INSIDE PMB
November 2015

Cancer Therapy Evaluation Program
Division of Cancer Treatment & Diagnosis

9609 Medical Center Drive, Rockville, MD 20850

Tel: (240) 276-6575; E-mail: PMBAfterhours@mail.nih.gov

http://ctep.cancer.gov/branches/pmb/drug_training_videos.htm

INSIDE:

FAQ webpage:
http://ctep.cancer.gov/branches/pmb/faq.htm

PMB Shipments of Agents Stored at Room-Temperature

PMB has updated its process for shipping agents stored at room-temperature. These agents will ship in pre-qualified shipping systems to maintain acceptable shipping temperatures for the agents throughout normal transit times. The shipping system consists of an insulated container with various combinations of frozen, refrigerated, and room temperature bricks and/or phase-change materials in defined packing configurations to provide the intended shipping conditions. The containers/packaging configurations are qualified to maintain the product payload at either ambient conditions (between 2°C-25°C) or controlled room temperature conditions (between 15°C-25°C), depending on the shipping system used.

PMB has worked with our company collaborators to determine acceptable shipping conditions for each agent. The shipping conditions may differ from long-term storage conditions identified on the product label. Use of these containers was implemented to protect product integrity during transit throughout the year, including summer and winter temperature extremes.

Upon receipt, always refer to the agent product label for storage temperature.

Please refer to the PMB Policy and Guideline for Investigational Agent Ordering on the PMB website at:
http://ctep.cancer.gov/branches/pmb/agent_management.htm

Start-Up Supply

In general, sites can request initial agent supplies when a subject is being screened for enrollment onto the study.

Furthermore, approval for the initial agent supplies will depend on the agent availability at PMB and/or the study design. For example, the MATCH trial will only allow an initial supply once the subject is enrolled to a specific treatment arm.

Please note, having a trial open at the institution is not a good reason to request a "start-up" supply. If you need to order an initial supply, please add a comment in the OAOP designated comment field, which is labeled as "Designee Comments" before you submit the drug request.

The "Designee Comments" field in the OAOP can be used for any clarification that will support your drug request that may not seem to be within the approved 8-week supply quantity. Additional information such as the BSA, Dose Levels, etc. is very helpful to the PMB staff when they process the drug orders.

We appreciate your cooperation in the effort to minimize drug waste.

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Did you know that you can use OAOP for more than just ordering PMB-distributed agent?

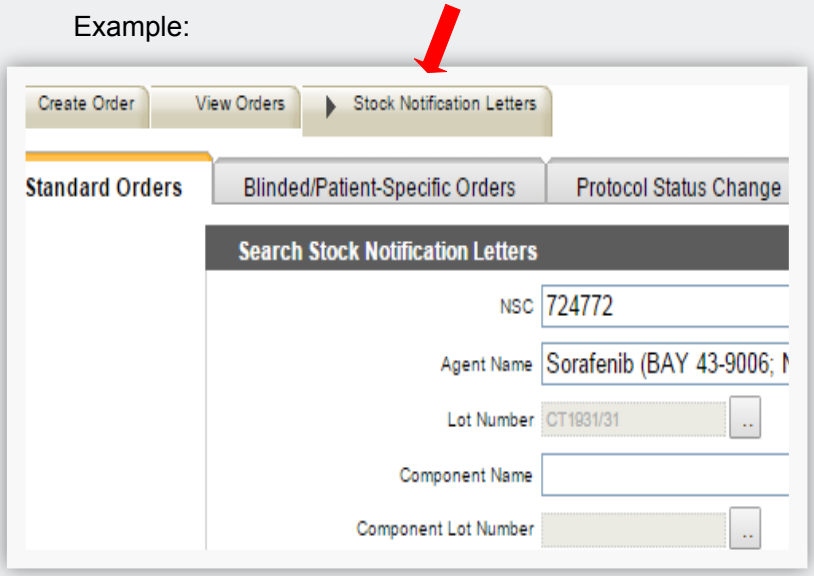
The ***stock notification letters tab*** is one of several functions of OAOP that can be very useful. PMB sends stock notification letters via email but the letters are also posted on OAOP. If you missed the email or misplaced the letter, you can use OAOP at any time to access these letters.

There are 5 subtypes of stock notification letters:

1) Expiration
2) Protocol Status
3) Recall
4) IND Withdrawal
5) Extension of Expiration

The two most commonly sent subtypes are **expiration** and **protocol status change.** The expiration stock notification letter indicates the expiration date of open label and blinded agents and what to do with the affected agent. The protocol status change stock notification letter indicates a status change to a particular protocol and what to do with the affected agent(s).

Example:



How do you query in OAOP for a stock notification letter?

1) Log into OAOP and click on the “stock notification letters” tab. It’s located next to “create order” and “view orders” tabs.
2) Select the type of letters you are looking for: standard orders, blinded/patient-specific orders, or protocol status.
3) For standard and blinded, patient-specific orders, start with agent and /or NSC # to execute your search. To help narrow down the results, add lot # for standard orders, Julian date range for blinded/patient-specific orders, or protocol number for protocol status. If you cannot find the agent lot# for standard orders, make sure this is a PMB distributed agent or that the correct lot identifier was documented.
4) Step by step directions can be accessed by clicking on the “Help” button at the top right corner of the screen.
5) The resulting letters are listed on the screen. If stock notification letters are found, read and follow the instructions provided. If no results are found, you can print or email the displayed confirmation. **No results mean a stock notification letter has not been issued based on the search criteria entered.**

For any questions, please call 240-276-6575, Monday through Friday from 8:30am to 4:30pm Eastern Time or email PMBafterhours@mail.nih.gov at any time.

Please also view our FAQ webpage: http://ctep.cancer.gov/branches/pmb/faq.htm.

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What do you do when you have multiple batch identifiers or lot #s listed on the agent label?

Example:

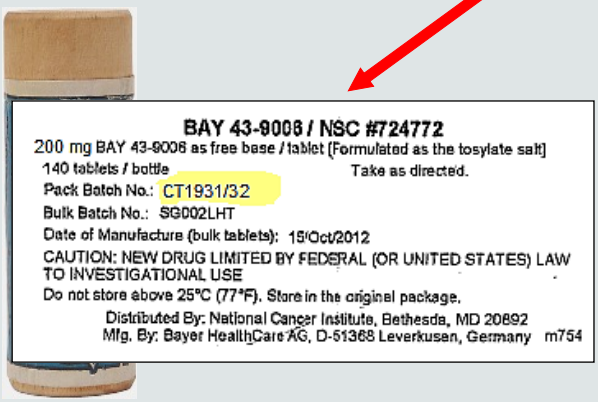
Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCTD, NCI
9609 Medical Center Drive
Room 5W228, MSC 9725
Bethesda, MD 20892-9725
Phone (240) 276-6575 Fax (240) 276-7893
Email: PMBafterhours@mail.nih.gov

SHIPMENT RECORD OF CLINICAL DRUG REQUEST

Date Authorized: 08/12/2014
Date Needed: 08/26/2014

Courier:
Account #
Acct Ref #
Order # 2014224-0043
Order Ref # O-1039409

NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1111	724772	Sorafenib (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	4	BAY CT1931/32



The answer is to look at the shipment record. Whenever you receive a shipment, a shipment record is included. There is a column labeled "MFG & LOT#." The lot# listed here should match one of the batch identifiers on your bottle (e.g. Pack Batch identifier, Bulk Batch identifier). This is the lot# you should list on your Drug Accountability Record Form (DARF). It's important to record the correct identifier on the DARF because stock recovery letters and recall letters are tracked using this identifier.

Please watch the video "Agent Receipt" in the PMB Investigational Drug Accountability series for more information. The video is located on our website: http://ctep.cancer.gov/branches/pmb/drug_training_videos.htm

Umbrella Trial Updates

The umbrella trial, Lung-Master Protocol (S1400) is designed to test the impact of different drugs on different mutations in a single type of cancer. The rationale for this trial is to bring safe and effective drugs to patients faster and to facilitate FDA approval of new drugs.

According to the SWOG Group meeting in the fall 2015, 816 sites have the protocol open, and 190 have at least one patient registered. Of the 419 registered patients, 166 have been randomized to the sub-studies.

Currently, the study is being amended to remove the randomization within each arm; thus, all patients will receive the investigational agent according to their Genomic identification. Furthermore, later this year, Arm I - nivolumab + ipilimumab versus nivolumab alone will be open to replace Arm A.

Arms	Gene mutation	Treatment	Accrual
A	Non-match	MEDI4736	99
B	PI3K	GDC-0032 vs. Docetaxel	15
C	CDK4/6	Palbociclib vs. Docetaxel	27
D	FGR	AZD4547 vs. Docetaxel	16
E (closed)	HGF	Rilotumomab + Erlotinib vs. Erlotinib	9