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.
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.
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.
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.
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.
Information in this section also varies according to the type of agent order, either Standard Order or Patient Specific Order.
Note the differences between the two shipping records. The Patient Specific Order shipping record does not have the Manufacturer or identifier. However, it lists the patient ID number and the patient initials.
Now let’s discuss the identifier. In this shipping record, the identifier is CT1931/32.
Multiple Identifiers

BAY 43-9008 / NSC #724772

200 mg BAY 43-9008 as free base / tablet [formulated as the tosylate salt]
140 tablets / bottle
Take as directed.
Pack Batch No.: GTC1931/32
Bulk Batch No.: SG002LHT
Date of Manufacture (bulk tablets): 15/Oct/2012
CAUTION: NEW DRUG LIMITED BY FEDERAL (OR UNITED STATES) LAW TO INVESTIGATIONAL USE
Do not store above 25°C (77°F). Store in the original package.
Distributed By: National Cancer Institute, Bethesda, MD 20892
Mfg. By: Bayer HealthCare LLC, D-51369 Leverkusen, Germany

However, upon receipt of the agent, you also checked the bottles and found that the label of the bottle has 2 identifiers: a Pack Batch identifier and a Bulk Batch identifier. So which identifier should be recorded on the Oral DARF?
You should use the agent label identifier that matches the identifier on the shipping record.
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.
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.
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.
“DG”= Dangerous Goods

<table>
<thead>
<tr>
<th>NCI Protocol #</th>
<th>NSC</th>
<th>Agent Name</th>
<th>Strength &amp; Formulation</th>
<th>QTY</th>
<th>MFG &amp; LOT #</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDS-1234</td>
<td>567</td>
<td>Temsirolimus (CCI-779)</td>
<td>25 mg For Injection 1.2 mL Vial dual pack</td>
<td>4</td>
<td>WYP AB5/1G</td>
</tr>
</tbody>
</table>

**DG** **Affix Excerpted 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.
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.
Now, let’s look at an example of a Patient Specific shipping record. As discussed previously, the Manufacturer and the identifier of the agent are not available, but the patient ID and the patient initials are provided.
However, you need to record an identifier on the DARF upon receipt of the shipment. Since it is not available on the shipping record for Patient Specific Orders, how or where can you obtain an identifier?
The identifier for the Patient Specific supplies can be found in the upper right hand corner of the agent label. The number contains 9 digits.
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.
Oral DARF for Patient-Specific

Now you can record that identifier on the DARF in the Manufacturer and Lot Number Column.
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.
As you put away your agents, make sure to retain a copy of the shipping record with your accountability records. Store the agents according to the Policy and Guidelines for Accountability and Storage of Investigational Agents.
Thank you for watching this video tutorial. Additional PMB Investigational Drug Accountability videos are available through our YouTube Playlist.

Please note that the video and any items displayed within the videos are subject to change. Check back periodically for updates.

Questions can be directed to the Pharmaceutical Management Branch, CTEP, NCI by phone Monday through Friday from 8:30am to 4:30pm Eastern Time or by email any time.