

INCIDENTS

- Ability to report:
 - Suspect Product
 - Damaged
 - Quantity errors
- Status Categories:
 - Open
 - Under Review
 - Closed

To create an Incident when the received product is suspect, damaged or missing:
Click on the View Invoices button from the homepage

INMAR
intelligence



- INCIDENTS
- VIEW INVOICES
- VIEW PEDIGREES
- BORROW / CREATE PEDIGREE
- TRADE / SELL / RETURN
- FIRST RESPONDER RESUPPLY FORMS
- USP <800> HAZ DRUGS 100
- REPORTING

Select the applicable invoice

INMAR intelligence

View Invoice/Shipment

Invoice Number # PO Number Invoice Date Seller Shipped From Shipped To Facility All Received

Invoice #	Purchase Order #	Inv. Date	Seller	Shipped From	Shipped To	Facility	
4307335	PO-4307335	07/08/2019	CARDINAL HEALTH 110, LLC	CARDINAL HEALTH 110, LLC	RXT Pharmacy	Demo Instance	
4305143	PO-4305143	07/04/2019	BAXTER HEALTHCARE 1 Baxter Parkway Deerfield, IL 60015	FRG Distribution 2025 Tenth Way San Jose, CA 95128	RXT PHARMACY 11307 H Avenue, Suite 110 King of Prussia, PA 19406	Demo Instance	
4305142	PO-4305142	07/04/2019	PFIZER INC INJECTABLE @ 2754 FIELDS DRIVE LAKE FOREST, IL 60045	FRG Distribution 2025 Tenth Way San Jose, CA 95128	RXT PHARMACY 11307 H Avenue, Suite 110 King of Prussia, PA 19406	Demo Instance	
4305141	PO-4305141	07/04/2019	McKesson Drug Company 1 First Street SAN FRANCISCO, CA 94104	FRG Distribution 2025 Tenth Way San Jose, CA 95128	RXT PHARMACY 11307 H Avenue, Suite 110 King of Prussia, PA 19406	Demo Instance	

How to Report and View Incidents

Click on the “Report Incident” button in the upper right-hand corner

INMAR intelligence

INVOICE | CARDINAL HEALTH 110, LLC

Transaction Set Control Number: 34590001
Shipment Number:

[RETURN TO INVOICES](#) [REPORT INCIDENT](#)

Invoice #	Purchase Order #	Invoice Date	Order Date	Shipment Date	Sold By	Shipped From	Shipped To
4307335	PO-4307335	Jul/08/2019	Mar/30/2020	Jul/08/2019	CARDINAL HEALTH 110, LLC	CARDINAL HEALTH 110, LLC	RXT Pharmacy

All Received

Received	Item Number	Quantity	Quantity Received	CL	Product Info	Pedigree Link
<input type="checkbox"/>	LPC: UI- 309046530619	5			00904653061: METHADONE HCL 10MG 10X10UD	

Carton Number: DROP SHIPMENT

On the Incident Overview page, populate the following fields:

Incident Overview - brief description

Incident Date

Incident Type

- Suspect,
- Damaged
- Missing Product

Remediation Type

- Suspect Product Reported
- Product Returned to Distributor
- Missing Product Reported


RETURN TO INVOICE

Incident Overview

Incident Overview

Incident Type

Suspect Product

Damaged Product

Missing Product

Incident Date

Remediation Type

Suspect Product Reported

Product Returned To Distributor

Missing Product Reported

Destination – choose location where it was shipped to

Destination

NORRISTOWN GENERAL HOSP

Remediation Overview

- Remediation Overview – brief description of what was done with product
- Comments – if any

Incident Status

Open

Under Review

Closed

Comments

Incident Status

- Open – if reporting
- Under Review – suspect product reported or if returned for replacement / credit
- Closed – Investigation complete or received replacement or credit

Product	Lot Number	NDC	Product	Form	Strength	Package	Manufacturer	Include in Incident?
	UI-309046530619	00904653061	METHADONE HCL 10MG 10X10UD					<input checked="" type="checkbox"/>
	UI-359011410200	59011041020	OxyContin	TABLET, FILM COATED, EXTENDED RELEASE	10mg/1	2 BLISTER PACK in 1 CARTON (59011-410-20) > 10 TABLET, FILM COATED, EXTENDED RELEASE in 1 BLISTER PACK	Purdue Pharma LP	<input type="checkbox"/>
	UI-304096028048	00409602804	MORPHINE 5MG/ML 10X30ML PF					<input type="checkbox"/>

Under "Include in Incident?" column, toggle applicable line item

Click on Save button

To report a suspect or potential counterfeit product

Create an incident

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Incident Overview [BACK TO INCIDENTS](#) [VIEW INVOICE](#)

Incident Overview	Incident Date	Destination	Incident Status
Seal is broken, appears to be tamper	03/26/2020	RXT PHARMACY	Open
Incident Type	Remediation Type	Remediation Overview	
Suspect Product	Suspect Product Reported	Quarantined in red bin	
Comments			
Notified DoP L.J. Brennen			

Incident Items

Invoice Item	Lot Number	NDC	Product	Form	Strength	Package	Manufacturer	View/Generate 3911 Form	Pedigree Link
UPC: 368462383018	UPC- 368462383018	068462038301	Eszopiclone ESZOPICLONE TAB 2MG GLEN 100	TABLET, FILM COATED	2mg/1	100 TABLET, FILM COATED in 1 BOTTLE (68462-383-01)	Glenmark Pharmaceuticals Inc., USA		

Then on the incident overview screen

- click on the image under  View/Generate 3911 Form

DSCSA regulation states you have 24 hours to report a suspect product upon discovery

FDA Form 3911

DEPARTMENT OF HEALTH AND HUMAN RESOURCES
Food and Drug Administration
Drug Notification

Form Approved: OMB No. 0910-0806
Expiration Date: December 31, 2018
See PRA Statement at bottom of form.

1. Type Of Report (Select one):
 Initial Notification
 Follow-Up Notification
 Request for Termination

2. Incident Number (Provide this number, assigned by FDA, if you selected Follow-up Notification of Request for Termination above; see instructions)
N/A

3. Date of Initial Notification to FDA: 03/30/2020
 4. Date Company Determined Product Was Registered: 03/26/2020
 5. Classification of Notification: - Select Classification -

6. Name of Product as it Appears on Label:
Eszopiclone

7. Primary Ingredient(s) (if known):
Eszopiclone

8. Drug Use: - Select Drug Use -
 9. Drug Description: - Select Drug Description -

10. Strength of Drug: 2mg/1
 11. Dosage Form: - Select Dosage Form -

12. Quantity of Drug (Number and Unit): 2 EA
 13. NDC (if applicable): 68462038301
 14. Serial Number (if applicable):

15. Lot Number(s):

Will pre-populate from incident, will need to complete form then print or save as a pdf

Show it to your legal department along with the pedigree information

You must also notify who you received the drug from

Incident Overview – to get the pedigree information click on pedigree link

Incident Items									
Invoice Item	Lot Number	NDC	Product	Form	Strength	Package	Manufacturer	View/Generate 3911 Form	Pedigree Link
UPC: 368462383018	UPC- 368462383018	068462038301	Eszopiclone ESZOPICLONE TAB 2MG GLEN 100	TABLET, FILM COATED	2mg/1	100 TABLET, FILM COATED in 1 BOTTLE (68462-383-01)	Glenmark Pharmaceuticals Inc., USA		

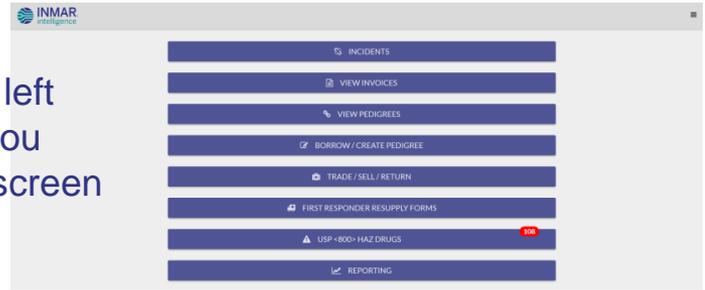


Email completed Form 3911 and product T3 to: drugnotifications@fda.hhs.gov

For complete instruction on FDA Form 3911:
<http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm>



Inmar logo top left corner, takes you back to home screen



**For additional platform support
please contact Client Accounts**

Thank you for your time!

