Centralized Entry Review Pilot

U.S. Food and Drug Administration
Office of Regulatory Affairs

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Introduction

Import personnel from the Office of Regulatory Affairs (ORA) discovered both benefits and challenges when they conducted a pilot in which entry reviewers made initial decisions about imports arriving outside their own districts.

During the 49-day pilot, a group of ORA employees from across the country performed entry review of certain imports arriving at any one of 14 ports located in six districts. The pilot, called Centralized Entry Review (CER), returned a wealth of information, some of which can be applied to operating procedures.

Typically, brokers or filers electronically submit information about their imports, and entry reviewers working in the district where the imports arrive review the information.

During the pilot, only the entry review portion of the screening process was changed; local district personnel continued to handle any necessary next steps, including compliance actions, examinations or product sampling.

“The pilot is already showing us how to improve the process as it is currently practiced,” said Melinda K. Plaisier, Associate Commissioner for Regulatory Affairs. “In that respect, it exceeded the goal of giving us in-depth data to help inform future decisions about whether to pursue centralized entry review.”

Among many other findings, the pilot quantified problems that slow down entry review, costing both importers and ORA time and money. Findings suggested opportunities for improvement and led to recommendations for a renewed emphasis on more frequent training for both industry and ORA entry reviewers, standardization of entry decisions, and improved communications. Specific changes to data systems also appear warranted from the result.

Most, if not all, improvements suggested by the pilot, were applicable not only to any potential future plans, but also, to current practices as well. The U.S. Food and Drug Administration (FDA) will consider each recommendation.

Project Background

The need for optimal efficiency is critical, given that the volume of imports has steadily increased by 10 percent annually over the past decade and types of imports are ever more diverse. Yet the number of fulltime FDA employees in imports has remained constant.

Moreover, most ports experience unpredictable peaks and troughs, meaning that on any given hour or day, things at one port could be slow even as another port is overwhelmed.

In an effort to address these challenges, FDA has been working to develop initiatives to optimize resource utilization and improve system performance across import operations. Additionally, an industry working group (now part of the Advisory Committee on Commercial Operations of Customs and Border Protection) comprised of more than 65 representatives spanning the import community, has been looking at import interaction between FDA and the trade. This group proposed a set of recommendations to FDA which they believe will enhance efficiencies and best practices of the import process. One of the recommendations was to centralize the entry review process. ORA decided to pursue a pilot to determine the feasibility, potential impacts, and possible efficiencies of centralizing entry review.

Launch date, length of pilot, days of coverage, and hours of operation were determined based on historical volumes to ensure that high volume months, days, and hours would be included. The pilot was launched August 12, 2013, and operated seven days a week, rather than the usual five days a week, including Monday – Friday from 7 a.m. to 4 a.m., 7 a.m. to 10:30 p.m. on Saturdays and 6 a.m. to noon on Sundays.

Due to the distinct nature and challenges of each mode of transport, the pilot was limited to express couriers and involved four major express couriers whose deliveries arrived at 14 ports across the country. Participants included DHL, FedEx, IBC, and UPS making entry at ports in Alaska (Anchorage), California (Los Angeles, San Francisco, Oakland, Ontario), Florida (Miami), Tennessee (Memphis), and New Jersey (Newark).

The Automated Broker Interface (ABI) messaging system was utilized to reach the brokerage community regarding pilot port selection, share information about the use of the Import Trade Auxiliary Communications System (ITACS) for document submission, and to communicate any significant system issues. Additionally, daily emails were provided to the FDA “home” districts regarding assigned work. Email boxes and a general phone number were also set up to receive documents and feedback from both internal and external stakeholders.

Project Findings

ORA gathered a comprehensive set of performance metrics before and throughout the pilot that ended September 30, 2013—six weeks earlier than planned due to the unanticipated federal government shutdown. The pilot brought to light opportunities for improvement to the entry review process and to import approaches.

For reasons unrelated to the pilot, the pilot's start also encountered unanticipated challenges that significantly impacted review time, including a problem with an upgrade to the system utilized for entry review— a problem that has since been repaired.

Adjustments to operations were also made during the pilot. For example, ORA ultimately utilized 18 full-time reviewers, instead of the planned 12. Further, initial instructions to entry reviewers were modified several times to achieve an optimum balance - speeding up entry review without bogging down the overall process.

Timeliness

Initially, review for the imports handled by the pilot group took more than twice the time as review conducted in ports that were not part of the pilot. However, dramatic improvement did occur as reviewers adapted to the new processes. By September 15, those initial admissibility decisions were taking equal amounts of time in pilot and non-pilot ports. From that date forward, pilot ports were generally reaching admissibility decisions faster than non-pilot ports.

There were vast differences in the average review times for different commodities. Review time can vary by product due to the complexity of admissibility requirements, accuracy and depth of information submitted with the electronic entry, auto lookup functionality, and the reviewer's familiarity with a product. Center for Drug Evaluation and Research (CDER) and Center for Veterinary Medicine (CVM) products took the longest time. Center for Biologics Evaluation and Research (CBER) commodities took the least time—10 hours on average compared to 30 hours for CDER and CVM products.

Compliance

Pilot entry reviewers submitted a large volume of detention requests, which put a significant strain on current resources. While this may have been caused by several factors, it is believed that it was due to the pilot workgroup instruction to the pilot entry reviewers to base admissibility a decision strictly on what was transmitted in the original electronic submission. If compliance could not be verified based upon the electronic data submission, the entry reviewer sent the entry to compliance for further review. While this approach lowered review times in the entry review process, it significantly increased

compliance work and time for product clearance. The workgroup revised this instruction during the pilot to find a suitable equilibrium.

Training

In addition to more comprehensive training for pilot entry review participants, the pilot made clear the need for more training and outreach on a national level. More frequent and in-depth training for FDA personnel, as well as routine refresher training, would help to increase consistency of reviews. Additionally, training and outreach to the import community is vital to increasing data quality. This will serve to expedite review time and maximize FDA's electronic functionalities.

Guidance

During the pilot, reviewers were provided with a single set of instructions, which was updated as necessary. This allowed reviewers to achieve more consistent review. However, as operations are currently district specific, these instructions resulted in a large initial increase in the workload for district compliance officers and required additional entry review resources. Feedback from most stakeholder groups indicated that there is a need for both general and commodity-specific import guidance as well as a national entry review procedure. National guidance would bring consistency to the import process, would improve overall management of import operations, and would establish clear business practices.

Communication

Communication with internal and external stakeholders was a critical component in the planning process. Even with the extensive pre-planning, communication during the pilot proved to be challenging, and survey respondents noted a significant decrease in routine industry communications. While some of the issues were the result of operating in a temporary environment, any future considerations would need to ensure that external stakeholders could reach FDA when necessary and internal stakeholders could experience seamless communication and feedback mechanisms.

Data Quality

The pilot highlighted problems with electronic data submissions. These often lack the requisite information to maximize use of FDA's electronic system. This occurs, for example, when voluntary affirmations of compliance are not supplied or when the declared firms or product information submitted by the brokers/filers does not match FDA's internal databases. Additionally entry data may contain contradictory information, such as a product code differing from the importers description. During the pilot, document review was necessary to verify that the transmitted information matched the entry documentation, or to determine if the documents contained additional information not submitted in the original electronic submission.

For example, our quality audits found that brokers/filers submitted an incorrect product code to FDA for 40 percent of the entries in both pilot and non-pilot ports. Also, as indicated by the experience of FDA personnel and industry feedback, the commodity types most frequently cited for poor data quality were medical devices, pharmaceuticals, and antibiotics, in that order. Additionally, there was insufficient information supplied in the electronic entry to make an initial admissibility decision in 70 percent of non-pilot entries and 17 percent of pilot entries. While some issues in reconciling data submissions during the pilot may have been the result of the reviewers lack of familiarity with the commodity type, many of the issues were the result of inadequate or inaccurate data transmission by filers, as demonstrated by the large number of updates and rescreens necessary. Time spent looking up missing or incorrect information adds significantly to review time and drives down productivity.

Information Technology

The pilot revealed that FDA's electronic screening tools are not being fully utilized. Poor data quality, or lack of electronic data, reduces the speed and efficiency that these tools are capable of providing. Also, ITACS use is very low even though FDA has requested filers to submit entry documents via ITACS. Although ITACS is extremely valuable for industry and for entry reviewers, especially reviewers working from home, ITACS use among couriers in the pilot was very low — less than one percent. ITACS can provide FDA personnel with a one-stop shop for import documentation. When ITACS is not used for document submission, the reviewer must take time to upload electronically all entry documents in order to conduct additional field or compliance work, but if all filers were to utilize ITACS as it was designed, documents would be readily available. The average time needed for import review could be reduced drastically by ensuring that all necessary documents are provided from the start. With planned upgrades, ITACS will ease communications between FDA and filers/brokers. The experience in the pilot suggests strategies and incentives be developed to increase ITACS use, but ITACS needs to be fully tested to ensure it is capable of managing high volumes.

Additionally, the experience in the pilot suggested changes related to data queries. Several potential fixes to the Online Reporting Analysis and Decision Support System (ORADSS) system would allow FDA to pull larger and more complex sets of data. Additionally, the use of SharePoint or Tableau for the purpose of sharing and displaying reports should be explored.

Entry Review Process

The entry review process and speed of review varied greatly among FDA reviewers in the pilot program. Differences included the placement of remarks, use of non-standardized verbiage, and steps taken prior to forwarding entries to the "home" district. Through

national guidance and routine training, these discrepancies could be mitigated and would ensure a more consistent review process across all ports.

By taking advantage of time zone differences and allowing work at home, FDA was able to expand hours of operation while exploring a centralized review process. The courier services, which have extended hours of business operations, were particularly pleased with the expanded hours provided during the pilot. Entry reviewers who chose to work from home reported being very satisfied, although managing remote workers over four time zones requires additional consideration. A shared communication platform was identified as a need to prevent multiple reviewers accessing emails at the same time and thereby creating confusion or duplicating efforts. Even though a centralized review process does pose some significant challenges in the areas of communication and coordination, this model of review offers a more flexible way to quickly adapt entry review resources to fluctuating workload.

Industry Response

Industry respondents were generally receptive to a centralized review process assuming there would be adequate staffing and communication, improved work procedures, and industry input at all stages. They added that they somewhat or highly support centralized entry review, if properly managed, for all modes of transport and commodity types.

During the CER pilot, industry noticed a difference once adjustments were made to the pilot, unanticipated problems like the entry review application outage were solved, and the process became more familiar to ORA personnel.

“During the last two weeks of the pilot, the FDA performance improved dramatically,” said one industry survey respondent. Overall, industry liked expanded weekend coverage and noted better freight movements and, at some pilot ports, improved service.

Survey respondents said FDA should provide the industry examples of common shipment errors, provide guidelines for commodity-specific documentation, and provide a plan for major service failures that affect customer service.

Final Comments

The many lessons learned will not only inform future decisions of whether to pursue centralized entry review, but the unprecedented depth of analysis will also help improve the process as it is currently performed.

“A lot of hard work and effort went into this pilot, and we will continue to evaluate and apply the lessons learned.” said Plaisier.

Questions and comments can be submitted to FDA at FDAImportsInquiry@fda.hhs.gov.