



# IMPORTS

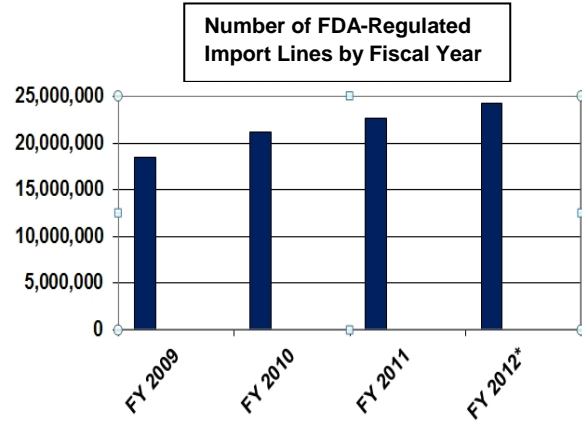
## PREDICT FACT SHEET

PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting) is the FDA's electronic screening tool for import operations that replaces the legacy screening tool in OASIS (Operational and Administrative System for Import Support). It works behind the scenes to screen all lines of imported product electronically submitted to the FDA via the US Customs and Border Protection interface.

MARCS (Mission Accomplishment and Regulatory Compliance Services) Imports Entry Review is FDA's new application used to make initial admissibility decisions, assign field work, and display the results of the PREDICT risk-based screening and database lookups.

National rollout of PREDICT began in September of 2009 to all 16 import Districts and was completed in December 2011.

PREDICT is designed to calculate a customized risk score for every line in an entry. Score calculations are based on numerical weights assigned to inherent risk rules, data anomaly rules, data quality rules, and the compliance history of firms (ex. manufacturer, shipper, and consignee) and product associated with the line.



The application of rules results in the generation of a cumulative score for a specific line. The rules can generate negative increments (good credit), neutral (no increment change), or positive increments (increased bad risk). The higher the cumulative score, the greater the identified risk.

Each line receives a percentile rank based on all other lines screened over the past 30 days. The risk rank is designed to focus FDA's limited resources using a risk-based approach.

Rules addressing a FDA field assignment, an Import Alert, an Import Bulletin, or District/Center requested criteria are explicitly flagged to be manually reviewed and have no impact in the calculation of the score.

PREDICT's automated database lookups link to data stored in Center databases, such as a firm's registration

and product listing and approval status. The results of these lookups are presented to the FDA staff in the PREDICT mashup to more efficiently review the compliance status of applicable firms and products.

Open source intelligence validated by FDA staff is used to develop rules to proactively target issues that may potentially impact public health.

Complete and accurate data transmitted allows FDA to more efficiently and effectively make admissibility decisions by holding higher risk products for review and examination while allowing lower risk products to enter domestic commerce without further FDA review.



\*Projected