ADMINISTRATIVE MESSAGE 04-2563 12/20/2004

TITLE: OGA-TWO NEW REJECT REASON CODES FOR INVALID REGISTRATION

TO: ALL ABI FILERS

FROM: THE FOOD & DRUG ADMINISTRATION

FDA IS ADDING TWO NEW REJECT REASON CODES FOR INVALID PRIOR NOTICE REGISTRATION. THESE NEW CODES ARE BEING ADDED TO PROVIDE MORE SPECIFIC INFORMATION ON WHY THE MANUFACTURER REGISTRATION NUMBER PROVIDED IS CONSIDERED INVALID AND HAS BEEN REJECTED. USE OF THESE NEW CODES WILL BEGIN ON JANUARY 20, 2005.

CURRENTLY THE THREE REGISTRATION REJECT REASON CODES INCLUDE:

R = MISSING REGISTRATION
F = REGISTRATION NOT ON FILE
M = MISMATCH IN REGISTRATION

IN THE PAST, FDA WAS SENDING ONLY AN "M" FOR BOTH REGISTRATION NOT ON FILE AND FOR MISMATCH IN REGISTRATION. IN THE FUTURE "F" WILL BE RETURNED WHEN THE NUMBER PROVIDED VIA THE PFR AFFIRMATION OF COMPLIANCE IS NOT AND HAS NEVER BEEN ON FILE AND "M" WHEN THERE IS A MISMATCH BETWEEN THE REGISTRATION NUMBER AND THE FIRM TRANSMITTED AS THE MANUFACTURER IN THE FD01 RECORD.

THE TWO NEW REASON CODES TO BE INCLUDED ARE:

I = INVALIDATED THIS MEANS THAT FDA HAS INVALIDATED THE REGISTRATION DUE TO PROBLEMS WITH THE FIRM NAME AND ADDRESS OR LEGITIMACY OF THE PARTY WHO FILED THE REGISTRATION.

C = CANCELLED THIS MEANS THE FIRM OR THEIR AGENT HAVE CANCELLED THE REGISTRATION.

WITH THE ADDITION OF THE TWO NEW REASON CODES THE FOLLOWING IS THE CURRENT LIST OF FDA REJECT REASON CODES:

THE CODES APPEAR IN THE BN APPLICATION, FD02 RECORD FROM POSITIONS 64 THROUGH 78. NOTE THAT A CODE FOR A GIVEN POSITION MAY VARY.

POSITION	CODE	DESCRIPTION
64	F	FOREIGN CONSIGNEE
65	R, F, M, I, C	INVALID REGISTRATION R = MISSING REGISTRATION F = REGISTRATION NOT ON FILE M = MISMATCH IN REGISTRATION I = INVALIDATED REGISTRATION C = CANCELLED 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 CURRENTLY BEING USED FOR LACK OF BILL OF LADING(BOL) OR AIRWAY BILL (AWB) CHECK BEFORE CALLING FDA.
75	P	PN DATA REQUIRED (APPLIES TO ENTRY FILERS ONLY - USE CP TO SEND PN DATA AFTER REJECT.
76	W	WARNING PN DATA NOT REQUIRED (FILER WILL NOT RECEIVE A CONFIRMATION NUMBER).
77	E	INVALID EXEMPTION (FME) QUALIFIER.
78	C, E, X	C = INVALID PNC NUMBER E = EXPIRED PNC NUMBER X = CANCELLED PNC NUMBER

ADMINISTRATIVE MESSAGE 05-0019 01/05/2005
TITLE: OGA-IMPORTANT PRIOR NOTICE ADMINISTRATIVE MESSAGES

TO: ALL ABI FILERS FILER FDA PRIOR NOTICE ENTRIES

FROM: CBP TRADE SUPPORT OFFICE

SUBJECT: IMPORTANT PRIOR NOTICE ADMINISTRATIVE MESSAGES
PRIOR NOTICE REJECTS

SOME RECENT TEMPORARY PROGRAMMING ISSUES HAVE MADE THE PREVENTION OF PRIOR NOTICE REJECTS ESPECIALLY IMPORTANT. THE PURPOSE OF THIS MESSAGE IS TO REVIEW THE CAUSES OF THE REJECTS AND THE ABI ADMINISTRATIVE MESSAGES THAT WERE ISSUED TO PREVENT THOSE REJECTS.

1. REJECT "F" FOREIGN-BASED CONSIGNEE

A FOREIGN-BASED CONSIGNEE SHOULD NEVER BE SENT. THIS SUBJECT IS COVERED IN ADMINISTRATIVE MESSAGE 04-2525. THIS MESSAGE EXPLAINS THE ONLY SCENARIO IN WHICH A FBC CAN BE SENT WITHOUT GENERATING A REJECT. THIS REJECT IS VERY TIME CONSUMING TO CORRECT.

2. THE 'N' REJECT OTHER REASON- CALL FDA NO BOL/AWB SENT

THE 'N" REJECT IS GENERATED WHEN THE AFFIRMATION OF 'BOL' FOR BILL OF LADING (OTHER THAN AIR) OR AWB (AIR) IS NOT SENT AS AN AFFIRMATION OF COMPLIANCE. ONE OR THE OTHER IS REQUIRED DEPENDING ON THE MODE OF TRANSPORTATION. THIS IS COVERED IN ADMINISTRATIVE MESSAGE 04-2375

3. THE "P" REJECT PRIOR NOTICE REQUIRED

THIS REJECT IS MOST OFTEN GENERATED WHEN THE FILER DISCLAIMS A FD3 CODED TARIFF NUMBER. IT CAN ALSO HAPPEN ON TARIFF NUMBERS CODES FD1, FD2 OR WITH NO CODE AT ALL. THIS IS BECAUSE FDA HAS EDITS ON CERTAIN FDA PRODUCT CODES. SEE ADMINISTRATIVE MESSAGES 04-0586 AND 04-2171.

4. THE "C" REJECT INVALID PNC NUMBER

THIS NUMBER IS GENERATED WHEN THE PRIOR NOTICE CONFIRMATION NUMBER (PNC) IS NOT ON FILE. THE MOST COMMON REASON IS MIS-TYPING THE NUMBER. FILERS SHOULD BE ESPECIALLY CAREFUL TO SEND VALID PNC NUMBERS.

IF YOU HAVE ANY QUESTIONS ABOUT THESE REJECTS OR ADMINISTRATIVE MESSAGES PLEASE CONTACT YOUR CLIENT REPRESENTATIVE OR CLIENT REPRESENTATIVE JOHN OGLIORE @JOHN.OGLIORE@DHS.GOV.

CLIENT REPRESENTATIVE BRANCH

ADMINISTRATIVE MESSAGE 05-0098 URGENT 01/28/2005
TITLE: OGA-END-DATE OF FME EXEMPTION REASON CODE "Y" FEB 1, 2005
TO: ALL ABI FILERS

FROM: FOOD & DRUG ADMINISTRATION

SUBJECT: END-DATE OF FME EXEMPTION QUALIFIER "Y" ON FEBRUARY 1, 2005

ON JULY 20, 2004, FILERS WERE NOTIFIED VIA ABI ADMINISTRATIVE MESSAGE 04-1667 THAT PRIOR NOTICE MANUFACTURER REGISTRATION "EXEMPTION" REASON CODE "Y" WOULD BE END-DATED AND CONTINUED USE AFTER THAT END-DATE WOULD CAUSE REJECTION OF PRIOR NOTICE SUBMISSIONS

THIS QUALIFIER TO THE FME AFFIRMATION OF COMPLIANCE CODE WILL BE END-DATED EFFECTIVE FEBRUARY 1, 2005.

IF A MANUFACTURER'S REGISTRATION NUMBER IS NOT PROVIDED BECAUSE THE MANUFACTURER IS EXEMPT FROM REGISTRATION OR THERE IS A VALID REASON WHY A MANUFACTURER'S REGISTRATION NUMBER IS NOT BEING PROVIDED, ONE OF THE FOLLOWING EXEMPTION OR REASON CODES MUST BE USED AS A QUALIFIER TO THE FME AFFIRMATION OF COMPLIANCE CODE. AS PREVIOUSLY ANNOUNCED VIA ABI ADMINISTRATIVE MESSAGE THE VALID FME QUALIFIER EXEMPTION/REASON CODES INCLUDE:

FME QUALIFIER CODES

EXEMPTION CODES A - J

A. FACILITY IS OUT OF BUSINESS
B. FACILITY IS A PRIVATE RESIDENCE
C. FACILITY IS A RESTAURANT
D. FACILITY IS A RETAIL FOOD ESTABLISHMENT
E. FACILITY IS NONPROCESSING FISHING VESSEL
F. FACILITY IS NONBOTTLED DRINKING WATER COLLECTION AND DISTRIBUTION ESTABLISHMENT
G. INDIVIDUAL GIFT LABEL NAME/ADDRESS IN LIEU OF REGISTRATION NUMBER
H. GROWER SATISFIES FARM EXEMPTION (21 CFR 1.226(B); 1.227(B)(3)
I. SAMPLES - QUALITY ASSURANCE, RESEARCH OR ANALYSIS PURPOSES ONLY
J. U.S. MANUFACTURING FACILITY THAT IS NOT REQUIRED TO REGISTER

REASON CODES K - O
K. UNABLE TO DETERMINE THE REGISTRATION NUMBER OF THE MANUFACTURER
L. UNABLE TO DETERMINE IDENTITY OF MANUFACTURER - PROVIDING IDENTITY OF MANUFACTURER'S HEADQUARTERS
M. UNABLE TO DETERMINE IDENTITY OF MANUFACTURER OR HEADQUARTERS - PROVIDING INVOICING FIRMS IDENTITY
O. GIFT PACK FOR NON-BUSINESS PURPOSES - PROVIDING SINGLE PRIOR NOTICE AND IDENTITY OF PACKER

THE FOOD & DRUG ADMINISTRATION

ADMINISTRATIVE MESSAGE 05-0312 03/23/2005
TITLE: OGA-FDA:IMPORTANT! PRIOR NOTICE MANUFACTURER REGISTRATIONS

TO: ALL ABI FILERS, ESPECIALLY FDA PRIOR NOTICE FILERS
CORRECTION TO ADMIN 05-0304

FROM: THE FOOD & DRUG ADMINISTRATION

SUBJECT: PRIOR NOTICE MANUFACTURER REGISTRATION ERRORS
REJECTION OF MANUFACTURER REGISTRATION ERRORS
CORRECTION TO ADMIN 05-0304

FDA APOLOGIZES FOR ANY MISUNDERSTANDING THE EARLIER COPY OF THIS ADMIN MAY HAVE CAUSED. ADMIN MESSAGE 04-2563 WAS ISSUED DECEMBER 20, 2004 ADVISING THE TRADE OF TWO ADDITIONAL REJECT REASON CODES.THEY ARE INCORPORATED IN THE CORRECTED VERSION BELOW.

FDA CONTINUES TO MONITOR THE VALIDITY OF MANUFACTURER REGISTRATION INFORMATION SUBMITTED AS PART OF PRIOR NOTICE. A REVIEW OF THE PRIOR NOTICE DATA SUGGESTS THAT THERE ARE TWO MAIN ERRORS ASSOCIATED WITH MANUFACTURER REGISTRATION INFORMATION THAT IS TRANSMITTED USING THE "PFR" AFFIRMATION OF COMPLIANCE (A OF C) CODE AND QUALIFIER THAT WILL RESULT IN THE PRIOR NOTICE SUBMISSION BEING REJECTED. SUBMISSIONS ARE REJECTED EITHER BECAUSE THE MANUFACTURER REGISTRATION NUMBER PROVIDED IS NOT ON FILE WITH FDA OR THERE IS A MISMATCH BETWEEN THE MANUFACTURER REGISTRATION NUMBER AND THE MID THAT WAS TRANSMITTED FOR THE MANUFACTURER. THE PROBLEMS INCLUDED IN THOSE MAJOR REASONS ARE EXPLAINED FURTHER BELOW.

NOTE: PREVIOUS USE OF A MANUFACTURER REGISTRATION NUMBER DOES NOT GUARANTEE THAT FUTURE TRANSMISSIONS WILL BE ACCEPTED BY FDA.

THE MOST COMMON "REGISTRATION NOT ON FILE" REJECTS ARE DUE TO:

1. TRANSMISSION OF A REGISTRATION NUMBER THAT WAS CANCELLED BY THE MANUFACTURER; OR

2. TRANSMISSION OF A REGISTRATION NUMBER THAT HAS BEEN DEACTIVATED BY FDA DUE TO PROBLEMS CONFIRMING VALIDITY OF THE REGISTRATION INFORMATION.

THE MOST COMMON MISMATCH REJECTS ARE DUE TO:

1. TRANSMISSION OF THE IMPORTER OR CONSIGNEE REGISTRATION NUMBER INSTEAD OF THE MANUFACTURER REGISTRATION NUMBER.

2. TRANSMISSION OF THE SHIPPER REGISTRATION NUMBER INSTEAD OF THE MANUFACTURER REGISTRATION NUMBER; OR

3. TRANSMISSION OF A MANUFACTURER REGISTRATION NUMBER WHERE THE COUNTRY OF THE MANUFACTURER DOES NOT MATCH THE COUNTRY ASSOCIATED WITH THE MID USED THE THE TRANSMISSION.

THE REJECT CODES FOR INVALID REGISTRATION APPEAR IN THE BN APPLICATION

BN02 RECORD IN POSITION 65 AND INCLUDE:
(ALSO SEE ADMINISTRATIVE MESSAGE 04-2563 FOR FULL EXPLANATION)

I INVALIDATED BY FDA DUE TO PROBLEMS WITH THE FIRM NAME AND ADDRESS OR LEGITIMACY OF THE PARTY WHO FILED THE REGISTRATION.
C CANCELLED BY THE FIRM OR THEIR AGENT
F REGISTRATION NOT ON FILE
M MISMATCH IN REGISTRATION

IF YOU RECEIVE A FDA REJECT CODE RELATED TO THE MANUFACTURER'S REGISTRATION NUMBER, THE APPROPRIATE STEPS MUST BE TAKEN TO VERIFY THAT THE REGISTRATION NUMBER IS UPDATED AND VALID AND THAT THE CORRECT CORRESPONDING MID WAS USED IN THE TRANSMISSION. YOU WOULD THEN TRANSMIT THE VALID REGISTRATION NUMBER IN THE ABI OGA CORRECTION TRANSACTION COMMONLY KNOWN AS THE 'CP' CORRECTION. IF AFTER MAKING EVERY EFFORT TO DETERMINE THE CORRECT MANUFACTURER REGISTRATION NUMBER YOU ARE STILL UNABLE TO DO SO, YOU SHOULD DOCUMENT ALL EFFORTS AND TRANSMIT THE "FME" A OF C CODE WITH THE MOST ACCURATE "REASON CODE" LISTED BELOW (REASON CODES K - O) IN THE ABI 'CP' TRANSACTION. IF FDA DETERMINES THAT DUE DILIGENCE IN OBTAINING THE REGISTRATION NUMBER WAS NOT EXERCISED, SUBMITTERS MAY BE SUBJECT TO CIVIL MONETARY PENALTIES AND FINES.

FME QUALIFIER REASON CODES:

K UNABLE TO DETERMINE THE REGISTRATION NUMBER OF THE MANUFACTURER.

L UNABLE TO DETERMINE IDENTITY OF MANUFACTURER - PROVIDING IDENTITY OF MANUFACTURER'S HEADQUARTERS (IN FDA MID FD01 RECORD POS 48-62).

M UNABLE TO DETERMINE IDENTITY OF MANUFACTURER OR HEADQUARTERS - PROVIDING INVOICING FIRM'S IDENTITY (IN FDA MID FD01 RECORD POS 48-62)

O GIFT PACK FOR NON-BUSINESS PURPOSES - PROVIDING SINGLE PRIOR NOTICE AND IDENTITY OF PACKER (IN FDA MID FD01 RECORD POS 48-62)

IN CASES WHERE THE REGISTRATION NUMBER IS EITHER NOT ON FILE OR OTHERWISE INVALID, AN AGENT OF THE MANUFACTURER SHOULD CONTACT THE FURLS REGISTRATION HELP DESK AT 1-800-216-7331 (INSIDE US) OR 1-301-575-0156 (OUTSIDE OF US).