

Common Problems Observed

Merril Racke

Bob Rodriguez

Brigitte Hofmann

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Code of Federal Regulations title 21 sec 10.85

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Accurate, consistent, complete data

- To expedite entry screening, importers and entry filers must provide:
 - Consistent, accurate identifiers for firms
 - Accurate product codes
 - All of the relevant affirmations of compliance
- With correct data, Reviewers will be able to issue 'may proceeds' quickly for low-risk, non-violative shipments

Wrong Consignee and Importer

- Costs money, FDA mails a notice to the consignee and Importer
- Causes confusion, a unrelated party gets a FDA notice of detention or even a release.
- May result in a refusal even if the consignee or importer could have answered the charges

Obvious Errors: Examples

- Country of Origin does not match the manufacturer's country in the entry
- Product code does not match
 - Quantity does not match description
 - Tablets but quantity is 100 ml
 - Description does not match product code
 - Product code provided is 86HQC
Phacofragmentation unit but docs and importer description "Plastic Optical lenses"

Things to help

- Please put contact information on entry docs including Fax numbers.
 - Looking up fax number for remote filers is a problem
- Try to make entry numbers conspicuous
 - Cover sheet for fax should have the entry number

Biggest Error: Failure to Respond

- Docs requested
- Detention
- Requests for more information

Why Biggest Error.

Failure of an importer or filer to respond to a detention notice or to not request an extension before the response date is not an FDA error. The refusal will stand see "Regulatory Procedures Manual" 2011, Chapter 9 "Import Operations And Actions" sect. 9-9 "Notice of Refusal of Admission"

Questions