Briefing Slides for Importers and Entry Filers

FDA Office of Regulatory Affairs
Office of Resource Management

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Topics

- Purpose of PREDICT, relationship to OASIS and MARCS
- Overview of import processing workflow
- PREDICT methods, screening rules, risk types
- Pilot test and production rollout
- Violation rates vs. PREDICT screening results
- Automated system “May proceed” rates
- Entry data quality, and why it really matters with PREDICT
OASIS and MARCS

- **OASIS**
  - Operational and Administrative System for Import Support
  - Legacy imports system operating 24/7 FDA-wide since 1998.

- **MARCS**
  - Mission Accomplishments and Regulatory Compliance Services – import and domestic
  - Under construction. MARCS Imports will eventually replace all of OASIS.
  - MARCS Entry Review is currently replacing the entry review application (only) from OASIS.
PREDICT

- Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
- Replaces the electronic screening function of OASIS for import admissibility determinations.

Purpose ---

Improve import screening and targeting to ---

- Prevent the entry of adulterated, misbranded, or otherwise violative goods
- Expedite the entry of non-violative goods
PREDICT is not MARCS Entry Review

- PREDICT functions mostly behind the scenes.
- MARCS Entry Review replaces the legacy entry review screens from OASIS.
- Entry reviewers have access to PREDICT screening results through a “mash-up” within MARCS Entry Review.
Entry filer

Firms, product code

Firms, product code

FDA district entry reviewer

“FDA review” message

“May proceed” message

Customs

OASIS

PN screening – food

Prior Notice Center

 PN screening – food

 Precedent

Admissibility screening

PREDICT

Yes

No

FDA review

Message

“May proceed” message

Review?

Yes

No

Prior Notice Center

STOP

Entry filer

Firms, product code

FDA district entry reviewer

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Admissibility screening

PREDICT

Yes

No

FDA review

Message

“May proceed” message

Review?

Yes

No

Prior Notice Center

STOP
Workload: Import entry lines, in millions (excluding mail and baggage)
PREDICT purpose and method

- Improve the targeting of entry lines by –
  - Scoring each entry line on the basis of a wide range of risk factors
  - Increasing the number of automated, real-time, “may proceed” decisions for lower-risk lines, thereby giving entry reviewers more time to evaluate the higher-risk lines
  - For those lines not given an automated “may proceed,” providing reviewers with the scores and the reasons for those scores
PREDICT purpose and method

- Using automated data mining and pattern discovery for rules development
- Utilizing open-source intelligence
- Providing automated queries of Center databases where relevant (i.e., registration and listing, marketing approval status, low-acid canned food scheduled processes, etc.)
Examples of source data for PREDICT screening rules

- Ratings of inherent product risks
- Results of field exams and sample analyses from previous entries
- Results of facility inspections, foreign and domestic
- Accuracy of product and facility coding by entry filers and importers
Examples of source data for PREDICT screening rules

- Data anomalies within the current entry
- Admissibility history with respect to the manufacturer, exporter, importer, and consignee for the current product (at industry and more specific levels)
- Open source intelligence pertaining to the manufacturer, foreign locale, product, etc.
Risk types to be included in targeting scores

- Compliance risk (probability of violation)
- Product-related
  - Inherent health risk (Type 1)
  - Incremental health risk in view of previous FDA analytical results for products of the same manufacturer (Type 2)
  - Risk of the product being the target of economic adulteration with hazardous consequences; i.e., wheat flour or milk adulterated with melamine and cyanuric acid; counterfeit drugs with missing or different inactive ingredients, etc. (Type 3)
Pilot test

- Prototype PREDICT application
- Conducted during the summer of 2007
- Covered 32,696 entry lines of seafood entering at five ports within Los Angeles District
- In comparison to the legacy system ---
  - Violation rates for field exams and sample collections were substantially higher
  - Health significance of the violations found was greater
  - The automated “may proceed” rate was substantially higher, thereby expediting the entry of lower-risk products
## Timeline: Production rollout
--- All products, all FDA Centers ---

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>Sept. 25, 2009</td>
<td>Los Angeles District rollout</td>
</tr>
<tr>
<td>February 2010</td>
<td>Abrupt, serious slowdown of all field IT applications nationwide -- legacy &amp; modern, domestic &amp; import</td>
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<tr>
<td>Early March 2010</td>
<td>New York District rollout</td>
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<tr>
<td>Late March 2010</td>
<td>Further rollout on HOLD due to IT infrastructure and MARCS Entry Review application performance issues. Without that application, reviewers cannot see data from PREDICT.</td>
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<tr>
<td>Summer 2010</td>
<td>Troubleshooting done under contract by MITRE Corp. Some improvements made to the network and to the configuration of the field PCs. Migration of agency enterprise systems to contractor-hosted data center begins.</td>
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<tr>
<td>Sept. 21, 2010</td>
<td>Rollout resumes with the training of users in Seattle and San Francisco Districts</td>
</tr>
<tr>
<td>October 2010</td>
<td>PREDICT is running well, but the Entry Review application remains agonizingly slow.</td>
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<tr>
<td>Mid-March 2011</td>
<td>A problem with server environment settings is found and fixed. This dramatically improves the performance of MARCS Entry Review. Users rejoice.</td>
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<tr>
<td>April 2011</td>
<td>Nationwide rollout resumes successfully at Florida and San Juan Districts, followed by Atlanta and Minneapolis Districts.</td>
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<tr>
<td>May 2011</td>
<td>System to be deployed to New Orleans, Philadelphia, Cincinnati, Detroit, Chicago, and Baltimore Districts.</td>
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<tr>
<td>June 2011</td>
<td>System to be deployed to New England and Southwest Imports Districts. Nationwide rollout will be complete.</td>
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Violation rate: Field and label exams

81,480 field and label exams for entries submitted Oct 2009 through Nov 2010

The higher the PREDICT targeting score, the more likely the violation.
Violation rate: Samples analyzed
11,282 sample collections for entries submitted Oct 2009 through Nov 2010

The higher the PREDICT targeting score, the more likely the violation.
Expedited release of lower-risk shipments

LOS, NYK, SAN, SEA Combined System "May Proceed" Rate

Note: Nearly all drug and medicated feed entry lines are being held for marketing status lookups by entry reviewers. Those lookups are not yet automated by PREDICT.
Automated system “may proceed” rates
Examples by type of product

<table>
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<th>Examples</th>
<th>Rates as of March 29, 2011</th>
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<tbody>
<tr>
<td>Human foods</td>
<td>39.5%</td>
</tr>
<tr>
<td>Housewares &amp; food-related</td>
<td>86.5%</td>
</tr>
<tr>
<td>Cosmetics</td>
<td>23.5%</td>
</tr>
<tr>
<td>Medical devices</td>
<td>15.2%</td>
</tr>
<tr>
<td>Drugs</td>
<td>3.2%</td>
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- Electronic screening standards are uniform nationally.
- Automated database lookups have not yet been implemented for drugs or medicated feeds.
Efficiency

- PREDICT improves the efficiency of entry review. It automatically clears about three times as many entry lines of lower-risk products as does the legacy system. This substantially reduces entry reviewer workload, allowing reviewers to devote more time to targeting higher-risk products.

- PREDICT performs automated queries of Center databases for issues such as registration, listing, and product approval, and it furnishes entry reviewers with the results as appropriate. This function has been implemented for medical devices, electronic products, and low-acid canned foods. It will be implemented for drugs later this year.
Affirmations of compliance are data elements submitted voluntarily to FDA to expedite the entry review process. For example:

- New drug application number
- Device 510(k) clearance number
- National drug code (NDC)
- Radiological health product report accession number
Needed from entry filers:
Accurate, consistent, complete data

- To expedite entry screening by PREDICT, importers and entry filers must provide:
  - Consistent, accurate identifiers for firms
  - Accurate product codes
  - All of the relevant affirmations of compliance

- With those data PREDICT will be able to issue system 'may proceeds' quickly for lines with lower targeting scores

- OASIS tracks FDA corrections of data submission errors, and PREDICT uses these data to adjust the targeting scores for future entry lines
PREDICT automated database lookup not performed because the filer did not submit necessary data

“This device line is missing information required to perform an auto look up (Listing number … not transmitted)”
With PREDICT:
Affirmations of compliance

- With **accurate and complete** affirmations of compliance (NDA, ANDA, PMA, 510(k), NDC numbers, etc.), PREDICT will be able to do the automated lookups for marketing status.

- If an automated lookup fails, the entry line will be forwarded to a reviewer for manual processing.
Entry lines not given a “may proceed” by PREDICT go to an entry reviewer for manual processing.
Receiving inconsistent MIDs for the same foreign facility is a serious data quality issue for FDA.

Typical: 6 different MIDs for one facility. Current record: >100.

The lack of a reliable, truly unique identifier seriously undermines the targeting process, and can enable shipments to evade import alerts and bulletins.

Submitting a new MID for an established facility will often cause PREDICT to view the facility as new, and the targeting score will be substantially elevated.

The long-term solution is to replace the MID with a unique, reproducible identifier.
With PREDICT the quality of the data you submit to FDA counts more than ever.

Importers need to work closely with filers to ensure data quality.

Poor data quality or missing data will increase the targeting scores for your subsequent entry lines (importers and filers).

Higher targeting scores increase the likelihood of examination and/or sampling by FDA.

Data error rates are available to the public through the Freedom of Information Act.
Questions?