

Welcome to the flagship issue of the NCI CTEP Pharmaceutical Management Branch's "Inside PMB." Several things have occurred to us:

- You in the field may not receive amended protocols or information from Principal Investigators as quickly as you'd like.
- We could do a better job of spreading good news.
- Many of you don't speak the same language we do (we speak government-ese!), and we could explain a few terms.

We hope you find this information useful. Please send questions, comments and suggestions to [pmbafterhours@mail.nih.gov](mailto:pmbafterhours@mail.nih.gov).

## INTRODUCING...

### PMB AFTER HOURS



Despite many requests to move our office to a warm, sunny, palm-tree covered, tropical location, we remain located in beautiful downtown Rockville, Maryland. Many of our customers, however, are located to the left of us on the map, and that means a time difference! We close at 4:30, just as our California customers are finishing lunch. So.....

Need to reach us? Try our new after hours e-mail address:

[pmbafterhours@mail.nih.gov](mailto:pmbafterhours@mail.nih.gov)

We'll forward your e-mail to the appropriate PMB person, and the appropriate person will answer the next business day.

## CH-CH-CH-CHANGES!

The NCI will not receive any further shipments of **CCI-779** ampules. We will stock only **vials** once the remaining 25 mg ampules are depleted. Only 25 mg and 125 mg vials are available. Wyeth has not manufactured the 75 mg vial, noted in all of the NCI protocols, and they may or may not manufacture this strength in the future.

*Remember: CCI-779 kits include a vial of both drug and diluent. Only the accompanying diluent should be used to reconstitute a given drug vial. Once reconstituted (with the appropriate diluent), the concentration of the initial dilution is 2.5 mg/mL for the amps versus 10 mg/mL for the vials. After dilution with normal saline (to a concentration 0.1 mg/mL to 1 mg/mL), the ampule formulation is stable for 8 hours whereas the vial formulation is only stable for 4 hours.*

**Look for INSIDE PMB quarterly! Next issue: November, 2003**

## NUMBERS

Number of line items shipped to clinical sites by the NCI Clinical Repository monthly:

7,200

Number of line items returned to the NCI Clinical Drug Repository monthly:

4,300

Per cent of items returned to us that must be destroyed:

100

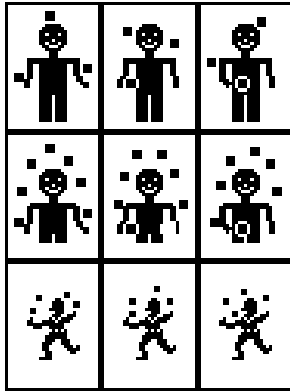
**WHAT THIS MEANS: Please order conservatively, and avoid "starter" supplies. Remember - most orders can be delivered in 24 hours!**

## WHAT IS AN NSC NUMBER?

The NSC number is a universally recognized unique identification number that identifies a specific compound throughout the entire lifespan of that specific agent (not just while it is investigational). The "NSC" refers to the former Cancer Chemotherapy National Service Center.

## WHAT IS A JULIAN DATE?

A julian date is a 5 or 7 digit number that identifies a specific day of a specific year. It is based on the Julian calendar, introduced by Julius Caesar in Rome in 46 B.C. that established the 12-month year of 365 days with a leap year every 4 years. The digits of the number represent the year and the day of the year. So a julian date of 01001 or 2001001 is January 1, 2001 and 04366 or 2004366 is December 31, 2004. PMB uses these numbers on the label of every double-blind agent and also as a part of every order, transfer or return number. So 2003182-0001 is the first regular order we processed on July 1, 2003 and T03182-0012 is the twelfth transfer we processed that day.



# JUGGLE THOSE AGENTS!

OH NO! The study closed and you still have OODLES of agent! What's Pharmaceutical Management Branch (PMB) policy ?

"DCTD supplied investigational agents may be transferred within an institution (intra-institutional transfer) from a completed DCTD sponsored protocol to another DCTD approved protocol that utilizes the same agent and formulation." If your transfer doesn't fit neatly into these parameters, please contact PMB to request an exception to policy. Some tips to consider before requesting a transfer:

Special Exception (or Compassionate Use) protocols must be completed before agent can be transferred. To close out a Special Exception protocol, the investigator must submit a Report of Independent Investigator to the Special Exceptions Coordinator. Please contact the Special Exceptions Coordinator before requesting a TRC, Group C Transfer, or Special Exception transfer.

Only non-dispensed agents in whole containers (vials, bottles, etc.) can be transferred! Approved transfers must be documented on the Drug Accountability Record Form (DARF).

Transfer Investigational Agent Forms are available on our website, <http://ctep.cancer.gov>, and completed forms may be faxed to (301) 402-0429.

For additional information, contact PMB by phone at (301) 496-5725 or via e-mail at [pmbafterhours@mail.nih.gov](mailto:pmbafterhours@mail.nih.gov)

## HAIL AND FAREWELL

- The PMB will withdraw the IND for SU5416 (NSC 696819) on December 31, 2003. At this time, only one patient remains in treatment.
  - All remaining PSC-833 will expire on August 31, 2003. No further lots will be manufactured. All patients should complete treatment on or before August 31, 2003
- We welcome two new products:
- Triapine® (NSC 663849), an " -heterocyclic carboxaldehyde thiosemicarbazone (HCT), is a ribonucleotide reductase (RR) inhibitor that acts on the M2 (R2) subunit. The HCTs are the most potent RR inhibitors, being 65 to 5,000 times more potent than hydroxyurea. Triapine® is supplied by Vion Pharmaceuticals and is administered intravenously.
  - GTI-2040 (NSC 722929) is a 20-mer oligonucleotide that is complementary to the R2 component of ribonucleotide reductase (RNR) mRNA. Supplied by Lorus Technologies, it is also administered IV.

And **CONGRATULATIONS** to PS-341 (bortezomib, NSC 681239) which was recently approved for the treatment of patients with multiple myeloma who have received 2 previous therapies: Its new handle is Velcade®.

## WHO ARE WE?

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## A DILLY OF A PROBLEM

So you ordered trastuzumab (Herceptin™, NSC 688097), and you didn't use it, and now it's expired? Closer examination reveals that only the diluent is expired?

Consider replacing just your diluent. Diluent is now available; use trastuzumab's NSC, but write "0 mg" or "Diluent Only" on the order form.

## Say this ten times fast: BEVACIZUMAB

At the recent American Society of Clinical Oncologists' meeting in Chicago, bevacizumab (bev -A-sciz [as in C ]-zoo-mab; Avastin®, NSC 704865) was the talk of the town! A combination of bevacizumab plus chemotherapy improved survival in previously-untreated metastatic colorectal cancer patients in a phase 3 trial. The trial exceeded what the study was designed to demonstrate. The trial also met the secondary endpoints of progression-free survival, response rate, and duration of response.

Immediately, CTEP set about creating a mechanism for expanded access to the agent. Now, Protocol TRC-0301, "A Multicenter Study of the Anti-VEGF Monoclonal Antibody Bevacizumab (Avastin®) Plus 5-Fluorouracil/ Leucovorin in Patients with Metastatic Colorectal Cancers that Have Progressed After Standard Chemotherapy" is available.

Patients can call 1-800-FOR-CANCER for more information and referrals.

Clinicians can call the PMB Treatment Referral Center at (301) 496-5725.

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