

CCR Number	ESUB-053
Title	Fix issue within the Notice of Shipment (B) template where the Total Quantity question within the Product Description screen is not always available
Business Owner	ONADE
Change Type	Defect
Components	Submission Type: I-B-OT
Severity	High
Application Release	Version 1.05.00 – 2/12/2018

Change Description

Within the Notice of Shipment (I/B/OT) submission type there is a business rule associated to the “Is this going directly to an investigator or institution where research will be conducted?” (i.e., the rule driving question) within the General Information section.

Rule Driving Question

Is this going directly to an investigator or institution where the research will be conducted? ●

Yes

No

When responding with a “Yes”, section 1.2 “Product Description” is enabled with the long-form. However, when responding with a “No”, section 1.2 “Product Description” is enabled with the short-form.

The Product Description long-form consists of the following questions:

- Does the drug product have a USP monograph?
- Product Established Name
- Proprietary Name
- Pharmacological Category
- Dosage Form
- Dosage Form, Other Text
- Dosage Form Variation
- Dosage Form Variation, Other Text
- Route of Administration
- Route of Administration, Other Text
- Route of Administration Variation
- Route of Administration Variation, Other Text
- Total Quantity (Wt. or Vol.) and Concentration of Drug(s) Shipped (or Received)

The Product Description short-form consists of the following questions:

- Does the drug product have a USP monograph?
- Product Established Name
- Proprietary Name
- Pharmacological Category

When responding to the rule driving question correctly the first-time through, the changes to the Product Description section were adjusted as intended. However, two defects were identified when the rule driving question was switched from “Yes” to “No”, or vice-versa.

Identified defects:

1. When switching from “No” to “Yes”, the Total Quantity question is no longer available within the long-form.
2. When multiple product descriptions were added before the switch in the rule driving question, only the last selected product description item is adjusted to the proper form.

With the latest change, both defects have been corrected.