INSIDE PMB

May 2005

WASH THEIR MOUTHS OUT WITH SOAP!

Committing generic names to memory is harder every year, and saying them out loud is almost dangerous. Six individuals were selected by lottery after submitting answers to last month's matching game, which appeared on page 2 (Hint, hint). The correct answers:

1. d. alvocidib (flavopiridol)
2. f. apolizumab (Hu1D10)
3. h. becatecarin (XL119)
4. i. bevacizumab (rhuMAb VEGF)
5. g. erlotinib (OSI-774)
6. a. ferumoxtran-10 AMI-227
7. j. gefitinib (ZD1839)
8. b. glucarpidase (carboxypeptidase)
9. e. oblimersen (G3139)
10. c lenalidomide (CC-5013)

Winners included from the north, Rupert Hay, Huntington, WV; Virna Ignacio Almuete, Baltimore, MD; Thomas Kostecki and his Cavelier King Charles Spaniels in Madison, WI (guess what he took? Cookies or biscuits?) From the south, the winners were Jennifer Worrell, Jacksonville, FL; Mary Dover, Jonesville, AR; and Stacy Wolter, Louisville, KY.

LAST CALL FOR QUESTIONS?

Eleven words in the February issue of INSIDE PMB generated more e-mail than we have ever received:

The new expiration date for the DARF is Nov 30, 2007.

Clever readers went to our website (http://ctep.cancer.gov) to download a copy, only to find the expired form. We responded to the flurry of inquiries by posting the new form ASAP. Then, a number of people indicated that they couldn't open the Adobe document, so we mailed copies to them. We're trying to determine why some sites are experiencing difficulty with the download. It may be that the new form on the site is a write-able Adobe document–it allows you to fill in the top portion with site and protocol specific information.

Then, Susan Nelson asked, *"When typing in the protocol title on this new form, only a small portion of the title fits. Is this abbreviated title okay or should we be handwriting in the entire protocol title?*"

Some sites have a short, sweet "working title" and this would be a perfect place to use that. If the protocol document itself does not have a short title or a working title, you can develop one. Consider typing in as much of the title as fits, or developing a different type of abbreviated title. Please include the protocol number and capture the intent of the title. *{We are revising the write-able form to accommodate longer titles.}*

QUOTE OF THE QUARTER

"Because they don't e-mail pmbafterhours@mail.nih.gov and ask to be added."

Newsletter Editor's response after the Branch Chief Skip Hall hollered, "How come we are spending so much money mailing hard copies of the newsletter? Why aren't our customers on the electronic distribution list?"

Look for INSIDE PMB quarterly! Next issue: August, 2005

TOO MUCH SHARING

Please do not EVER send your **social security number** (or someone else's, for that matter) to PMB. Folks sometimes do this when they fax requests for investigator numbers. We don't need it, don't want it, won't ask for it!

Ordering Outside the United States: CARBOXYPEPTIDASE!

PMB no longer supplies special exception carboxypeptidase ($CPGD_2$, glucarpidase, NSC 732443) to international locations. Protherics has contracted with IDIS World Medicines in the UK to respond to requests from countries with authorized carboxypeptidase distribution under "named patient basis." IDIS's telephone (+44 (0) 20 8410 9014) is manned at all times. Registration with IDIS before ordering is necessary to process your request quickly. You can also contact IDIS World Medicines using these E-mail addresses:

Hospitals: hospitals@idispharma.com
Community Pharmacists: retail@idispharma.com
Pharmaceutical Industry: pharma@idispharma.com .

May I please speak to Christy?
NOT NECESSARILY!

Sites calling to request IBs often ask for Christy! Instead, please let the technical receptionist know you're calling for an Investigational Brochure, or E-mail ibcoordinator@mail.nih.gov. If Christy is indisposed, someone else will help you!

Pharmaceutical Management Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute
6130 Executive Boulevard
Suite 7149
Rockville, Maryland 20852
(301) 496-5725
Order fax: (301) 480-4612
Other fax: (301) 402-0429
E-mail: pmbafterhours@mail.nih.gov

PMB AFTER HOURS

Speaking of carboxypeptidase...you cannot make inquiries about carboxypeptidase on the after hours E-mail. Anything else is OK!

So.....Have a question after 4:30 PM Eastern Daylight time or too busy to call? Try our after hours E-mail address at any time of the day or night:

pmbafterhours@mail.nih.gov

INVESTIGATOR'S HANDBOOK: NOT JUST FOR INVESTIGATORS!

The Investigator's Handbook guides various aspects of therapeutic drug development... protocol writing/submission, reporting requirements, drug accountability, and record retention.

■Part D is of particular relevance to pharmacy, covering agent distribution requirements and accountability, storage, and returns procedures.

■Part E discusses nonresearch use of investigational agents including special exception request criteria.

■Appendix XIV contains recommendations for antineoplastic medication handling with references to the ASHP technical assistance bulletin.

■Answers to frequently asked questions can be found in the handbook. For example, how long should investigational records (including drug accountability) be kept? According to Section 10.4, "for at least 2 years after an NDA or BLA has been approved or the IND has been closed."

See http://ctep.cancer.gov/handbook/index.html

CAPER: light-hearted recreational activity for diversion or amusement
CAEPR: a typo or a clever acronym

Have you seen the new Comprehensive Adverse Event and Potential Risks (CAEPR) thingie? The CAEPR replaces the reported adverse event and potential risks list, formerly found in the pharmaceutical data sheet, AND includes the updated ASAEL. It's pretty snazzy. To celebrate this new, improved document, we devised a caper for you. Send your answers to pmbafterhours@mail.nih.gov and you'll qualify for our next drawing. Four winners will receive homemade goodies.

Match the agent on the left to its adverse event on the right:

1. triapine	a. gray hair reverts to natural color
2. imatinib	b. frequent, watery poopies
3. SQ* azacitidine	c. extreme sensitivity to cold
4. oxaliplatin	d. autoimmune colitis
5 SAHA	e. methemoglobinenia
6. bevacizumab	f. acne-like rash
7. BAY 439006 tosylate	g. hand-foot syndrome
8. bortezomib	h. anorexia, dehydration
9. cetuximab	i. hypertension
10. MDX-010	j. violaceous (purple) discoloration lasting up to ten days

For extra credit (in case you get a couple wrong) tell us what you call pickled flower buds from the *Capparis spinosa* used as a pungent relish in various dishes and sauces. (If you get this wrong, we will die laughing!)

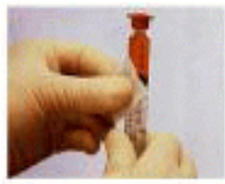
*SQ is no longer an acceptable abbreviation for JCAHO-accredited places, so please do not copy us.

FAQS: INJECTABLE AGENTS IN VIALS

Two patients receive the same agent on the same open label NCI study at the same institution. Can we share vials?

■Yes, if the patients are being treated on the same day, this is acceptable. Document this on the DARF by noting patient initials/ number used 1 vial and patient initials/ number used 0 vials. Tie the lines together with a " ".

■This is not how you document trastuzumab, our only multi-dose vial. Trastuzumab is documented by mg (often with confusing results).



Our patient's dose of godzillaplatin is 104 mg, and the NCI-supplied vials contain 100 mg in 5 mL, but they have ample overfill. If we can draw 5.2 mL from the vial, can we use it instead of opening another vial?

■You bet! Have at it, especially if the vial was filled by the manufacturer. If the product is lyophylized, however, please make sure that you reconstituted it exactly as directed, and the overfill isn't the result of an error. (Please note that you might want to suggest to your physicians that the difference between 104 mg and 100 mg is very small, and they can round to 100 mg without a problem in most cases.)

IMPORTANT: BLINDED STUDY DRUG RETURNS!

Recent blinded protocol status changes will undoubtedly create questions about returns:

■Protocol NCIC-BR.19 has closed to accrual and treatment and S0023 has closed to accrual with no further randomization to or treatment with ZD1839/placebo. All patients must discontinue treatment with ZD1839/placebo immediately and return remaining medication to the investigator.

■Protocol NSABP-B-36 has been amended to remove the celecoxib/placebo component from the study. PMB will continue to supply open-label epirubicin in one shipment for patients randomized to the FEC arm at the time of patient randomization.

To return drug used on these protocols:

■Return only undispensed, unopened clinical supplies to NCI with a completed Return Drug List, available at http://ctep.cancer.gov/forms/. Please remember: List each patient I.D. as a separate line item!

■Document dispensed clinical supplies (opened and unopened bottles) returned by the patient; destroy them on-site in accordance with institutional policy.

■Please see the memo distributed by the responsible Cooperative Group for additional information.

THE END