

Slide 1



Welcome to this video tutorial on Agent Receipt in the PMB Investigational Drug Accountability series.

This video will review the NCI investigational agent shipment record and proper accountability when agent is received by a Control Dispensing Area.

Slide 2



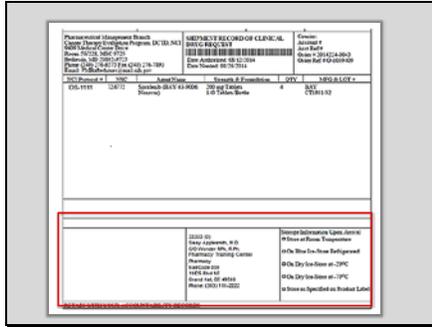
Each agent shipment will contain a shipping record. Upon receipt of the agent, it's important to verify the contents of the agent shipment against each shipping record.

Slide 3



The shipping record has three main sections. The top section of the shipping record pertains to the shipper. This section contains the PMB's address, Date Authorized or the date that PMB processed the drug request, and the Date Needed. It will also provide specific details about the courier, an order number and its reference number.

Slide 4



The bottom section of the shipping record contains shipping information consisting of the ordering investigator's name, the shipping designee, and the shipping address. This section also contains the recommended storage temperature of the agent upon arrival. It is possible that the shipping conditions of an agent may differ from the storage conditions of that agent.

Slide 5



And in the middle section, the NCI protocol number, the NSC number, the agent name, strength & formulation, quantity, the manufacturer's abbreviated name and the Lot number. Please note that we will refer to the Lot number as the identifier throughout this presentation.

Slide 6



Information in this section also varies according to the type of agent order, either Standard Order or Patient Specific Order.



Slide 10

**Standard Order Shipping Record**

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9000 Medical Center Drive Room 3027C, MDCT 4775 Bethesda, MD 20892-0772 Phone (301) 427-4775 Fax (301) 710-7899 Email: PMA@pharm.msd.usg.gov		<b>SHIPMENT RECORD OF CLINICAL          PRECIPITANTS</b> Date Authorized: 08/07/2014 Date Shipped: 08/26/2014		Control Account # Order Ref # 2014214803 Order Ref # 03100000	
NCI Protocol # 1306 ID# 1111 72472 Agent Name Sandath (BAY 43-8096; Sandath)	Agent Name Sandath (BAY 43-8096; Sandath)	Strength & Formulation 200 mg Tablets 140 Tablets/Bottle	QTY 2	MFG # 142 * BAY CT1931/32	

**Agent Label**

<b>BAY 43-8096; MSC #72472</b> 200 mg BAY 43-8096 tablets (containing 200 mg of active ingredient)	
Product Name: CT1931/32 Batch Number: 4200101	Date of Manufacture (Date Mfg) (YYYYMMDD) 02/20/2014
Do not store above 25°C (77°F). Protect from light.	

You should use the agent label identifier that matches the identifier on the shipping record.

Slide 11

**Standard Order Oral DARF**

<b>Investigational Agent Accountability Record          Oral Agents (OAR)</b>						
Name of Investigator Phases Training Center	Investigator Name Dr. Aggarwal	NCI Protocol # 1306	Agent Name Sandath (BAY 43-8096; MSC 72472)	Strength & Formulation 200 mg Tablets 140 Tablets/Bottle	QTY 2	MFG # 142 * BAY CT1931/32

Record that identifier on the DARF in the Manufacturer and Lot Number Column. It's important to record the correct identifier on the DARF because stock recovery letters and recall letters are tracked using this identifier.

Slide 12

**Single Agent Strength with Multiple Identifiers**

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9000 Medical Center Drive Room 3027C, MDCT 4775 Bethesda, MD 20892-0772 Phone (301) 427-4775 Fax (301) 710-7899 Email: PMA@pharm.msd.usg.gov		<b>SHIPMENT RECORD OF CLINICAL          PRECIPITANTS</b> Date Authorized: 08/07/2014 Date Shipped: 08/27/2014		Control Account # 100000 Order Ref # 2014214803 Order Ref # 03100000	
NCI Protocol # 1306 ID# 1111 72472 Agent Name Sandath (BAY 43-8096; Sandath)	Agent Name Sandath (BAY 43-8096; Sandath)	Strength & Formulation 200 mg Tablets 140 Tablets/Bottle	QTY 2	MFG # 142 * BAY CT1931/32	
ID# 1111 72472 Agent Name Sandath (BAY 43-8096; Sandath)	Agent Name Sandath (BAY 43-8096; Sandath)	Strength & Formulation 200 mg Tablets 140 Tablets/Bottle	QTY 1	MFG # 142 * BAY CT1931/31	

Sometimes, there are multiple identifiers on the same shipping record for the same agent strength. In this example, you received 2 bottles of identifier CT1931/32 and 1 bottle of identifier CT1931/31. Thus, carefully verify the shipping record against what you received.

Slide 13

**Expiration Date on Agent Label**

Investigational Agent Accountability Record  
 Phase 2 of 4 months (03)

Lot #	Qty	Strength	Formulation	Expiration Date	Remarks
101	1	100 mg	Tablets		

Also upon receipt, you may discover that the agent is labeled with an expiration date. Record that expiration date on the Oral DARF in the Expiration Date Column. If the expiration date is not available, leave the Expiration Date Column blank.

Slide 14

**"DG"= Dangerous Goods**

SHIPMENT RECORD OF CLINICAL DRUG REQUEST

NCI Protocol #	NCI	Agent Name	Strength & Formulation	QTY	MEQ & LOT #
05-999	88364	Teniposide (C13-770)	25 mg For Injection 2 ml, Vial	4	W/P ADT/10

\*\*\*DG\*\*\* Affix Transport Quantity Label for each shipment

The middle section of the shipping record may contain special notes such as DG. A DG means Dangerous Goods. Certain agents will be labeled as DG because they require special handling and packaging for the transport. Expired or recalled DG agents need approval from the PMB for local destruction when the agent cannot be returned to the NCI Clinical Repository for proper disposal.

Slide 15

**Manufacture Date and Shipped Quantity**

SHIPMENT RECORD OF CLINICAL DRUG REQUEST

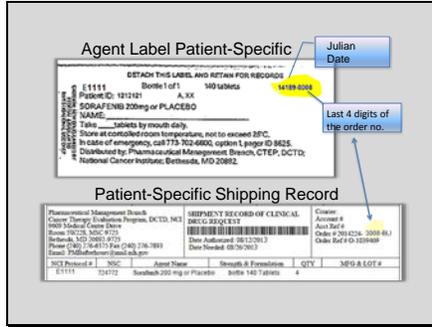
NCI Protocol #	NCI	Agent Name	Strength & Formulation	QTY	MEQ & LOT #
05-9999	76360	XL184 (Cubismab)	60 mg Tablets 30 Tablets/Bottle	1	PATB P0013P

The right vial, supply for this protocol is 1 bottle per patient.

Other special notes that will be populated in the middle section could be a manufacture date when the agent label does not have it or a change in ordering quantity from what was originally requested, usually an eight week supply.

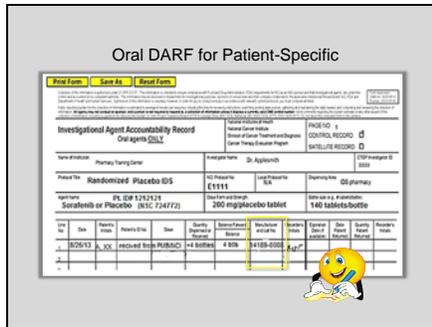


Slide 19



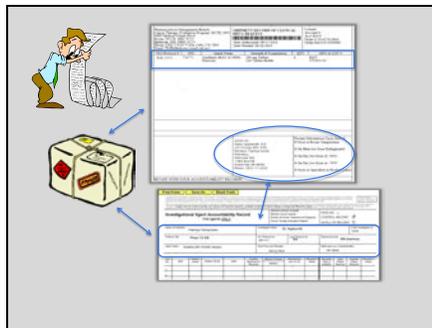
The first 5 digits are the Julian Date followed by 4 digits, which are the last 4 digits of the order number on the shipping record.

Slide 20



Now you can record that identifier on the DARF in the Manufacturer and Lot Number Column.

Slide 21



Finally, ensure that you received the correct agent. Carefully cross verify the agent shipment contents against the shipping records and the information on the DARF. If there is a discrepancy, contact the PMB immediately at 240-276-6575.



