

**SUPPORTING NARRATIVE AND COMMENTARY FOR THE  
SUBSET OF RECOMMENDATIONS OF THE COAC 1USG FDA WORKING GROUP  
(GENERALIZED FOR THE BORDER INTERAGENCY EXECUTIVE COUNCIL TO BE BROADLY  
APPLICABLE TO OTHER PARTNER GOVERNMENT AGENCIES)  
Final Version (November 6, 2014)**

**EXECUTIVE SUMMARY**

The current COAC 1USG FDA Working Group (FDA WG) was formed in the 2<sup>nd</sup> Quarter of 2014, with representation from the pharmaceutical, medical device, and food sectors, as well as express carriers and customs brokers. The work group initially divided into three teams representing the three industry sectors, but the pharma and device teams were ultimately merged, as their issues and concerns were found to be very similar. FDA field and import experts 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 fail to pass the automated screening criteria in PREDICT. According to FDA, only 30% of entry release data lines get an automated “may proceed” (AMP) 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 AMPs, allowing them to redeploy their limited resources toward higher risk shipments. This will enhance FDA’s ability to conduct high level investigation work as it relates to product safety requirements under FD&C Act.

The FDA WG developed recommendations in the areas of data quality, processes and procedures, information technology, and communication (both in terms of transactional messaging, outreach, and informed compliance). In addition to the 11 formal COAC recommendations which were voted on and unanimously approved during the October 7 public meeting, the 1USG subcommittee also made 21 additional recommendations, which were not voted on, directly to the FDA. Of the 32 total FDA recommendations, the FDA WG has identified 18 items for the Border Interagency Executive Council (BIEC) that are general enough to be broadly applicable to all Partner Government Agencies (PGAs) (in some cases, with minor wording changes). This paper and accompanying matrix include that subset of 18 recommendations.

This white paper is intended to provide the BIEC with a 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. Many of the narrative comments are specific to FDA processes and have been left that way in the paper, but others have been edited to be more broadly applicable to all agencies. Please note, in some cases, the narrative comments are the thoughts of a single team member, but the FDA WG Leads thought it was important to include them nonetheless. Recommendations without additional narrative are felt to be self-explanatory, but the BIEC 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

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- 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
- Bill Earle (observer), COAC / National Association of Beverage Importers Inc.

**Working Group Trade Members by Sector**

*Food Sector*

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

*Medical Devices/Pharma Sectors*

- Kaye Mortensen, Bristol Myers Squibb
- 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**

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- Sandra Abbott, FDA
- Max Castillo, ACE/ITDS Liaison, FDA
- Anthony 'Tony' Nicoli, Division of Compliance Systems, FDA
- Ted Poplawski, Division of Import Operations, FDA
- 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, FDA

**Government Participants - CBP**

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

**Centers of Excellence and Expertise**

- Agriculture and Prepared Products: 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**

**BIEC Recommendation #1 (FDA Rec #1):** Consistent with the 1USG single window concept, CBP and the PGAs 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 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 the PGAs as soon as possible, upon receipt, rather than holding it for a specified time based on mode of transportation (MOT).

**Additional Narrative:**

Early and synchronized admissibility of (in the case of food) Prior Notice and Entry submissions improve time and risk assessments under both sections. 21 CFR and all applicable regulations should be amended to permit much earlier submissions. A 1USG single window, single entry for all imports should be permitted. CBP and the PGAs should support a single entry, for all information, with the earliest required data submission (currently the Importer Security Filing under 19 CFR 149). Earlier, unified submissions would seem to provide the agencies with greater upstream visibility to assess risk, resolve

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discrepancies provide for earlier admissibility decisions, ideally before the goods' physical arrival at the port of entry.

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**BIEC Recommendation #2 (FDA Rec #2):** Working with the PGAs, CBP should develop a mechanism in ACE for importers/filers to amend specific 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 codes 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 the PGAs should allow the filer to update/correct its transmission to include the correct port code without raising the risk score assigned by the PGA.

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**BIEC Recommendation #3 (FDA Rec #3):** The PGAs 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 when that information is already on file with the agency and can be maintained on an account basis should not prevent automated PGA release for participants in the trusted trader program.

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**BIEC Recommendation #4 (FDA Rec #4):** The PGAs should incorporate some measurement of an importer's "known" or "trusted" status in their targeting.

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**BIEC Recommendation #5 (FDA Rec #6):** Foreign site identification numbers (e.g. MID, DUNS, IOR, FEI, FFR, etc.) used by CBP and other agencies in ACE should be reduced to a single identifier, creating a uniform standard in ACE/ITDS.

**Additional Narrative:**

Entity resolution (MID, DUNS, IOR, FEI, FFR, etc.) should be a priority for CBP and the 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 (and other agency) 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

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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 remove 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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**BIEC Recommendation #6 (FDA Rec #7):** PGAs 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 the PGAs 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 the relevant PGAs 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.

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

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**BIEC Recommendation #7 (FDA Rec #11):** PGA 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 the PGA, and a full audit trail should be maintained for any changes that have been made to an entry.

**Additional Narrative:**

Real-time detailed communication from the PGAs 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 automated/expedited releases and more efficient reviews. As an example, 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, and the updated/corrected code should be provided. Similar processes should also be used by other PGAs.

The PGAs should provide real-time messaging to filers/importers when an entry contains errors or has been updated by a PGA entry reviewer.

PGAs 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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**BIEC Recommendation #8 (FDA Rec #14):** CBP should work with the PGAs to define optional Intended Use Codes in the PGA Message Set allowing the trade to indicate reasons for disclaiming PGA requirements 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. This may be particularly effective in sorting out whether the US Goods being returned should be subject to PGA review.

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**BIEC Recommendation #9 (FDA Rec #15):** CBP should include PGA Workshops as regular breakout sessions 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 the PGAs to host periodic outreach and training events for importers and filers, with targeted training at ports with higher rates of delay in the PGA release process.

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**BIEC Recommendation #10 (FDA Rec #16):** The PGAs should establish a Help Desk for providing timely guidance to importers/filers on import issues, with a targeted response time not to exceed 24 hours. The PGAs should consider embedding this resource in the relevant CBP Centers of Excellence & Expertise (CEEs).

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**BIEC Recommendation #11 (FDA Rec #17):** The PGAs should publish Informed Compliance Publications (ICPs) (or Compliance Policy Guides) defining exactly what information (mandatory vs. voluntary) is required for various product categories 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. The PGAs should better educate the trade about what data elements are publicly available on the PGA websites or through other automated means.

**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. A similar process for other PGAs with mandatory and voluntary data elements would also be beneficial.

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**BIEC Recommendation #12 (FDA Rec #18):** The PGA's global teams 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 PGA websites. Programs could be designed to focus on industries or products. PGAs should also consider developing YouTube videos or webinars that can be repeated on demand w/out additional resources.

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**BIEC Recommendation #13 (FDA Rec #20):** Importers need a better understanding of which PGA-regulated imports are more likely to go “docs required” or more often require human review so we can be more proactive with our responses. The PGAs should publish FAQs listing which types of shipments generally require documents, labels, or human review. Also rather than uploading documents, special supplemental data should be accepted rather than document images because where there is paper/PDF, there is inefficiency and cost.

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**BIEC Recommendation #14 (FDA Rec #27):** CBP and the PGAs should consider consolidating and integrating PGA field/port operations into corresponding CBP Centers of Excellence and Expertise (CEEs), to provide better uniformity and resource utilization.

**Additional Narrative:**

The PGAs 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 PGA and CBP officials, improved, collaborative, and standardized admissibility decisions can be made.

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**BIEC Recommendation #15 (FDA Rec #28):** The PGAs should develop a process whereby frequent importers of US Goods Returned can proactively provide additional information regarding the nature of the business via DIS in ACE in order to obtain an automated PGA release and prevent human review. Wherever possible, the PGAs should consider eliminating document requirements and instead rely on value-added supplemental data.

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**BIEC Recommendation #16 (FDA Rec #29):** The PGAs should re-evaluate how they define high risk and low risk. More sophisticated risk algorithms should also be developed to better target areas known to have a higher incidence of violative products.

**Additional Narrative:**

The FDA Centers (and all PGAs) 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 by FDA. 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 PGAs’ Import Operations groups 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 the PGAs.

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**BIEC Recommendation #17 (FDA Rec #31):** CBP, via the BIEC, should encourage the 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, the PGAs should use periodic trade surveys to identify current areas of opportunity, allowing the agencies to better focus on areas that need further analysis or attention.

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**BIEC Recommendation #18 (FDA Rec #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 the PGAs.

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**CONCLUSION**

The COAC and FDA WG trade members would like to thank the BIEC, and especially 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 the agencies to better deploy their valuable and limited resources to the primary mission of protecting the public health by assuring the safety, effectiveness, quality, and security of our imported goods.

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BIEC Ref	Recommendation	Approved by COAC Vote on 10/7/2014	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 the PGAs 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 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 the PGAs as soon as possible, upon receipt, rather than holding it for a specified time based on MOT.	X		X		X			X	
2	Working with the PGAs, CBP should develop a mechanism in ACE for importers/filers to amend specific data elements, including port codes, without having to cancel and replace the entire entry.	X		X	X		X		X	
3	The PGAs 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 when that information is already on file with the agency and can be maintained on an account basis should not prevent automated PGA release for participants in the trusted trader program.		X	X		X				X
4	The PGAs should incorporate some measurement of an importer's "known" or "trusted" status in their targeting.		X	X		X	X		X	
5	Foreign site identification numbers (e.g. MID, DUNS, IOR, FEI, FFR, etc.) used by CBP and other agencies in ACE should be reduced to a single identifier, creating a uniform standard in ACE/ITDS.	X		X	X				X	
6	PGAs should pre-validate importer/filer datasets (master data) outside of the entry process.		X	X	X	X	X			X
7	PGA 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 the PGA, and a full audit trail should be maintained for any changes that have been made to an entry.	X		X				X	X	

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8	CBP should work with the PGAs to define <u>optional</u> Intended Use Codes in the PGA Message Set allowing the trade to indicate reasons for disclaiming PGA requirements 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		X	
9	CBP should include PGA Workshops as regular breakout sessions 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 the PGAs to host periodic outreach and training events for importers and filers, with targeted training at ports with higher rates of delay in the PGA release process.	X		X				X	X	
10	The PGAs should establish a Help Desk for providing timely guidance to importers/filers on import issues, with a targeted response time not to exceed 24 hours. The PGAs should consider embedding this resource in the relevant CBP Centers of Excellence & Expertise (CEEs).		X	X		X		X	X	
11	The PGAs should publish Informed Compliance Publications (ICPs) (or Compliance Policy Guides) defining exactly what information (mandatory vs. voluntary) is required for various product categories 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. The PGAs should better educate the trade about what data elements are publicly available on the PGA websites or through other automated means.		X	X		X		X	X	
12	The PGA's global teams 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 PGA websites. Programs could be designed to focus on industries or products. PGAs 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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13	Importers need a better understanding of which PGA-regulated imports are more likely to go “docs required” or more often require human review so we can be more proactive with our responses. The PGAs should publish FAQs listing which types of shipments generally require documents, labels, or human review. Also rather than uploading documents, special supplemental data should be accepted rather than document images because where there is paper/PDF, there is inefficiency and cost.		X	X				X	X	
14	CBP and the PGAs should consider consolidating and integrating PGA field/port operations into corresponding CBP Centers of Excellence and Expertise (CEEs), to provide better uniformity and resource utilization.	X		X		X				X
15	The PGAs should develop a process whereby frequent importers of US Goods Returned can proactively provide additional information regarding the nature of the business via DIS in ACE in order to obtain an automated PGA release and prevent human review. Wherever possible, the PGAs should consider eliminating document requirements and instead rely on value-added supplemental data.		X	X		X			X	
16	The PGAs should re-evaluate how they define high risk and low risk. More sophisticated risk algorithms should also be developed to better target areas known to have a higher incidence of violative products.		X	X		X				X
17	CBP, via the BIEC, should encourage the 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, the PGAs should use periodic trade surveys to identify current areas of opportunity, allowing the agencies to better focus on areas that need further analysis or attention.	X		X		X		X	X	X
18	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 the PGAs.	X		X		X		X	X	

D = Data; P = Process; I = Information Technology; C = Communication/Education  
S = Short-Term; L = Longer-Term

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						D	P	I	C	S	L	
1	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.	X		X		X				X	
2	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	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
4	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		
5	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 identifier, creating a uniform standard in ACE/ITDS. The creation and maintenance of FEIs require B28res 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	
6	7	FDA should pre-validate importer/filer datasets (master data) outside of the entry process.		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
	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
7	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
	13	FDA should consider making "type of activity conducted at the facility" 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. Registrants should be required to indicate <u>all</u> types of activity that are conducted at a particular facility.		X			X		X			X

8	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	
9	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	
10	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	
11	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	
12	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	
	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	
13	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	CBP should collaborate with FDA to implement a standardized filer evaluation process, based on nationally published standards and documented written guidance to the brokerage industry on how the evaluations will be conducted. Entry data sent by CBP 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. FDA messaging to filers via ACE is critical to improving data quality and is a key component in a standardized filer evaluation.	X				X			X	
	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	
14	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
15	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		
16	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		
17	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
18	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