Secure Supply Chain Pilot Program (SSCPP) Evaluation Plan

Introduction

The SSCPP is a voluntary pilot program intended to assist the Food and Drug Administration (FDA) in its efforts to prevent the importation of adulterated, misbranded, or unapproved drugs. Firms who participate in the SSCPP must either be manufacturers of approved finished drug product or API subject to an approved application, and will provide FDA with detailed information about their supply chain prior to importation. Firms who are selected to participate in this pilot will receive expedited review at designated ports of entry.

The goal is to allow FDA to determine the feasibility of developing a secure supply chain program, thus creating incentives for drug manufacturers to develop secure routes to import finished drugs and APIs. This would allow FDA field personnel to focus on higher-risk drug products that do not comply with applicable FDA requirements, such as but not limited to diverted and counterfeit drugs.

If the program is successful FDA will evaluate if we can devote resources to developing an adequate program. In addition FDA will be in a better position to inform future efforts to implement drug import regulations or policies. Such efforts may include modifying Agency Systems to accommodate new data requirements identified during the pilot program that will result in a more efficient use of FDA resources.

Evaluation Goals

The goal of this evaluation is to assess whether importers can comply with drug imports requirements established by FDA and to assist the Agency with expediting admissibility decisions. Three program objectives were identified.

1. Determine the number of participating firms that consistently submit all the correct information

2. Determine if participation in the pilot program leads to a decrease in the amount of time needed for admissibility decision (expedited review time)

3. Use evaluation analyses to inform future drug imports regulation and/or policy.

Data

The information FDA will utilize to conduct the evaluation analyses is:

1. To determine the number of firms that consistently submit all the correct information, at least three data points will be compared to check for any discrepancies in the information provided:
   - Information submitted in the SSCPP application
   - Documentation submitted upon importation
   - Information submitted in MARCS (Mission Accomplishment and Regulatory Compliance Services) Imports OASIS[1] (Operational and Administrative System for Import Support).

2. Time needed to make the admissibility decision will be calculated by examining the time of entry receipt to the time of admissibility release. The review time is defined in twenty-four hour increments, i.e. the number of days. No historical data currently exist for this program to establish a baseline. Therefore FDA will use data retrieved from MARCS Imports OASIS for the current import entry release dates specific to the products/companies participating in the pilot program to compare against:
   - Review time for participant firm's submissions where all information was properly transmitted
   - Review time for participant firm's submissions where all information was not properly transmitted
   - Review time for non-participant firms with similar products

   Comparison will be made among the proposed review times to determine if there is a benefit (decreased review time) to participation in the pilot program and properly transmitting the necessary information.

3. Analyze the data to determine if there are gaps in the submission of information and how that missing information affects the admissibility review period.

Audit and Reports

- Quarterly audits will be conducted to assess if there are any changes to the application that would affect the firm's qualification for participation in the program. In addition, the audits will also identify FDA process deviations that may affect the program effectiveness and appropriate follow-up measures. Apparent modifications will be addressed as appropriate to reduce bias in the outcomes.

- Annual reports will also be developed outlining the findings and recommendations from the pilot at the end of each year of the pilot.

[1] MARCS Imports OASIS is an automated FDA system for processing and making admissibility determinations for shipments of foreign-origin FDA-regulated products seeking to enter U.S. commerce.