**RECOMMENDATIONS OF THE COAC 1USG FDA WORKING GROUP (CONSOLIDATED, SORTED, RENUMBERED, NARRATIVES REMOVED)**
**Version 2 (October 2, 2014)**

| # | Recommendation | For COAC Vote | Read at Meeting, But No Vote | Potential BIEC Items | Category * | | | | Term ♦ | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | D | P | I | C | S | L |
| 1 | Consistent with the 1USG single window concept, CBP and FDA should accept and review advance data submissions as early as possible in the transit cycle to allow for preclearance prior to arrival. Earlier, consolidated entry submissions would provide the agencies (CBP, FDA, and other PGAs) with greater upstream visibility to assess security and admissibility risks, engage the trade to resolve risks, and provide for earlier admissibility decisions, ideally well before the physical arrival of the goods at the port. CBP should share arrival information with FDA and the other PGAs as soon as possible, upon receipt, rather than holding it for a specified time based on MOT. The data sent to FDA should include the filer's processing port, so FDA knows where to target the related filer evaluation when Remote Location Filing is being used. | X | | X | | X | | | X | |
| 2 | Working with FDA, CBP should develop a mechanism in ACE for importers/filers to amend specific FDA data elements, including port codes, without having to cancel and replace the entire entry. | X | | X | X | | X | | X | |
| 3 | FDA should develop and implement a multi-sector account-based trusted trader program that provides reduced targeting and pre-clearance for known, compliant, and vetted partners who provide advance data, allowing the agency to focus its limited resources on shipments deemed to be greater risk. Further, an importer's failure to provide repetitive voluntary data elements (such as establishment registration number) when that information is already on file with the agency and can be maintained on an account basis should not prevent an AMP in PREDICT for participants in the trusted trader program. | | X | X | | X | | | | X |

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| | | | | | D | P | I | C | S | L |
| 4 | FDA should incorporate some measurement of an importer's "known" or "trusted" status in the PREDICT targeting, and give it a higher weight than currently given to Firm Compliance History. In addition, when the CBP IOR and FDA Importer are the same party, the PREDICT risk score should be lower. | | X | | | X | X | | X | |
| 5 | When applicable, import alerts should include the related foreign establishment registration number (or DUNS number) to facilitate better automated monitoring of the Import Alert database by importers and filers. FDA should also rethink how import alerts are communicated, and to whom, so companies whose products are impacted get direct notification. Import alerts should also be as narrow as possible, to target specific sources/manufacturers of violative product rather than impacting importers who obtain the same product from a different country/source. | | X | | | X | | X | X | |
| 6 | Foreign site identification numbers (e.g. MID, DUNS, IOR, FEI, FFR, etc.) used by CBP, FDA and other agencies in ACE should be reduced to a single ID number, creating a uniform standard in ACE/ITDS. The creation and maintenance of FEIs requires FDA resources that could be better deployed to other higher risk targeting activities. Similarly, when an importer does provide multiple identification numbers for a foreign facility (e.g., FFR and DUNS) and these numbers are aligned, the targeting should be lower. | X | | X | X | | | | X | |
| 7 | FDA should pre-validate importer/filer datasets (master data) outside of the entry process. | | X | X | X | X | X | | | X |
| 8 | FDA should establish a single, central data repository used by all Centers (CDER, CDRH, CBER, etc.), rather than having PREDICT ping against multiple systems and databases. Maintaining a single database, as opposed to multiple, would require fewer FDA resources. | | X | | | | X | | | X |

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| | | | | | D | P | I | C | S | L |
| 9 | FDA should eliminate the quantity and value input requirements when addressing FDA holds since neither are indicators of violative products. | | X | | X | | X | | X | |
| 10 | When comparing the relative risk of an import line to the past 30 days, PREDICT should compare it only to the same sector (i.e., food to food, pharma to pharma, device to device) to get a more accurate indicator of true risk. | | X | | | X | X | | X | |
| 11 | FDA transactional messaging built into ACE should be specific and timely, in real-time, notifying the filer what's missing, incorrect, or has been changed by FDA, and a full audit trail should be maintained for any changes that have been made to an entry. | X | | X | | | | X | X | |
| 12 | FDA should improve the process for building Product Codes by incorporating more functionality into the system and adding a process for importers/filers to request new more descriptive product codes. The 1USG Subcommittee and FDA WG will provide a list of suggested enhancements in the narrative report to FDA. | | X | | | X | | X | | X |
| 13 | FDA should consider making "firm type or activity" a mandatory field in the FFR application, to allow for better targeting of shipments where the "manufacturer" in a Prior Notice submission was defined as a "warehouse only" entity on their FFR application. | | X | | | X | X | | X | |
| 14 | CBP should work with FDA to define <u>optional</u> Intended Use Codes in the PGA Message Set allowing the trade to indicate reasons for disclaiming FDA on certain imported goods where the HTS code may trigger but the goods aren't subject, thereby avoiding the need for manual review. | X | | | X | X | X | | X | |

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| | | | | | D | P | I | C | S | L |
| 15 | CBP should include an FDA Workshop as a regular breakout session at the annual Trade Symposium, where importers/filers have an open forum to discuss issues and ask questions. The relevant CEEs should also partner with FDA to host periodic outreach and training events for importers and filers, with targeted training at ports with higher rates of non-AMPs. | X | | X | | | | X | X | |
| 16 | FDA should establish a Help Desk for providing timely guidance to importers/filers on FDA Product Codes and AOC codes, with a targeted response time not to exceed 24 hours. FDA should consider embedding this resource in the relevant CBP Centers of Excellence & Expertise (CEEs). | | X | | | X | | X | X | |
| 17 | FDA should publish Informed Compliance Publications (ICPs) (or Compliance Policy Guides) defining exactly what information (mandatory vs. voluntary) is required for various product categories (i.e., medical devices manufactured by a foreign TPM for a US-specs developer) and clearly advising the trade of the impact of not providing the optional elements at the time of entry. To ensure consistency and promote a common understanding by all stakeholders, these ICPs should be used as the official guidelines by importers, filers, and the agencies. FDA should better educate the trade about what data elements/AOCs are publicly available on the FDA website or through other automated means (e.g., the CDRH searchable databases). | | X | X | | X | | X | X | |
| 18 | FDA's global team should provide additional outreach and education outside the US for foreign suppliers/shippers/mfrs on US import requirements, terminology, and use of tools on the website. Programs could be designed to focus on industries or products (e.g., dental products, hearing aids). FDA should also consider developing YouTube videos or webinars that can be repeated on demand w/out additional resources. | | X | X | | | | X | X | |

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| | | | | | D | P | I | C | S | L |
| 19 | FDA should provide better guidance regarding FDA Units of Measure (UOMs) when different from CBP UOMs, explaining why they are different, when applicable, to improve the trade's understanding and use. | | X | | X | | | X | X | |
| 20 | Importers need a better understanding of which FDA-regulated imports are more likely to go “docs required” or more often require human review so we can be more proactive with our responses. FDA should publish FAQs listing which types of shipments generally require documents, labels, or human review (e.g., R&D, unapproved products, IFE, coloring, US Goods Returned, etc.). Also rather than uploading documents, special supplemental data should be accepted rather than document images. Where there is paper/PDFs, there is inefficiency and cost. | | X | | | | | X | X | |
| 21 | CBP and FDA should provide guidance to the trade regarding the compliant use of Section 321 entries for FDA-regulated goods. | X | | | X | X | | | X | |
| 22 | FDA should provide better guidance regarding the import requirements for medical device components when the importer is a parts distributor and is not the manufacturer of a finished, listed device. In addition, FDA should provide better guidance re: what components are actually regulated and therefore subject to FDA review at the border. | | X | | | | | X | X | |
| 23 | FDA should continue to provide filer error reports, ideally including HAWB #, to improve the accuracy of importer datasets going forward. In addition, FDA should generate blinded "common error" reports on a periodic (monthly/quarterly) basis and make those reports available to the trade via DIS in ACE. Routine analysis of root causes leading to repetitive non-AMPs, and the corresponding efforts to eliminate them, would increase the level of PREDICT AMPs and reduce manual reviews. | | X | | X | | | X | X | |
| 24 | FDA should implement a standardized filer evaluation process and have the guidance available to the brokerage industry. | | X | | | X | | | X | |

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| 25 | FDA should increase the use/functionality of ITACS, eliminating duplicate communication that often occurs via email, fax, and traditional mail. To the extent possible, ITACS should also interface with the ACE Document Imaging System (DIS) to provide bidirectional communication to the trade. FDA should add account management functionality to ITACS, allowing brokers to manage multiple subaccounts for their filer code and control who has access to which entries. | | X | | | X | X | X | X | |
| 26 | On an account basis, FDA should allow the importer to designate where Notices of Action are sent (importer, filer and/or consignee). Alternatively, NOAs should be disseminated via ITACS/DIS so all interested parties have immediate access. | | X | | | X | | X | X | |
| 27 | CBP and FDA should consider consolidating and integrating FDA field/port operations into corresponding CBP Centers of Excellence and Expertise (CEEs), to provide better uniformity and resource utilization. | X | | X | | X | | | | X |
| 28 | FDA should develop a process whereby frequent importers of US Goods Returned can proactively provide additional information regarding the nature of the business (e.g., medical devices routinely imported for recalibration) via ITACS/DIS in order to obtain an AMP and prevent human review. Wherever possible, FDA should consider eliminating document requirements and instead rely on value-added supplemental data. | | X | | | X | | | X | |

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| 29 | FDA should re-evaluate how it defines high risk and low risk, in particular for FDA Centers (e.g., CBER) that currently consider their entire spectrum of regulated products to be high risk, allowing for no differentiation among them. More sophisticated risk algorithms should also be developed to better target areas known to have a higher incidence of violative products (e.g., FFR requests by US agents for sites with existing FFRs). | | X | X | | X | | | | X |
| 30 | FDA should continue the weekly entry program, which allows participating importers to submit fewer/aggregated entries for frequently imported low-risk goods. Reducing the number of entries requiring FDA review allows the agency to deploy its limited resources to higher-risk shipments. | | X | | | X | | | X | |
| 31 | CBP, via the BIEC, should encourage FDA and other PGAs to continue to consult with the trade via COAC and its subcommittees and working groups, in alignment with the 1USG single window concept. In addition, FDA should use periodic trade surveys to identify current areas of opportunity, allowing the agency to better focus on areas that need further analysis or attention. | X | | X | | X | | X | X | X |
| 32 | To ensure full agency buy-in, any actions taken to fulfill these recommendations should be pushed down from the Commissioner level to the operational level at both CBP and FDA. | X | | X | | X | | X | X | |
| | | | | | | | | | | |

* D = Data; P = Process; I = Information Technology; C = Communication/Education

♦ S = Short-Term; L = Longer-Term

◊ F = Food; P = Pharma; D = Devices

# SUPPORTING NARRATIVE AND COMMENTARY FOR THE RECOMMENDATIONS OF THE COAC 1USG FDA WORKING GROUP (CONSOLIDATED)
## Version 1 (October 2, 2014)

**BACKGROUND**

The current COAC 1USG FDA Working Group (FDA WG) was formed in the 2nd Quarter of 2014, with representation from the pharmaceutical, medical device, and food sectors, as well as express carriers and brokers. The work group initially divided into three teams each representing an industry sector, but the pharma and device teams were ultimately merged, as their issues and concerns were found to be very similar. FDA also participated, along with CBP, in several of the WG meetings.

The primary goal of the FDA WG was to develop recommendations that would help improve the quality of data submitted to FDA and reduce the number of rejects that don't pass the automated screening process in PREDICT. According to FDA, only 30% of lines get an automated "may proceed" at the time of entry, with the remainder requiring some level of manual review by FDA personnel. As FDA moves towards implementation of the ACE/ITDS single window and the PG message set, they would like to see a higher level of automated may proceeds, allowing them to redeploy their limited resources to higher risk shipments. This will enhance FDA's ability to conduct high level investigation work as it relates to product safety under FD&C Act.

The FDA WG has developed recommendations in the areas of data quality, processes and procedures, information technology, and communication (both in terms of transactional messaging, and outreach and informed compliance). In addition to the formal recommendations that will be brought to vote at the October 7 public meeting, the 1USG subcommittee will also take the opportunity to present additional recommendations and suggestions, not to be voted on, directly to FDA. This paper includes both sets of recommendations.

This white paper is intended to provide FDA with a more narrative description of the drivers and issues behind the recommendations, putting them in better context for an improved understanding of the root causes the FDA WG is hoping to address. Please note, in some cases, the narrative comments are the thoughts of a single team member, but the FD WG Leads thought it was important to include nonetheless. Recommendations without additional narrative are felt to be self-explanatory, but FDA should feel free to contact the FDA WG Leads (Susie Hoeger and/or Scott Boyer) for further clarification as needed.

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**WORKING GROUP MEMBERS / OBSERVERS**

**COAC members**

- Susie Hoeger – FDA Working Group Lead/1USG Subcommittee Co-chair/ Abbott
- Scott Boyer – FDA Working Group Co-Lead/ Kraft Foods
- Mary Ann Comstock – 1USG Subcommittee Chair/ UPS Supply Chain Solutions
- Ted Sherman (observer) – COAC Trade Co-chair/ Target Corporation
- Matt Fass (observer) – COAC / Maritime Products International

**Working Group Trade Members by Sector**

*Food Sector*

- Mark FeDuke, VLM Foods Inc.
- Kate Weiner, Cargill

*Medical Devices/Pharma Sectors*

- Kaye Mortensen, Bristol Myers Squib
- Warren Hastings, Cardinal Health
- Cheryl Zellmer, Medtronics
- Ron Keegan, Ranbaxy Laboratories

*Customs Brokers*

- Maggie Smith-Ranney - Coppersmith
- Travis Hull - Livingston
- Rene Romero – Am-Mex International
- Barbie Clarke – Williams Clarke

*Express Couriers*

- Stuart Schmidt - UPS
- Sandy Jacobs - FedEx
- Amy Smith - DHL
- Vincente Martinez, DHL (Representative)

*Associations/Consultants*

- Michael Mullen, EAA
- John McGowan, STTAS

**Government Leadership**

- Maria Luisa Boyce – COAC Designated Federal Officer -CBP
- Douglas Stearn, Director, Office of Enforcement and Import Operations -FDA
- Domenic Veneziano, Director, Division of Import Operations - FDA
- Cynthia Whittenburg, Executive Director, TPP, OT - CBP
- Augustine Moore, Acting Executive Director, CCS, OFO - CBP
- Brenda Brockman Smith, Executive Director, ABO, OT, CBP

**Government Participants - FDA**

- Sandra Abbott, FDA
- Max Castillo, ACE/ITDS Liaison, FDA
- Anthony 'Tony' Nicoli, Division of Compliance Systems, FDA
- Ted Poplawski, Division of Import Operations
- Cynthia LaFountain, Watch Commander, Division of Food Targeting Defense, FDA
- Alison Nicoli, OEIO/DIO/PDIB, FDA
- Michael Fesko, Office of Policy and Risk Management, FDA
- Jamie Hughes, Center for Food Safety and Nutrition, FDA
- Carole Jones, Center of Device and Radiological Health, FDA
- Steven Branch, Center of Drug Evaluation and Research

**SUPPORTING NARRATIVE AND COMMENTARY FOR THE**
**RECOMMENDATIONS OF THE COAC 1USG FDA WORKING GROUP (CONSOLIDATED)**
**Version 1 (October 2, 2014)**

**Government Participants - CBP**

- Vincent Annunziato, Director, ABO, OT, CBP
- Jeff Nii, Director IAR, TPP, OT -CBP

*Centers of Excellence and Expertise*

- Agriculture: Greg McCann
- Pharmaceutical/Medical Devices: Leon Hayward, Christian Hughes, Anthony Orosz
- Electronics: Anne Maricich, Sherrie Hoffman

*OTR Support*

- Trudy Rutland, OTR - CBP
- Steve Graham, OTR -CBP
- Michael Schreffler, OTR- CBP

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**RECOMMENDATIONS AND ADDITIONAL NARRATIVE**

**Recommendation #1:** Consistent with the 1USG single window concept, CBP and FDA should accept and review advance data submissions as early as possible in the transit cycle to allow for preclearance prior to arrival. Earlier, consolidated entry submissions would provide the agencies (CBP, FDA, and other PGAs) with greater upstream visibility to assess security and admissibility risks, engage the trade to resolve risks, and provide for earlier admissibility decisions, ideally well before the physical arrival of the goods at the port. CBP should share arrival information with FDA and the other PGAs as soon as possible, upon receipt, rather than holding it for a specified time based on MOT. The data sent to FDA should include the filer's processing port, so FDA knows where to target the related filer evaluation when Remote Location Filing is being used.

**Additional Narrative:**

Early and synchronized admissibility and (in the case of food) Prior Notice submissions improve time and risk assessment under both sections. 21 CFR should be amended to permit earlier submissions. A 1USG single window, single entry for all imports should be permitted. FDA and CBP should support a single entry, for all information with the earliest CFR requirement, Importer Security Filing – "10+2" under 19 CFR 149. Earlier, combined submissions would seem to provide the FDA with greater upstream visibility to assess risk, resolve discrepancies provide for earlier admissibility decisions, ideally before the goodso physical arrival at the port of entry.

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**Recommendation #2:** Working with FDA, CBP should develop a mechanism in ACE for importers/filers to amend specific FDA data elements, including port codes, without having to cancel and replace the entire entry.

**Additional Narrative:**

With regards to port codes in particular, to avoid errors in the future, CBP should accept the port code from the filer and allow the carrier's port code transmission to override the filer port code submission.

If this is not feasible from an IT perspective, CBP and FDA should allow the filer to update/correct its transmission to include the correct port code without raising the risk analysis score assigned by FDA.

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**Recommendation #3:** FDA should develop and implement a multi-sector account-based trusted trader program that provides reduced targeting and pre-clearance for known, compliant, and vetted partners who provide advance data, allowing the agency to focus its limited resources on shipments deemed to be greater risk. Further, an importer's failure to provide repetitive voluntary data elements (such as establishment registration number) when that information is already on file with the agency and can be maintained on an account basis should not prevent an automated may proceed (AMP) in PREDICT for participants in the trusted trader program.

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**Recommendation #4:** FDA should incorporate some measurement of an importer's "known" or "trusted" status in the PREDICT targeting, and give it a higher weight than currently given to Firm Compliance History. In addition, when the CBP IOR and FDA Importer are the same party, the PREDICT risk score should be lower.

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**Recommendation #5:** When applicable, import alerts should include the related foreign establishment registration number (or DUNS number) to facilitate better automated monitoring of the Import Alert database by importers and filers. FDA should also rethink how import alerts are communicated, and to whom, so companies whose products are impacted get direct notification. Import alerts should also be as narrow as possible, to target specific sources/manufacturers of violative product rather than impacting importers who obtain the same product from a different country/source.

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**Recommendation #6:** Foreign site identification numbers (e.g. MID, DUNS, IOR, FEI, FFR, etc.) used by CBP, FDA and other agencies in ACE should be reduced to a single ID number, creating a uniform standard in ACE/ITDS. The creation and maintenance of FEIs requires FDA resources that could be better deployed to other higher risk targeting activities. Similarly, when an importer does provide multiple identification numbers for a foreign facility (e.g., FFR and DUNS) and these numbers are aligned, the targeting should be lower.

**Additional Narrative:**

Entity resolution (MID, DUNS, IOR, FEI, FFR, etc.) should be a priority for CBP and FDA to resolve in the ACE environment, which can lead to it being the solution for the other agencies using ACE/ITDS. Too many numbers are currently used to identify foreign sites subject to FDA requirements, creating too much opportunity for error and misalignment.

The Trade would like FDA to provide (in writing) some details about where they are going with the DUNS numbers and what they are currently planning to do with MIDs, manufacturer (not shipper) names/addresses, FEIs, and the AOCs for establishment registrations (FFR, REG, DEV). There is a lot of

confusion on this among the WG group members on this topic, so we need a common understanding of FDA's current plan.

Many compliance and trade facilitation problems long known to government and trade relate to the challenges with the proper creation of MIDs and FEIs. CBP is already planning to eliminate the use of MIDs, and we hope other agencies will follow suit.

The anticipated use of DUNS numbers for FSMA requirements is an important, unique opportunity for the FDA to simplify (eliminate) use of other foreign site numbers. FDA should consider the elimination of FEIs altogether. FDA should only use of two numbers: the relevant establishment registration number (FFR, DEV, REG) and the DUNS number. FEIs are not required by law and are prone to inaccuracy and duplication due to three different ways they can be created (FDA employee, FDA Registration, and by creation of CBP Manufacturer IDs (MIDs)). The elimination of FEIs will eliminate the related risk of human error, allowing FDA to better deploy resources that are currently spent on FEI creation and database maintenance.

Moreover, FEI numbers for international sites are essentially unavailable for use by the trade. FEIs can only be obtained through a FOIA request unless there is a need to protect the facility, e.g. contract manufacturer. In that circumstance they are not available via FOIA. Domestic FEIs for manufacturers can be queried by brokers but the function isn't available for foreign facilities.

If use of FEIs continues, a clearer understanding of the reasons for protecting international FEIs would be helpful. If the trade is has no effective ability to manage the accuracy and effective use of FEIs, then all aspects of international FEIs – creation, accuracy, and maintenance – require FDA resources. FEIs at this point seem to not be required by any 21 CFR provisions. Problems with FEIs, which are "cross-walked" from MIDs, impede effective PREDICT scoring and AMPs. Erroneous and multiple site MIDs impact the utility of international FEIs for targeting of inadmissible FDA goods and also timely AMPs for legitimate FDA goods.

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**Recommendation #7:** FDA should pre-validate importer/filer datasets (master data) outside of the entry process.

**Additional Narrative:**

Rather than waiting to identify data issues at the time of entry when perishable and/or life-saving goods are sitting at the port, it would be much more efficient for importers, filers, and FDA if the agency was able to validate the importer/filer data sets outside of the entry process. Under this proposed process, importers/filers would submit entire master data sets to FDA for validation, and the agency would respond by indicating which lines have issues or data anomalies. We are not asking the agency to provide us with the correct data elements (which could run contrary to data privacy concerns), but merely to flag the lines/products that have data anomalies, leaving it to the importer to research and resolve the issues. This would lead to significant improvements in data quality, and would ensure accurate data submissions for all future imports of a particular item.

This data validation process has already been conducted on a limited basis for certain importers/filers in certain ports, thereby demonstrating its feasibility.

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**Recommendation #8:** FDA should establish a single, central data repository used by all Centers (CDER, CDRH, CBER, etc.), rather than having PREDICT ping against multiple systems and databases. Maintaining a single database, as opposed to multiple, would require fewer FDA resources.

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**Recommendation #9:** FDA should eliminate the quantity and value input requirements when addressing FDA holds since neither are indicators of violative products.

**Additional Narrative:**

The filer error reports provided to the FDA WG indicate that quantity and value discrepancies had the highest frequency of errors/issues impeding an AMP. Quantity and value are optional fields that are not required under 21 CFR and have not proven to be an effective indicator of a good's admissibility. Quantity and value discrepancies should not be considered indicators of higher risk in PREDICT or during manual review.

Unified entry release/Prior Notice filing may be linked to quantity errors as Prior Notice may often be reported prior to loading the cargo conveyance in the truck and rail environment. This is particularly true for bulk commodities.

Value reporting errors may be linked to the fact that the Customs value for entry summary is not often determined at the time of filing FDA information. Value is often adjusted with additions and subtractions to arrive at the correct transaction value for CBP reporting purposes. Also, there are numerous commodities that are sold in transit or after delivery in the USA, and at the time of border crossing the value is unknown or subject to change.

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**Recommendation #10:** When comparing the relative risk of an import line to the past 30 days, PREDICT should compare it only to the same sector (i.e., food to food, pharma to pharma, device to device) to get a more accurate indicator of true risk.

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**Recommendation #11:** FDA transactional messaging built into ACE should be specific and timely, in real-time, notifying the filer what's missing, incorrect, or has been changed by FDA, and a full audit trail should be maintained for any changes that have been made to an entry.

**Additional Narrative:**

Real-time detailed communications from FDA in the form of an ACE PGA message set similar to customs validation responses is needed. Importers and brokers must be immediately notified when there are apparent errors. The importers and brokers need to have the ability to immediately correct errors or provide additional information well before the goods arrive at the port of entry. Initially this may cause intensive exchanges, but as the trade learns from the responses the information provided will improve and facilitate more AMPs and more efficient reviews. Currently there is no active or timely feedback

from FDA. If an importer or filer is submitting information they believe to be correct and it is causing an error and manual review the same mistake will be repeated wasting resources. A messaging system would allow the trade to learn from mistakes and improve the quality of information submitted going forward.

FDA should communicate with the filer when Product Codes and AOCs are invalid/incorrect and whose accuracy is essential to FDA screening and AMPs. A message should be sent to the filer anytime the product code is updated by the FDA. The updated/corrected code should be described.

FDA should provide real-time messaging to filers/importers broker when an entry contains errors or has been updated by an FDA entry reviewer.

FDA should automatically reject an entry (with specific, descriptive messaging) when information is missing, or when data elements do not match (e.g., if the FDA manufacturer doesn't match the FFR).

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**Recommendation #12:** FDA should improve the process for building Product Codes by incorporating more functionality into the system and adding a process for importers/filers to request new more descriptive product codes. The 1USG Subcommittee and FDA WG will provide a list of suggested enhancements in the narrative report to FDA.

**Additional Narrative:**

FDA can improve the process for providing product codes by:

a) Communicating to the trade about codes which are frequently incorrect or whose accuracy is essential to FDA screening and AMPS.

b) Adopting a ruling system, like the Customs binding ruling, that would specify product codes, particularly for complex products, in response to a request from the trade. Adding these product codes to PREDICT would ensure an AMP if all other data was correct and the product was deemed low risk. Also provide the ability to request that a product be added to the database.

c) Creating a more robust product library to cover commonly imported products (e.g. "Alfredo sauce"). In many cases we are forced to use the "NEC" or "99" categories which raises the likelihood that predict or an inspector will request an inspection or additional documentation. This adds time and cost to the clearance process for manufacturers and importers.

d) More sophisticated search engine with Boolean capabilities.

e) Tie into other FDA databases such as medical devices.

f) Use of common names such as "Adult Diapers" in addition to more technical terms such as "Garment, Protective, For Incontinence".

g) A larger viewing screen for would be helpful to allow the user to see more items at one time.

h) Printer friendly version of a session would allow a user to document how a product code was arrived upon.

i) Update the product code builder tutorial.

j) Definitions given when a cursor “rolls over” elements of the product code.

k) Better descriptions, particularly in cases with multiple choices (e.g., industry codes 45 & 46 “food additives” industry codes 20, 21 & 22 for “fruit or industry” codes 24 & 25 for “vegetables”).

l) Dual use products should be clearly indicated in each industry (e.g., pharmaceutical necessities & food additives).

m) PC builder may construct a product code which later turns out to be invalid. All codes should be checked against FDA database for validity.

n) The PC builder should provide the related FDA units of measure (UOMs).

o) The PC builder should identify or suggest the related AOCs that are likely required for the product. This enhancement would facilitate greater and more accurate use of AOCs.

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**Recommendation #13:** FDA should consider making "firm type or activity" a mandatory field in the FFR application, to allow for better targeting of shipments where the "manufacturer" in a Prior Notice submission was defined as a "warehouse only" entity on their FFR application.

**Additional Narrative:**

With regards to FDA Prior Notice in general: Although beyond the initial focus of this group, PN submissions are an upstream requirement which must be satisfied before the PREDICT admissibility screening process may begin. In the course of the FDA WG Food Sector discussions, some findings and recommendation related to PN were identified.

Common causes of incorrect manufacturers in PN:

1. Importers/filers inputting shippers and “exporter only” firms as manufacturers.

2. Inputting one manufacturer and assigning that manufacturer to all lines throughout the shipment. (This should not occur, as FDA reporting is at the line level not the header level. However, entry lines may need further refinement or breakdown to accommodate additional reporting requirements, e.g. LACF items)

3. MID issues (already addressed)

The “type of activity conducted at the facility” is an optional field in the Food Facility Registration application but the system could be programed to reject any prior notice or OGA

entry data when a firm, identified as a "warehouse only" in their registration, is declared as the manufacturer. Making "Firm type or activity" a mandatory declaration in the registration application would make this work even better. There is some concern among FDA WG members that making this mandatory could cause more issues – for example, what if applicant does both? Sometimes they are a warehouse for foods they don't make and other times they are the manufacturer – we don't need more registration numbers to try to track!

This change would not only improve the DFDT prior notice data quality for manufacturers but will also assist in 801(a) AMP. Often automatic lookups of supplied FCE numbers end up trying to match the FCE to the "shipper" or "exporter only" firm as that's what is supplied as the manufacturer – so when the look-up fails, so does the AMP.

Common causes of incorrect Ultimate Consignees in PN:

1. Importers/filers input the headquarters office or home address which is not a location suitable for receiving a commercial size shipment. .

2. Importers/filers input PO Boxes rather than a physical address

This indicates a need for better education regarding the requirements for DFDT Ultimate Consignee.

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**Recommendation #14:** CBP should work with FDA to define <u>optional</u> Intended Use Codes in the PGA Message Set allowing the trade to indicate reasons for disclaiming FDA on certain imported goods where the HTS code may trigger but the goods aren't subject, thereby avoiding the need for manual review.

**Additional Narrative:**

Intended use codes are in the CATAIR. Each agency has them available, and would need to add them to their supplemental appendix and define what they are.

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**Recommendation #15:** CBP should include an FDA Workshop as a regular breakout session at the annual Trade Symposium, where importers/filers have an open forum to discuss issues and ask questions. The relevant CEEs should also partner with FDA to host periodic outreach and training events for importers and filers, with targeted training at ports with higher rates of non-AMPs.

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**Recommendation #16:** FDA should establish a Help Desk for providing timely guidance to importers/filers on FDA Product Codes and AOC codes, with a targeted response time not to exceed 24 hours. FDA should consider embedding this resource in the relevant CBP Centers of Excellence & Expertise (CEEs).

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**Recommendation #17:** FDA should publish Informed Compliance Publications (ICPs) (or Compliance Policy Guides) defining exactly what information (mandatory vs. voluntary) is required for various product categories (i.e., medical devices manufactured by a foreign TPM for a US-specs developer) and clearly advising the trade of the impact of not providing the optional elements at the time of entry. To ensure consistency and promote a common understanding by all stakeholders, these ICPs should be used as the official guidelines by importers, filers, and the agencies. FDA should better educate the trade about what data elements/AOCs are publicly available on the FDA website or through other automated means (e.g., the CDRH searchable databases).

**Additional Narrative:**

While AOCs are "voluntary" (especially for most food), FDA should clearly describe the benefits of submitting AOCs if the trade is to make investment in their use. Also, arranging the AOCs by sector: food, medical devices, and pharmaceuticals, by FDA Product Codes and by associated HTSUS codes would help the trade efficiently determine if a suitable AOC for their product is available. A document with all requirements for the commodity in one location would help the trade. The trade would also benefit from a better understanding of when and why multiple FDA lines are required for goods falling under a single CBP entry line.

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**Recommendation #18:** FDA's global team should provide additional outreach and education outside the US for foreign suppliers/shippers/manufacturers on US import requirements, terminology, and use of tools on the website. Programs could be designed to focus on industries or products (e.g., dental products, hearing aids). FDA should also consider developing YouTube videos or webinars that can be repeated on demand w/out additional resources.

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**Recommendation #19:** FDA should provide better guidance regarding FDA Units of Measure (UOMs) when different from CBP UOMs, explaining why they are different, when applicable, to improve the trade's understanding and use.

**Additional Narrative:**

Quantity issues (one of the most common errors identified by FDA) may also be linked to the breakdown of the unit required by FDA. Importers and brokers may not know what unit of measure (UOM) FDA is required for each FDA product code if different from the CBP required UOM.

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**Recommendation #20:** Importers need a better understanding of which FDA-regulated imports are more likely to go "docs required" or more often require human review so we can be more proactive with our responses. FDA should publish FAQs listing which types of shipments generally require documents, labels, or human review (e.g., R&D, unapproved products, IFE, coloring, US Goods Returned,

etc.). Also rather than uploading documents, special supplemental data should be accepted rather than document images. Where there is paper/PDFs, there is inefficiency and cost.

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**Recommendation #21:** CBP and FDA should provide guidance to the trade regarding the compliant use of Section 321 entries for FDA-regulated goods.

**Additional Narrative:**

The trade would benefit from a clearer understanding of whether it is acceptable to use Section 321 entries for FDA-regulated goods.

Per the FDA Investigations Operations Manual, "Section 321 entries for Customs are those entries with a value of $200 or less. Generally, this form of entry applies to articles which pass free of duty and tax, as defined in 19 C.F.R. 101.1(o), and imported by one person. Customs and FDA may conduct periodic "blitzes" to determine the volume and type of FDA-regulated goods admitted under Section 321 entries."

Unlike formal entries, entry data for Section 321 entries does not automatically feed to FDA. If a shipment qualifies for Section 321 under the Customs regulations, is it appropriate to use this provision for FDA regulated goods (e.g., for a product sample or other low value shipment), knowing that FDA will not have full visibility to the shipment?

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**Recommendation #22:** FDA should provide better guidance regarding the import requirements for medical device components when the importer is a parts distributor and is not the manufacturer of a finished, listed device. In addition, FDA should provide better guidance re: what components are actually regulated and therefore subject to FDA review at the border.

**Additional Narrative:**

PREDICT currently requires a Device Listing # to be provided in order to obtain an AMP, but the parts importer would likely not have access to its end-customer's device listing numbers, nor would they know with any certainty whether the component was going into a regulated medical device. In addition, FDA should publish better guidance re: what is considered a component of a medical device. What if the "component" is a sticker or basic #10 machine screw that I can buy at the hardware store? Does that really need to be declared to FDA as a component if I'm going to use it to screw the back of a medical instrument together?

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**Recommendation #23:** FDA should continue to provide filer error reports, ideally including HAWB #, to improve the accuracy of importer datasets going forward. In addition, FDA should generate blinded "common error" reports on a periodic (monthly/quarterly) basis and make those reports available to the trade via DIS in ACE. Routine analysis of root causes leading to repetitive non-AMPs, and the

corresponding efforts to eliminate them, would increase the level of PREDICT AMPs and reduce manual reviews.

**Additional Narrative:**

FDA systems are limited in the ability to query and analyze data errors or other root causes inhibiting AMPs. FDA systems need to have the capability to perform data quality control analysis considering the increased volume of FDA subject goods, the diversity of required and "voluntary" data and challenges to importers (CBP and FDA) to understand compliance and benefits for submitting optional information.

FDA should consider improving risk assessments at a higher level rather than at the transactional/entry level. For example, rigorous screening of FFR requests by US Agents, particularly requests for sites with an existing FFR, may be an indicator of higher risk. Analysis of repetitive non-AMPs and root causes with corresponding efforts to eliminate the root causes would improve use of PREDICT and resources required to do manual reviews.

Short term, FDA should actively communicate with the trade about data inaccuracies. Analysis of frequent line and product code discrepancies and feedback is more effective and efficient than asking the entire trade to always upload documents.

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**Recommendation #24:** FDA should implement a standardized filer evaluation process and have the guidance available to the brokerage industry.

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**Recommendation #25:** FDA should increase the use/functionality of ITACS, eliminating duplicate communication that often occurs via email, fax, and traditional mail. To the extent possible, ITACS should also interface with the ACE Document Imaging System (DIS) to provide bidirectional communication to the trade. FDA should add account management functionality to ITACS, allowing brokers to manage multiple subaccounts for their filer code and control who has access to which entries.

**Additional Narrative:**

Importers/filers should utilize ITACS if an auto-reject message indicates documents are required at the time of entry (well before arrival of the goods at the port of entry).

FDA should enhance ITACS capabilities to allow for electronic notices and two way communication between FDA and the trade. In addition, FDA should consider migrating all ITACS functionality into ACE/ DIS. Ideally, all CBP and PGA communications with the trade should be channeled through the ACE single window. We need a better understanding of whether ACE web interoperability allows FDA to access ACE and view what's in DIS, and what FDA's plans are for an ITACS/ACE interface.

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**Recommendation #26:** On an account basis, FDA should allow the importer to designate where Notices of Action are sent (importer, filer, and/or consignee). Alternatively, NOAs should be disseminated via ITACS/DIS so all interested parties have immediate access.

**Additional Narrative:**

FDA WG members would like to see the FDA NOA's go through ITACS. Mailing numerous copies to multiple parties is redundant and this could be a cost-saving opportunity for the FDA. In addition to this reducing the FDA resources needed to mail the NOA's to multiple parties, it would greatly reduce the turn-around time for information to be available to the recipient. This is typically the first indication we get regarding the issue causing the hold and the Compliance Officer we need to reach out to. Having to wait several days to get it by mail is an issue.

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**Recommendation #27:** CBP and FDA should consider consolidating and integrating FDA field/port operations into corresponding CBP Centers of Excellence and Expertise (CEEs), to provide better uniformity and resource utilization.

**Additional Narrative:**

FDA should consider placing staff with admissibility authority in the relevant CBP Centers of Excellence & Expertise (i.e., Agriculture/Prepared Foods and Pharma/Healthcare). By co-locating FDA and CBP officials, improved, collaborative, and standardized admissibility decisions can be made.

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**Recommendation #28:** FDA should develop a process whereby frequent importers of US Goods Returned can proactively provide additional information regarding the nature of the business (e.g., medical devices routinely imported for recalibration) via ITACS/DIS in order to obtain an AMP and prevent human review. Wherever possible, FDA should consider eliminating document requirements and instead rely on value-added supplemental data.

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**Recommendation #29:** FDA should re-evaluate how it defines high risk and low risk, in particular for FDA Centers (e.g., CBER) that currently consider their entire spectrum of regulated products to be high risk, allowing for no differentiation among them. More sophisticated risk algorithms should also be developed to better target areas known to have a higher incidence of violative products (e.g., FFR requests by US agents for sites with existing FFRs).

**Additional Narrative:**

The FDA Centers need to recognize that there is a spectrum of risk within the products they regulate. For example, not all biologics are the same, so they should not all be automatically considered high risk. Similarly, the fact that a low-risk Class I device could be used in conjunction with a higher-risk Class II device should not make the Class I device high risk "by association." These overly conservative definitions of risk do not allow the FDA Division of Import Operations to properly target items that are

truly of higher relative risk, and the agency does not have adequate resources to process everything as high risk. There must be some differentiation to allow for more effective allocation of resources by FDA.

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**Recommendation #30:** FDA should continue the weekly entry program, which allows participating importers to submit fewer/aggregated entries for frequently imported low-risk goods. Reducing the number of entries requiring FDA review allows the agency to deploy its limited resources to higher-risk shipments.

**Additional Narrative:**

Weekly Entry is a special Customs procedure for Foreign Trade Zones (FTZs) that is authorized by statute (19 USC 1484(i); 19 CFR 146.63(c)). The FDA developed its own Weekly Entry Filing (WEF) process in 1996 to align with the Customs program for FDA regulated merchandise; it has administered its WEF process since that time.

Weekly Entry reflects the unique commercial realities of FTZs, which are regulated by the U.S. FTZ Board, Customs, and the FDA. It supports high volume business activity that is physically located in the United States. The FTZ operations are authorized by the U.S. FTZ Board as being in the "public interest."

The FDA FTZ WEF process is only available for: (1) companies approved to operate as an FTZ by the U.S. FTZ Board; (2) that file an FDA-defined application; (3) after the FDA has reviewed their application at the local, HQ, and Center levels and determined the product to be low risk.

Terminating the program will result in a substantially increased administrative burden and cost for both industry and the FDA because separate entries will need to be filed and reviewed for each shipment of FDA regulated merchandise out of an FTZ. The result could be an increase of up to 100 or more additional Customs entries per week for each company that is currently using the FDE WEF process. This will lengthen the time necessary to ship low risk merchandise to consumers and increase costs to consumers, industry, and the FDA.

FDA regulated industries are a very significant percentage of FTZ activity, constituting approximately $4.382 billion in pharmaceuticals alone in 2013. Companies using the WEF process are diverse, including pharmaceutical companies, medical device companies, consumer products (tableware) companies, and motor vehicle manufacturers.

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**Recommendation #31:** CBP, via the BIEC, should encourage FDA and other PGAs to continue to consult with the trade via COAC and its subcommittees and working groups, in alignment with the 1USG single window concept. In addition, FDA should use periodic trade surveys to identify current areas of opportunity, allowing the agency to better focus on areas that need further analysis or attention.

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**Recommendation #32:** To ensure full agency buy-in, any actions taken to fulfill these recommendations should be pushed down from the Commissioner level to the operational level at both CBP and FDA.

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## CONCLUSION

The COAC and FDA WG trade members would like to thank the FDA for the opportunity to provide commentary and insight on the above issues, and we hope to continue our collaboration in the future. We feel the implementation of our recommendations will result in improved data quality and a higher level of automated may proceeds, allowing FDA to better deploy its valuable and limited resources to its primary mission of protecting the public health by assuring the safety, effectiveness, quality, and security of our imported goods.

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