

INSIDE PMB: February 2014

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

HOUSE KEEPING

The PMB is doing some major house cleaning this year. One of the major changes that PMB is working on is updating the PMB/CTEP Policies/Guidelines such as the policy and guideline of Investigational Agent Ordering, and Accountability and Storage of Investigational Agents. To address some of your concerns, we've posted some frequently asked questions (FAQs) on our CTEP web site. Two updated FAQs that you may find very useful are about patient returns of oral clinical supplies and how to access OAOP. If you can't remember what we have been writing about in our newsletter thus far, please see the FAQs. Better yet, check our webpage <http://ctep.cancer.gov/branches/pmb> for news and updates of the PMB policies and guidelines or FAQs.

Other changes ...

1. **Oral DARF is available.** There is no penalty for not using the Oral DARF now; however, starting on March 1, 2014, you need to use the Oral DARF for oral agent. For additional guidance, please check the new Policy and Guidelines for Oral DARF at CTEP/PMB webpage.
2. **Training videos** are in progress and not yet available. The training videos will provide detailed step-by-step guidance on various aspects of drug accountability.

Your comments are important to us as we implement these guidelines. We welcome your feedback by telephone, (240)276-6575 or email, PMBafterhours@mail.nih.gov.



New but not so new

Patient's wallet card

Front-line pharmacists often encounter routine alerts for potential drug-drug interactions (DDI) when filling prescriptions. However, DDIs are not apparent when patients receive study agents because the range of DDI experience in humans can vary from extensive to very limited. Nevertheless, both health-care professionals and patients alike should be aware of the potential for DDIs based on the most current information.

While the protocol serves as the source document for study team members, how is potential DDI information concisely conveyed to patients and others outside the study team?

PMB developed a protocol appendix specific for patients, their caregivers and non-study healthcare professionals. The patient handout alerts all prescribers that this patient is participating in a NCI study; patients should take this paper to all office visits. Study agent names are listed in addition to specific enzymes that are affected by the agent or in turn affect agent activity. The handout is accompanied by a patient wallet card, both of which are customizable for the protocol and the study agents.

The generic protocol template (with patient handout appendix) is available on the CTEP website (ctep.cancer.gov) under protocol development tools.



CALCULATING RETEST DATES FOR BLINDED SUPPLIES

Unlike open label trials, there are two options available for each dosage form: (1) an active agent; (2) or, an identical placebo compound. So how do you record necessary information on the Patient-Specific DARF?

1. Lot Number

PMB suggests that the number in the upper right-hand corner of the patient-specific label be used as the lot number for each product. This is a **9-digit number** composed of a **5 digit number** (a Julian date) followed by **4 digits** (the order number for that day) (e.g. 14022-0001). This number will change for each shipment even those for the same patient ID.

2. Expiration Dating

The calculation of a supplies' expiration date (or more accurately, its retest date) is based on a combination of the inventory management, ordering procedures, and the Julian date printed on each label.

Depending on the protocol, sites are allowed to order additional clinical supplies for a given patient a maximum of one month in advance of when those clinical supplies are to be dispensed to the patient. The ordering intervals are detailed in the pharmaceutical section of each protocol.

If a six-month clinical supply is provided per protocol, the shipment of additional clinical supplies from a given lot is stopped a minimum of seven months in advance of the lot's expiration date, thus allowing both the one month for advance ordering and the six months for the actual clinical supply to be exhausted before the lot's expiration date is reached. Ordering closer to the date of the next dispensing can help ensure acceptable dating in the event of treatment delays.

3. Patient-Specific Label

Each patient-specific label includes, in the upper right hand corner, a Julian date that indicates the day the order for those clinical supplies was received by PMB. (A Julian date is a five-digit number consisting of the two digits of the calendar year plus a day count.) A Julian date calendar can be downloaded from the web < [try http://amsu.cira.colostate.edu/julian.html](http://amsu.cira.colostate.edu/julian.html) > and stored with your DARFs to assist in translating those 5 digit dates to standard month, day, year dates.

For example, January 1, 2014 would have a Julian date of "14001" and December 31, 2014 would have a Julian date of "14365".

Continuing with our example above, if a six-month supply is provided, a retest date can be calculated for product received at the site that is seven months from the Julian date. That Julian date is printed on the bottle. Similarly, the retest date for a three (3) month supply of product would be four (4) months and the retest date for a six (6) week supply of product would be ten (10) weeks.

If the calculated retest date is reached and the clinical supplies have not been exhausted by the patient, the pharmacist should contact PMB at 240-276-6575 and ask to speak to the blinded studies pharmacist to review the dating. Please have the protocol number, the patient ID, and the Julian date handy when calling.



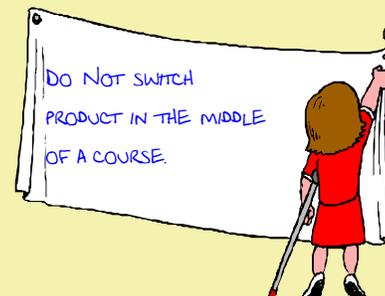
UPGRADED APPLIANCES

Chimeric MoAb 14..18 (NCI) - NSC 623408

Available until January 20, 2014

Patients will continue treatment with the NCI product if they are in the middle of the four-dose cycle on January 20th. Patients would then start with the United Therapeutics (UTC) product with the next scheduled cycle. Do not switch product in the middle of a course.

Affected protocols: ANBL0032, ANBL1221, NANT N2011-04, Special Exception



Chimeric MoAb 14.18 (UTC) - NSC 764038

Available from January 21, 2014 onward

Please consult the protocol to verify the source and preparation instructions prior to preparing doses of ch14.18 for administration.

The products from the NCI and United Therapeutics (UTC) should not be mixed together when preparing a dose for patient treatment.

The nominal concentrations, as well as the dosing and preparation instructions differ between the NCI and UTC products and caution should be used when preparing doses of ch14.18 for administration.

Affected Protocols: ANBL0032, ANBL1221, NANT N2011-04, Special Exception



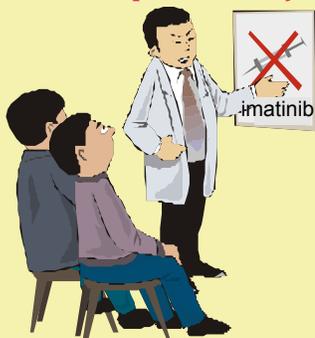
Olaparib (AZD2281) - NSC 747856

Tablets are now available for the phase 1-T cohort. Only dispense tablets to new patients. **Existing patients will receive capsules only.**

Affected Protocol: NCI 8348



STI571 (imatinib, Gleevec) - NSC 716051



The NCI supply of imatinib will expire on February 28, 2014 and there will be no other lots to replenish the current drug inventory.

Those patients who still need to take imatinib beyond February 28th must be switched to the commercial sources. Please check the latest version of the protocol for updated agent availability.

Affected Protocols: CALGB-10001, N0272

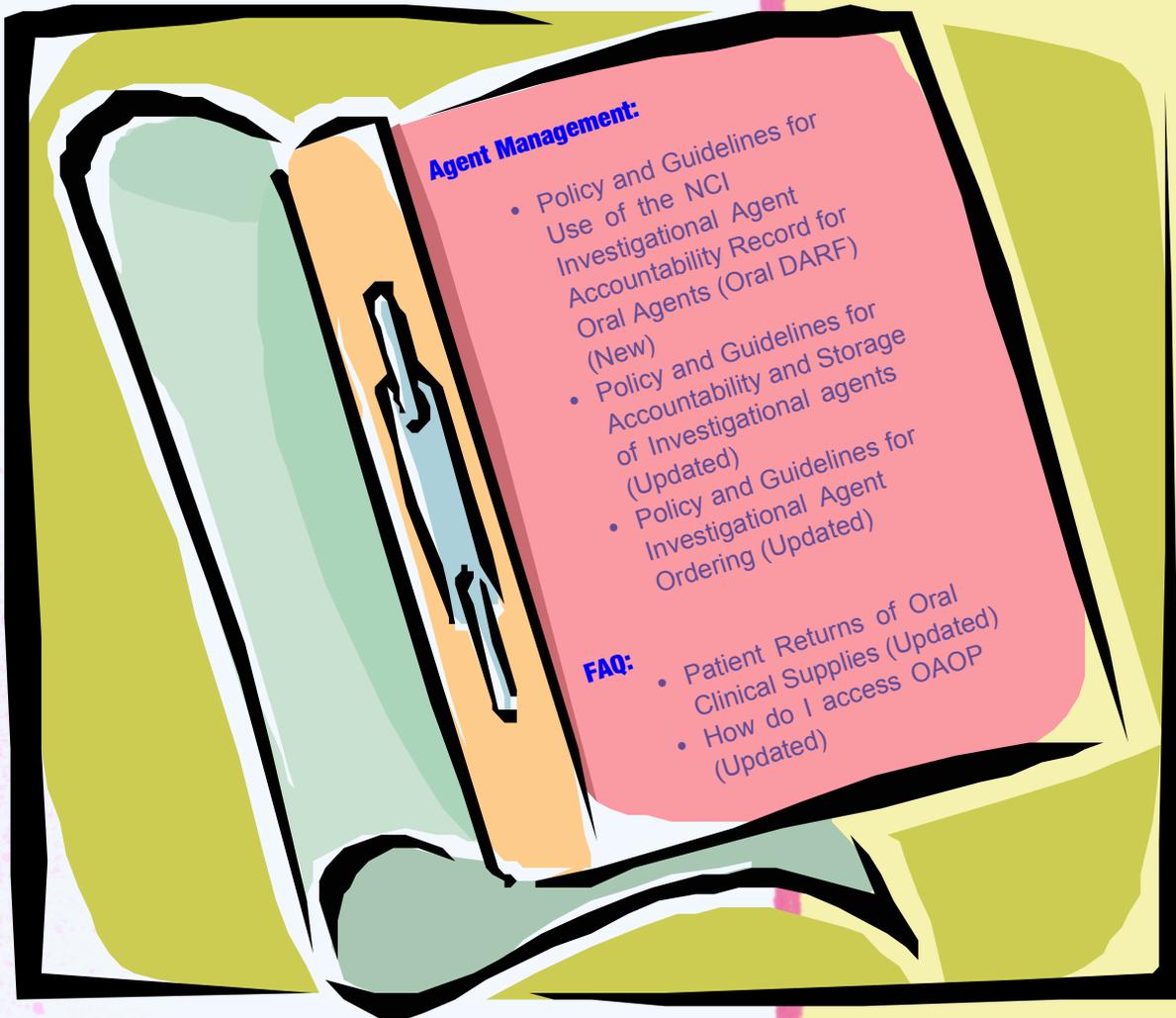
AMG 386 - NSC 751173

150 mg and 600 mg vials are now available for all open-label trials!!!

Affected Protocols: 9048, 9041, 9068, A091103, ADVL1115



Feature Column: Webpage Updates



Check the PMB webpage, <http://ctep.cancer.gov/branches/pmb> for exciting web updates. Review those documents especially as you implement the new NCI Oral DARF.

PLEASE LOOK FOR THIS FEATURE COLUMN IN FUTURE ISSUES!

A special thanks to COG, ECOG, SWOG, and Alliances' Pharmacy Committees for their comments and suggestions. We developed these documents with your questions in mind.

