Questions and Answers from the November 19, 2009 FDA - NCBFAA Webinar

The following is a list of questions that were submitted by those that participated in the November 19, 2009 FDA-NCBFAA webinar on PREDICT. Each of the questions that were submitted, were grouped together under a specific topic. The topics are listed below.

TOPICS:

I. Mission Accomplishments and Regulatory Compliance Services (MARCS) Imports Entry Review

II. Predictive Risk Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)

III. FDA's Import Trade Auxiliary Communications System (ITACS)

IV. FDA Affirmation of Compliance (AofC) Codes

V. FDA Product Codes

VI. Firm Identification Issues

VII. Data Requirements/Quality Issues

VIII. Import Alert Process and Removal from Detention Without Physical Examination (DWPE)

IX. Miscellaneous Topics

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I. Mission Accomplishments and Regulatory Compliance Services (MARCS) Imports Entry Review

Q. When will MARCs be available?
Q. Is this system rolling out across the US Ports at once, or will this start rolling out by regional ports at a time?

A. FDA's MARCS Imports Entry Review software is being rolled out to one FDA District at a time. All ports covered by a District will be impacted at the same time. This software includes the ability to view documents and shipment examination availability information transmitted to FDA via ITACS as well as the integration of our new screening tool (PREDICT).

II. Predictive Risk Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)

Q. When Predict new system is going to be operational?
Q. When will PREDICT be rolled out? Is the target still the beginning of December?

A. FDA's MARCS Import Entry Review system is being deployed over the next several months. FDA's new screening tool (PREDICT) is integrated into that software release. The initial rollout occurred on September 22, 2009 in the Los Angeles District. We hope to have it implemented nation-wide by the end of the summer.

Q. What is considered a higher risk commodity, besides food?

A. Each FDA Center is responsible for designating and making modifications to the risk rankings for the FDA regulated products they oversee. These risk rankings are one of the factors utilized by FDA's import screening process to determine which lines will be May Proceeded by our import system and which lines will be held for further review by our Import entry review staff.

Q. Should we expect more examinations to occur (sample review)?

A. The number of examinations performed is a function of Agency resources and priorities. Those priorities will be reflected in the guidance provided to our field staff by our new Import screening process. Our entry review staff will utilize the guidance provided and designate products for examination based on the resources available.

Q. How will PREDICT tackle bad actors who "simply" ship non compliant product under a sister company's MID and FDA registration number, slightly alter shipping pattern and notify parties?

A. There are artificial intelligence tools available to assist in the detection of anomalies, associations, and shipping patterns. Combining electronic analysis along with traditional investigative avenues will aid in detection. More importantly the Agency will take the appropriate regulatory action against firms and individuals that ship products in violation of FDA's laws and regulations.

Q. Will PREDICT take into consideration, and target accordingly, regular import volumes for highly compliant importers versus occasional/single time imports?

A. Yes.

Q. Is this going to get us a faster response from FDA?

A. When there is a compliant history for the firms and product involved and complete and accurate information is transmitted by the filer the review time will be expedited. However, when incomplete or inaccurate information is provided, the time to make an initial system admissibility decisions will increase. This is especially true when Affirmation of Compliance codes are needed to perform automated database look-ups to determine the validity of registration, listing, and product approval status. If not provided, not only will the automated database look-up fail, FDA will need to request additional information in order to perform manual database look-ups.

III. FDA's Import Trade Auxiliary Communications System (ITACS)

Q. What is the web-base site login for ITACS?
Q. Where is the ITAC information accessed?

A. Access to FDA's ITACS (Import Trade Auxiliary Communications System) is currently not available. We intend to deploy a "Beta" test with a limited number of filers located in Los Angeles, Buffalo and New York sometime before the end of January 2010. If the feedback received during that test period is positive and there are no problems related to FDA's capacity to receive, store, and retrieve the entry documentation received, we will make the application available to all filers and importers to utilize the functionality which allows the trade to query the status of an entry. If the test shows there are questions about the functionality available we will update training materials.

Initially document submission and submission of shipment examination availability will be limited to filers transmitting entries through Customs ports located in FDA's Los Angeles and New York Districts. That limitation is necessitated by the timing of the implementation of FDA's new MARCS Import Entry Review software which is being rolled out one District at a time. Only those Districts using the new software to make import admissibility decisions can access the documents and availability information. Filers in other parts of the country will be notified via CBP's Cargo Systems Messaging Service (CSMS) when they can utilize the additional functionality. We are developing a web-page which will contain training materials, implementation information, and a feedback mechanism. That web-page will be accessible via a link from http://www.fda.gov/ForIndustry/ImportProgram/default.htm . Additional functionality will be added as resources allow.

Q Will self-filers have access to this system?

A. Yes. Anyone with an entry number can use the ITACS functions initially being deployed. There is no trade confidential information being provided regarding individual entries via the entry status query function. The additional functions available include the, submission of entry documentation and submission of shipment examination availability. Account management may be added to ITACS in the future as new functionality is added.

Q. Will ITACS allow importers to view status or will that be limited to brokers?

A. Yes. Anyone with the entry number will be able to access ITACS to view entry status.

Q. Currently releases for FDA are not transmitted to the steamship lines - this is an issue when the entry is filed in another port and delivered inland after release and the broker does not want the delivery to take place until released. Is this FDA hold ever going to transmit to the Steamship line?

A. No. This is a limitation of ACS and AMS. Once ITACS goes on line a steamship company can query the status if they have entry number.

IV. FDA Affirmation of Compliance (AofC) Codes

Q. We find it very difficult sometimes to determine if a particular product requires an Affirmation of Compliance and qualifier. Is there a streamlined way to look this up?

A. Not currently. Updated informational materials related to current AofC codes and qualifiers will be posted shortly and will be available at http://www.fda.gov/ForIndustry/ImportProgram/default.htm . Several of the documents will group the codes by product area to aid the trade in determining the appropriate AofC codes to transmit.

Q. Will Affirmation of Compliance Codes become mandatory? Will there be a change of statute to accomplish this?

A. Transmission of AofC Codes is not mandatory at this time. Changes to regulatory authorities to require transmission of additional data elements required to make admissibility decisions are under consideration by Agency.

Q. For medical device, must affirmation of compliance (registration & MIDS) be listed on electronic submission for both manufacture and foreign exporter? Obviously mfg is needed

A. If the manufacturer is declared when a medical device is imported, the DEV affirmation should be used. If the exporter is declared as the manufacturer at time of import, the DFE affirmation should be used. The firm being declared as the manufacturer is required to list the device.

V. FDA Product Codes

Q. The Product Code Builder is not really user friendly in my opinion. Believe this should be addressed if they are expecting brokers to use Product Code Builder on line.

A. We recognize the problems with the current Product Code Builder and are try are working to obtain funding for redesign. We will look to the trade community for input on needed changes to the application in the future.

Q. Is there a list of product/product codes that have been updated?

A. No. As mentioned during the webinar, when major changes are made to FDA product codes that information is shared via CBP's Cargo Systems Messaging Systems (CSMS). We also indicated that filers should not rely on internally stored product codes for individual importer accounts but periodically check the on-line Product Code Builder to determine if new, more specific product codes have been added.

Q. Will this replace the actual creation of product codes?

A. There is currently no plan to replace the FDA product codes. Transmission of those codes will continue to be a requirement for FDA regulated products. We're unsure of the context of this question.

VI. Firm Identification Issues

Q. The issue may not only be inconsistent MIDs but inconsistent addresses from the foreign manufacturer (see CN)

A. We discussed many of the issues related to use of MIDs to identify foreign firms in import transactions. Until necessary data requirements and systems changes are implemented by CBP we are exploring the expanded use of Affirmation of Compliance codes to identify parties in transmissions of FDA regulated products. FDA definitely supports the move toward using a unique firm identifier, such as those provided by DUNS.

Q. If the brokers make an update to a mid will that merchandise get flag for sampling?

A. No. In the current CBP/FDA interface there is no transaction which allows filers to update the initial MID transmitted to FDA.

Q. Is there a way where the filer can confirm the MID? Is there a database to check?

A. Filers should query the MID using the built in capabilities of ABI and compare the output with the entry documents. If the MID returned has already been used to identify another firm filers should contact their ABI client representatives for guidance. CBP and FDA are exploring the use of other unique firm identifiers such as a DUNS number to mitigate the known problems with the MID.

Q. If FDA is aware of the registered manufacturers; why can't this be shared with the trade community?

A. Disclosure of this information is specifically prohibited by the Bioterrorism Act of 2002 and Final Rule on Food Facility Registration. Though firm registration numbers are linked with a FDA firm record (FEI), transmission of a MID which is not related to the same record can still be accurate. Every effort should be made by the importer and/or filer to get the exact firm name and address submitted at time of registration. That information can be used to help select the correct MID.

Q. Since ABI contains multiple MIDs for any particular company, how do we know which is the correct one for FDA?

A. The MID with the most accurate firm name and address for the site specific manufacturer is the MID which should be used. Filers can add a MID if none of the available MIDs do not accurately reflect the firm name and address.

Q. We have a big problem generating UNIQUE MID's especially with Chinese manufacturers due to the similarity of Chinese names and lack of numeric elements in the street address. The current MID format is becoming inadequate. Any comments? If there is no numeric element in the street address, we sometimes plug in the postal code to help create a unique code. Sometimes, however, this MID is already "taken." Brokers really need help and guidance from Customs on this.

A. Again, Filers should query the MID using the built in capabilities of ABI and compare the output with the entry documents. If the MID returned has already been used to identify another firm filers should contact their ABI client representatives for guidance. CBP and FDA are exploring the use of other unique firm identifiers such as a DUNS number to mitigate the known problems with the MID. FDA is also actively working to develop alternative methods to identify firms involved in the import transaction. We have already added new Affirmation of Compliance codes which enable filers to identify multiple growers represented in a line.

Q. How does FDA anticipate to handle MID codes that are identical for 2 different companies? From certain areas, with no street addresses applicable, the MID code for 2 different companies could be the same. It is not possible to verify which company is designated in CBP database at time of entry.

A. The filer needs to contact his ABI representative for assistance in building a truly unique MID for the firm.

VII. Data Requirements/Quality Issues

Q. Can you please explain how MID codes impact risk assessment using PREDICT? Will DUNS, or something similar, be required instead?

A. Because a firm may have many MIDS it impacts the ability to assess the track record of a manufacturer. i.e. If a filer created a new MID for a firm that has an excellent track record, that firm may be targeted because it appears to us to be a new firm with no history. Continuous use of the most correct MID will ensure creation of a consistent track record for the firm.

Q. If FDA wants to see additional information or they find information in their databases that wasn't provided will they share that with brokers so we can use it for future entries to expedite future shipments?

A. If FDA needs additional information to make an admissibility decision we will continue to request that information be provided via a request for entry documentation. Future functionality is planned to allow FDA to transmit requests for specific information via the CBP/FDA interface and for filers to transmit that information back to FDA. In the meantime, we will no doubt add the ability to transmit additional textual information, beyond that available in entry documentation, via ITACS in the future. We will continue to provide updates to existing guidance documents regarding data requirements, mandatory and voluntary. As we identify firms with high failure rates related to automated database look-ups, we will try to identify the data deficiency responsible for the failure and work with the FDA field, filers and importers to correct the deficiency.

Q. Where can we send a request for data error rates?
Q. How can you obtain a copy of the list of broker scores under FOIA. What is the name of the list or report to request?

A. Filer related data errors rates and results of filer evaluations can be requested under FOIA. Information on submitting a FOI request can be found at http://www.fda.gov/RegulatoryInformation/FOI/default.htm. This information would be obtained from our database and there no specific list or name associated with the data.

Q You mentioned FOIA - will the importer/filer scores be available via ITRAC also?

A. No. ITRAC is a CBP system and will not contain information about importer or filer errors identified by FDA or the relative ranking of a filer or importer's data quality.

Q. When these discrepancies are identified, how will it be communicated? Broker? Importer?

A. We are unsure of the context of this question. Currently we communicate with filers via outreach, CBP CSMS messages, and filer evaluations. If this is specific to filer or import data errors please see previous response.

Q. As a broker, use the Affirmation of Compliance & Product Codes supplied by the importers. It sounds as FDA is expecting brokers to verify accuracy... we should not be held responsible for accuracy.

A. A filer should make a good faith effort to insure the data supplied by an importer is accurate. The filer should impress upon the importer that complete and accurate transmission of entry data will expedite FDA admissibility processing. Further, importers and filers should work with manufacturers and/or shippers to ensure the accuracy of the data provided.

Q. As a food manufacturing company will we need to submit more information to the filers?

A. Complete and accurate information supplied to the filers is important for all commodities. For foods specifically, there are no new information requirements. However, manufacturers should provide importers and/or filers with their registration number as well as the most complete firm name and address for their site specific manufacturing plant. For LACF/AF products the FCE, SID, and container dimensions should be provided.

Q. It is my understanding that if we have a product manufactured by a third party that in addition to reporting our affirmation codes FDA will also be requesting information from the third party IE name of company and physical location.

A. FDA always requires a firm identifier to be transmitted in the record used to identify the manufacturer. Many FDA regulated commodities require information on the site-specific manufacturer. Where not required to provide the site-specific manufacturer, the firm identifier for the third party exporter can be transmitted in that record. One example is medical devices where the exporter does not know the identity of the manufacturer.

Q. If a broker/filer sends data for 5 different importers, and 3 of the importers have terrible record on data…does the filer gets bad rating? Does this negatively impacting the filers responsible importers?

A. Yes. The filer should evaluate the documents provided, compare the product code with the product description, and they should make sure the firm identifiers used are accurate.

VIII. Import Alert Process and Removal from Detention Without Physical Examination (DWPE)

Q. If results of sampling are logged, will manufacturers on import alert begin to be automatically removed after x number of nonviolative entries? Or will process remain same and timeline of removal indefinite?

Q. Clarification: Timeline is not indefinite; it's currently after 5 entries. However, FDA review of the petition to remove takes 6 months or more dependent on FDA reviewers workload. Will Predict change this and update import alerts faster?

A. No. PREDICT has no impact on those procedures. The current requirements for removal from DWPE are outlined in the FDA's Regulatory Procedures Manual. Removal from DWPE is often dependent upon the nature of the problem and the product and every removal requires review. In addition to the RPM you can check specific Import Alerts for special requirements.

Q. Is this valid for removal from import alert as well?

A. We do not understand the context of this question.

IX. Miscellaneous Topics

Q. What is the maximum number of HTS lines the current system will accept?

A. The maximum number of lines containing all the prior notice information is 644 lines. The maximum number of non-PN lines is 2,499.

Q. Will there be any FDA initiative to importers of a partnership that would potentially be a program like a C-TPAT, ISA (recognized by CBP), providing benefits to importers who have demonstrated above level compliance and operations.

A. We're working closely with CBP recognize C-TPAT and ISA programs as well as looking at other voluntary programs such as Good Importer Practices and other programs which are included in pending legislation.

Q. Why is there a trusted importer program (Qualified Trusted Importer Program – QTIP) for pharmaceuticals but not for food? We've offered to participate and open the books but no one at FDA seems interested/able to collaborate with food importers like CBP does via C-TPAT.

A. We are not aware of QTIP, however the FDA's Secure Supply Chain pilot for pharmaceuticals is a program, if found to be successful may be the template for clearance of other commodities.

Q. When you are a maquiladora manufacturer and you have the need to return raw material as it was originally, what we need to report to you? Is the Product code enough?

A. For most products there are no special exemptions or requirements for this type of product return. All FDA elements which would normally be required for this commodity apply.