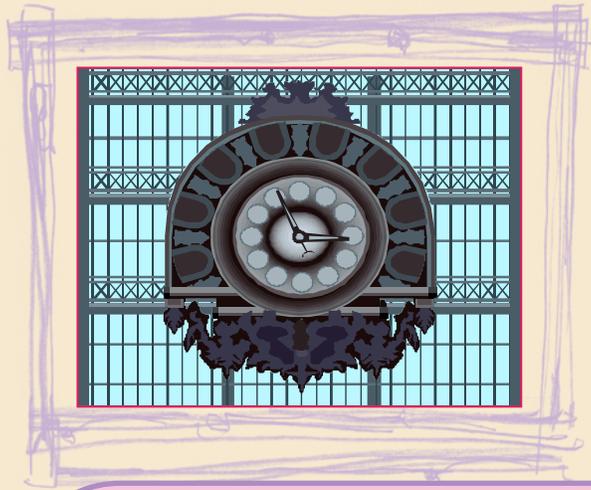


INSIDE PMB: NOVEMBER 2013

Cancer Therapy Evaluation Program • Division of Cancer Treatment and Diagnosis

U.S. Department of Health and Human Services • National Institutes of Health / National Cancer Institute

WHAT'S IN THIS ISSUE?



The clock is ticking. Tired of waiting! This is what happened last month while waiting to return to work from the government shut down. At the Pharmaceutical Management Branch, we understand that time is crucial. This issue of INSIDE PMB is devoted to time as it affects the way we do business at many levels. For our customers, this means having quick access to important information such as lot recovery letters or a need to report a temperature excursion. For PMB, it means providing reliable service even during the government shut down.

So, enjoy our three page newsletter. There is no deadline to reading this newsletter. No clock to remind you of the essence of time. Just you and the three pages.

SET YOUR CLOCK!!

It's never too late to plan ahead. Mother Nature sometimes surprises us with her creativity, especially in the winter. The next few months are full of government holidays.

So please plan ahead. Upcoming holidays:

- Thanksgiving (Nov 28)
- Christmas (Dec 25)
- New Year's Day (Jan 1)
- Martin Luther King Day (Jan 20)



Temperature excursion

We've all been there. The air conditioner breaks during a heat wave or the temperature of the refrigerator mysteriously goes out of range and the alarm is silent ... What to do?



- Move the affected products to another location maintained within the desired temperature range
- Determine how long the items were out of range and the minimum or maximum temperature reached.
- Review the protocol or Investigator Brochure (if available) for temperature excursion information
- Contact PMB (240-276-6575 or pmbafterhours@mail.nih.gov) for guidance. Have the following information available: protocol number, agent name, NSC number, description of the event, temperature range, duration of event and temperature log(s).

Our PMB staff will guide you based on the given information. We may seek advice from the drug company for additional information, and you may have to wait a little for a decisive answer. We may simply ask you to return the agent to the NCI Clinical Repository because the agent is no longer considered acceptable for clinical use. The bottom line is we need temperature excursion data for assessment.

IND WITHDRAWAL

We are providing you a list of the agents that have withdrawn their IND since May 2012. The agents and the dates of the IND withdrawal letters are listed in the table below. This is **not an all inclusive** and does not contain agents that were retired prior to the dates listed in the table.

The IND withdrawal letter provides you with instruction to return all remaining drug supplies to the NCI Clinical Repository. If you did not receive the letter, you can now obtain it via the OAOP.



requires IAM account



| NSC # | Agent | Date of Letter |
|---------|---|----------------|
| 694501 | SJG-136 | 31-May-13 |
| 726292 | MNL518 | 11-Jun-13 |
| 729280 | Obatoclox mesylate (GX15-070MS) | 16-Jul-13 |
| 745942 | Fostamatinib (R935788) | 16-Aug-13 |
| 707299* | rF-GM-CSF (Recombinant Fowlpox GM-CSF) | 14-Aug-13 |
| 710068* | rF-CEA(6D)/TRICOM [Recombinant Fowlpox- CEA(6D)/TRICOM] | 14-Aug-13 |
| 710658* | rF-TRICOM (Recombinant Fowlpox- TRICOM) | 14-Aug-13 |
| 374551 | Fenretinide (4-HPR) | 14-Aug-13 |
| 613795* | GM-CSF (sargramostim, Leukine) | 14-Aug-13 |

*Only for IND 9888



Expiration Date Lot Recovery Letter

The Pharmaceutical Management Branch (PMB) will only issue written shelf life information for CTEP agents via an official stock recovery letter. The official stock recovery letter will be issued once the agent has reached its maximum shelf life and its stability testing is completed. If you need specific information, speak directly with the PMB pharmacist in charge of the agent.

Where do letters go to?

1. The shipping designee's address at the time of shipment
2. The investigator(s) office address on the FDA Form 1572



Running out of time?
Need it now?

All stock recovery letters are now posted in the OAOP website. **Access requires an active IAM account.**

- Log on to the OAOP website <http://eapps-ctep.nci.nih.gov/OAOP/pages/login.jsp>
- Use your active IAM username and password
- Select the tab labeled "Stock Notification Letters"
- Select one or multiple search criteria (e.g. NSC, Lot number, etc.)
- Then, search.

The Protocol Status Change notices are also available via the OAOP website.

HOW TO AVOID DRUG SHIPMENT DELAY?



OAOP (Online Agent Order Processing) Saga

There are days that PMB staff feels we work 24/7, however, implementation of OAOP did not change how agent orders are processed and shipped to the clinical trial sites. Domestic order requests for next day delivery must be submitted to PMB by 2:00 pm Eastern Time and must be accompanied by an express courier account number to execute the shipment. Although we triage orders based on priority need-by-dates and on factors and conditions about how the agent is shipped, there is no guarantee orders will be shipped on the same day the request is received unless the request is accompanied by an express courier account number.

When you receive that "order has been submitted" notification from OAOP, shipment of the request does not happen immediately. Numerous processes occur at PMB as well as at the NCI Clinical Repository before the agent is picked-up by a courier. Although express courier services function 24 hours a days, they do not pick-up packages 24-hours a day. Couriers have scheduled pick-up times; this is the reason we have a cut-off time for order submission for next day delivery. So, please do not submit a request at 7:00 pm Eastern and request next day delivery.

Orders shipped via ground delivery service most often are not shipped the same day as receipt of the order request. Many of you have received an e-mail requesting an express courier number if your agent is shipped via ground delivery service and the requested need-by-date cannot be satisfied by this type of delivery service. Ground delivery service can take up to five business days to arrive at your site. This does not include the day the order is shipped.



The best way to accommodate receipt of your agent within the time-frame requested is to always plan ahead, order agents within a reasonable time period before they are required and request a need-by-date that is satisfied by the agent's normal shipment method.



AROUND THE GLOBE Did you know...

Lack of accrual? Need to reach target population? Need global data? These are some of the questions that we ask ourselves when we evaluate participation of foreign sites in our CTEP-sponsored trials. Conducting clinical trials globally is an option to meet the planned timelines and patient accrual especially in a large Phase II/III program. Understanding the benefit of adding certain population is critical to successful planning and implementation of clinical trials. So, PMB staff works diligently and is sensitive to the request. We assist our investigators and their international members with drug importation and ensure that the drug will arrive in time for patient care.

