ADMINISTRATIVE MESSAGE 04-2375 URGENT 11/09/2004

TITLE: OGA-FDA CORRECTIONS FOR REJECT 'N'

ALL ABI FILERS: PLEASE REVIEW ADMINISTRATIVE MESSAGE 04-2355.

WITH THE IMPLEMENTATION OF PHASE 5 OF THE FDA/BTA PROGRAM, THERE ARE ADDITIONAL EDITS IN PLACE AT FDA -- RESULTING IN ADDITIONAL REJECTIONS OF YOUR PRIOR NOTICE TRANSMISSIONS.

IF YOU RECEIVE A REJECTION CODE OF 'N' (OTHER REJECT REASON - CALL FDA),
YOU SHOULD SEND AN OGA/FDA CORRECTION USING THE CP APPLICATION -- AND YOU NEED TO INCLUDE THE BILL OF LADING INFORMATION. IF YOU HAVE A RAIL OR VESSEL SHIPMENT, YOU SHOULD SEND THE 'BOL' AFFIRMATION OF COMPLIANCE WITH A QUALIFIER THAT INCLUDES THE SCAC AND THE BILL NUMBER. IF YOU HAVE AN AIR SHIPMENT, SEND THE 'AWB' AFFIRMATION OF COMPLIANCE.

THIS WILL CORRECT YOUR ENTRY AND SATISFY THE FDA REQUIREMENTS.

ADMINISTRATIVE MESSAGE 04-2355 11/03/2004

TITLE: OGA-FDA PN EDITS/CHNGS 110804

FDA HAS PUBLISHED A REVISED COMPLIANCE POLICY GUIDE (CPG) FOR PRIOR NOTICE OF IMPORTED FOOD. THAT DOCUMENT IS AVAILABLE AT WWW.CFSAN.FDA.GOV/~PN/CPGPN4.HTML. THE FOLLOWING PROVIDES INFORMATION ON NEW PRIOR NOTICE (PN) EDITS/REJECTS AND OTHER SYSTEM CHANGES THAT WILL BECOME EFFECTIVE NOVEMBER 8, 2004.

MANUFACTURER REGISTRATION INFORMATION:

CBP WILL CONTINUE TO REJECT PN SUBMISSIONS UNLESS A MANUFACTURER REGISTRATION NUMBER IS PROVIDED FOR THE MANUFACTURER USING THE "PFR" AFFIRMATION OF COMPLIANCE (AOFC) OR THE "FME" AOFC CODE AND REASON CODE IS TRANSMITTED.

FDA WILL REJECT PN SUBMISSIONS WHICH CONTAIN A MANUFACTURER REGISTRATION NUMBER THAT IS INVALID (NOT ON FILE OR MISMATCHED). FDA WILL ALSO REJECT PN SUBMISSIONS RECEIVED WHICH CONTAIN A "FME" AOFC CODE IF THE REASON CODE QUALIFIER TRANSMITTED IS INVALID. SIX NEW REASON CODES HAVE BEEN ADDED TO INDICATE WHY A REGISTRATION NUMBER HAS NOT BEEN TRANSMITTED. THE NEW CODES ARE I-M AND O. N (NO) HAS BEEN END-DATED AND USE OF THIS CODE OR ANY OTHER CODE NOT LISTED BELOW WILL CAUSE AN FDA REJECT. WITH THE ADDITION OF THESE NEW REASON CODES, ZERO-FILL OF THE AOFC "PFR" QUALIFIER FIELD IS NO LONGER ALLOWED AND SUBMISSION WILL CAUSE AN FDA REJECT.

FME QUALIFIER REASON CODES:

A. FACILITY IS OUT OF BUSINESS
B. FACILITY IS PRIVATE RESIDENCE
C. FACILITY IS A RESTAURANT
D. FACILITY IS 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
K. UNABLE TO DETERMINE THE REGISTRATION NUMBER OF THE MANUFACTURER.
L. UNABLE TO DETERMINE IDENTITY OF MANUFACTURER - PROVIDING IDENTITY OF MANUFACTURERS 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

BILL OF LADING/AIRWAY BILL INFORMATION:

FDA WILL REJECT PRIOR NOTICE SUBMISSIONS FOR RAIL AND SEA MODES OF TRANSPORTATION UNLESS THE BILL OF LADING NUMBER IS PROVIDED USING THE "BOL" AOFC CODE AND QUALIFIER AND SUBMISSIONS FOR AIR MODE OF TRANSPORTION UNLESS THE AIR WAYBILL IS SUBMITTED USING THE "AWB" AOFC CODE AND QUALIFIER.

THE PNSI 1.5 RELEASE NOTES DESCRIBING SYSTEM MODIFICATIONS MADE TO

REFLECT CHANGES MADE IN THE CPG ARE AVAILABLE AT
WWW.CFSAN.FDA.GOV/~PN/PNSIREV.HTML AND ALSO REFERENCED AND LINKED AT
WWW.ACCESS.FDA.GOV/OAA/ AND WWW.CFSAN.FDA.GOV/~PN/PNOVIEW.HTML/

HOLDING FACILITY INFORMATION:

PNSI HAS BEEN MODIFIED TO ALLOW SUBMISSION OF HOLDING FACILITY INFORMATION IN THE CASE WHERE FDA HAS REFUSED A FOOD ARTICLE. IF FDA OR U.S. CUSTOMS AND BORDER PROTECTION (CBP) DIRECT AN ARTICLE TO A HOLDING FACILITY, A PARTY WITH THE KNOWLEDGE OF THE HOLDING FACILITY LOCATION, DATE AVAILABLE AT THE LOCATION, AND A CONTACT AT THE LOCATION ASSOCIATED
WITH THE PRIOR NOTICE MUST SUBMIT THE INFORMATION TO THE FDA. PNSI MUST BE USED TO SUBMIT THE HOLDING FACILITY INFORMATION FOR PNS INITIALLY SUBMITTED EITHER THROUGH THE AUTOMATED COMMERCIAL SYSTEM (ACS) OR THROUGH PNSI.

PNSI NOW ALLOWS ANY PARTY TO SUBMIT THE HOLDING FACILITY INFORMATION, REGARDLESS OF WHETHER OR NOT THEY TRANSMITTED THE ORIGINAL PRIOR NOTICE.
PN TRANSMITTERS CAN SEARCH FOR PNS SUBMITTED VIA THEIR ACCOUNT TO SUBMIT
HOLDING FACILITY INFORMATION. IF THE PN WAS SUBMITTED VIA ACS OR WAS SUBMITTED VIA PNSI BY A PN TRANSMITTER USING A DIFFERENT ACCOUNT, THE IDENTIFYING INFORMATION FOR THE ARTICLE CAN BE USED TO ALLOW ANOTHER TRANSMITTER TO SUBMIT THE HOLDING FACILITY INFORMATION.
ONCE HOLDING FACILITY INFORMATION HAS BEEN SUBMITTED, THE TRANSMITTER CAN VIEW THE STATUS OF THE HOLDING FACILITY INFORMATION SUBMISSION TO DETERMINE IF IT WAS MATCHED TO A PRIOR NOTICE THAT WAS ORIGINALLY SUBMITTED.

IF YOU ANY QUESTIONS ABOUT THE SYSTEM CHANGES OR THE CPG PLEASE CONTACT FDA'S PRIOR NOTICE CENTER AT (866) 521-2297.

ADMINISTRATIVE MESSAGE 04-2381 URGENT 11/10/2004
TITLE: OGA-FDA REJECTS FOR REGISTRATION NUMBERS
TO: ALL ABI FILERS

FROM: FOOD & DRUG ADMINISTRATION
CUSTOMS & BORDER PROTECTION

SUBJECT: FDA REJECTS FOR INVALID REGISTRATION, MISSING REGISTRATION AND MISMATCH IN REGISTRATION

THERE HAVE BEEN MANY REJECTS FOR INVALID REGISTRATION (R = MISSING REGISTRATION, F = REGISTRATION NOT ON FILE, M = MISMATCH IN REGISTRATION). CURRENTLY FDA IS SENDING AN "M" FOR BOTH REGISTRATION NOT ON FILE AND FOR MISMATCH IN REGISTRATION.

THESE REJECTS CAN BE CAUSED BY TRANSMISSION OF A ZERO-FILL OR OTHER "DUMMY" REGISTRATION NUMBER AS THE QUALIFIER TO THE PFR AFFIRMATION OF COMPLIANCE CODE. DISCONTINUE USE OF ZERO-FILL OR "DUMMY" NUMBERS IMMEDIATELY.

REJECTS CAN ALSO BE CAUSED BY TRANSMISSION OF MULTIPLE PFR AFFIRMATION OF COMPLIANCE CODES. THE PFR AND QUALIFIER MUST REPRESENT THE SAME FIRM TRANSMITTED AS THE MANUFACTURER IN THE FD01 RECORD. DO NOT TRANSMIT MULTIPLE PFR AFFIRMATIONS OF COMPLIANCE.

IF FILERS RECEIVE A REJECT OF "M" IN POSITION 65 OF THE BN02 RECORD OUTPUT THEY SHOULD FIRST CHECK TO ENSURE THAT A ZEROES WERE NOT TRANSMITTED, A "DUMMY" NUMBER WAS NOT USED AND THAT MULTIPLE PFR AFFIRMATIONS WERE NOT TRANSMITTED. IF NONE OF THESE CONDITIONS APPLY THEN THE FILER CAN DO THE FOLLOWING:

SUPPLY THE IMPORTER WITH THE RESULTS OF AN ABI MANUFACTURER ID (MID) QUERY FOR THE MID USED IN THE REJECTED TRANSACTION. HAVE THE IMPORTER VERIFY THAT THE NAME AND ADDRESS (INCLUDING THE ISO COUNTRY CODE) OF THE REGISTERED FIRM MATCH THE MID QUERY PROVIDED AND THAT THE REGISTRATION NUMBER HAS NOT EXPIRED OR BEEN CANCELLED. A COMMON PROBLEM DISCOVERED IS WHEN ONE OF THE ENTITIES HAS AN ISO CODE OF HK (HONG KONG) AND THE OTHER CN (CHINA). THE IMPORTER MAY ALSO NEED TO SUPPLY THE FILER WITH THE CORRECT MANUFACTURER ADDRESS INFORMATION WHICH WOULD ALLOW THE FILER TO DETERMINE THE CORRECT MID THAT APPLIES. THE FILER WOULD USE THE ABI MID QUERY AND IF THE MID IS NOT ON FILE THEN USE THE ABI ADD MANUFACTURER FUNCTION. THE CORRECT INFORMATION (EITHER THE CORRECT MID OR PFR) WOULD THEN NEED TO BE TRANSMITTED THROUGH THE 'CP "OTHER GOVERNMENT AGENCY" CORRECTION FUNCTION.

IF AFTER A GOOD FAITH EFFORT, THE MANUFACTURER REGISTRATION NUMBER CANNOT BE DETERMINED, FILERS CAN TRANSMIT A CP CORRECTION, REMOVING THE PFR AFFIRMATION AND QUALIFIER AND REPLACING THEM WITH THE AFFIRMATION OF COMPLIANCE "FME" AND QUALIFIER "K" FOR THE REASON CODE. REASON CODE "K" = "UNABLE TO DETERMINE THE REGISTRATION NUMBER OF THE MANUFACTURER).

FOOD & DRUG ADMINISTRATION
CUSTOMS & BORDER PROTECTION