INVALID PNC NUMBER E - EXPIRED PNC NUMBER X - CANCELLED PNC NUMBER

FOLLOWING IS A LIST OF ADMINISTRATIVE MESSAGES TRANSMITTED THROUGH ACS TO THE ABI FILER THAT ADDRESS PRIOR NOTICE FUNCTIONAL REQUIREMENTS:

MSG# XMIT DATE CONTENTS

03-2619 4 NOV 2003 PN REQUIREMENTS FOR ENTRY (APPLICATIONS HN,HI,EI)
03-2625 5 NOV 2003 PN REQUIREMENTS FOR INDEPENDENT PN (APPLICATION WP)

03-2891 15 DEC 2003 CLARIFICATION OF BN APPLICATION
04-0002 2 JAN 2004 UPDATE BN02 RECORD
04-0029 7 JAN 2004 DOCUMENT FORMAT OF B/L, AWB FOR PN
04-0031 7 JAN 2004 DOCUMENT PN CLOCK FORMAT
04-0586 24 MAR 2004 ALLOW PN REPORTING FOR HTS BLANK, FD1, FD2
04-0927 14 APR 2004 ADVISE THAT WARNING MSGS BECOME FATAL EFFECTIVE
MAY 13, 2004
04-0936 15 APR 2004 CLARIFY "PN INVALID" WARNING
04-0982 19 APR 2004 MAY 13 IMPLEMENTATION (PHASE III)
04-1147 29 APR 2004 FDA EDITS IN ABI - MAY 13
04-1240 12 MAY 2004 FDA BTA PHASE III PRIOR NOTICE
04-1667 20 JUL 2004 FDA BTA PN FOOD FACILITY REGISTRATION EXEMPTION
REASONS

IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT THE FDA PRIOR NOTICE CENTER
AT 866 521-2297 OR YOUR CLIENT REPRESENTATIVE

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