

So Whatsa Matta Wichu?!?

You don't like color?

In the last Inside PMB, we indicated that we now send Inside PMB to approximately 150 preferred customers electronically and in color, and invited you to join. And a few of you did join. But not enough. So we are running a contest...east versus west versus abroad.

Send an E-mail to pmbafterhours@mail.nih.gov asking to be added to the electronic distribution list. Indicate whether your state is east of the Mississippi, or west of the Mississippi (and be careful, we have a map). And if you are a non-US clinician, indicate your country. The first two new subscribers from each area will receive either a copy of the American Pharmaceutical Association's *Supervision: A Pharmacy Perspective* or two dozen home-baked cookies (or dog biscuits). Your choice.

That's Pandora's Box to You!



In the lower middle of the Clinical Drug Request (NIH-986) there's a sneaky little box that says, "MISCELLANEOUS: Urgent shipments must be accompanied by an express courier account number."

Note this:

- * Using your account can speed shipments normally sent by Priority Mail by at least 2 days.
- +Any request for delivery on Saturday must include a courier account number

(e.g. Fed-Ex, UPS, Airborne, etc.).

- * Urgent orders are subject to the same deadlines and requirements as regular orders.
- * A courier account number on your drug order is a request to ship using this account, even if the order is routine. If you don't want to be charged, please delete the account number from the CDR!*
- +If your request is truly urgent, please fax the CDR and then call us.

If you have questions about charging shipments to your courier account, please call PMB at 301-496-5725. We're happy to help!

**Very efficient people who have photocopied stacks of CDRs with courier account number pre-filled are paying for all of their shipments by accident. The taxpayers of the United States thank you!*

Santa Don't Deliver Drugs



PMB employees anxiously await the plethora of approaching US holidays! Veterans Day (11/11), Thanksgiving (11/25), Christmas (closed 12/24 this year), New Year's (closed 12/31 this year) and MLK's Birthday (1/17/05). And don't forget Inauguration Day (1/20/05)! Especially in December, we compete with Santa for shipping

space. PLEASE ORDER EARLY.

For non-US sites, we ask folks specifically to

UMake note in the comments section of any holidays in your country that may delay delivery to you. Plan ahead.

UNote approaching holidays on your drug orders when you send them, like this, "Monday the 24th of September is Heritage Day in South Africa; do not ship for delivery that day!"

USend boxes of your traditional holiday cookies to us to sample!

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

PMB AFTER HOURS

It's no co-inky-dinky that Kay Lockwood in Michigan has no trouble reaching us, but our customers east or west get the answering machine! We close at 4:30 eastern time.

So.....Need to reach us? Try our after hours E-mail address at any time of the day or night:

pmbafterhours@mail.nih.gov

Expect a response on the next business day!

Right Word on the Tip of Your Tongue?

Wondering if MALT is a beverage? Or how many ways you can say gefitinib? NCI's Enterprise Vocabulary Services (EVS) Project, a joint effort of the Center for Bioinformatics and Office of Communications, can help.

The NCI Thesaurus provides extensive details on some 40,000 cancer, drug, gene, anatomy, and other concepts. It can tell you that ZD 1839 and Iressa are other names for gefitinib, correct your mistaken assumption that you can chug MALT: MALT is Mucosa-Associated Lymphoid Tissue, & find the type of lymphoma arising from that tissue (with molecular, cellular, and clinical characteristics, as well as definitions and subtypes). It provides the base layer of the caCORE bioinformatics infrastructure, and is used in efforts such as the cancer Biomedical Informatics Grid (caBIG). Web accessible at: <http://nciterms.nci.nih.gov/>.

The NCI Metathesaurus uses NCI Thesaurus as a central reference terminology, but adds in some 2,200,000 terms from over 50 other terminologies such as MedDRA, ICD-O-3, ICD-10, MeSH, and SNOMED-CT. These terms are grouped by meaning into over 900,000 concepts, so you can find and translate meanings from one terminology to another. Web accessible at: <http://ncimeta.nci.nih.gov/>.

For more information on the EVS Project, see this Web page: <http://ncicb.nci.nih.gov/NCICB/core/EVS/>.

Who are we?

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Multidose Intron®A Pen: Confusion! Confusion!!!

Schering-Plough's new Intron® A multidose injection pen is available in several strengths with set dose indicators. For instance, the 60 MIU pen has 5 MIU, 15 MIU, and 20 MIU markings. One full turn (5 clicks) of the cap delivers 5 MIU. For the 30 MIU pen, however, one full turn (5 clicks) delivers 2.5 MIU, and for the 18 MIU multidose pen, one full turn (5 clicks) delivers 1.5 MIU.

Easy, RIGHT? ... Well, CALGB-90206's potentially confusing wrinkle is the maintenance dose of 9 MIU three times weekly using 60 MIU multidose pens. Please instruct patients to use the "click" method: nine clicks deliver 9 MIU. Each click provides 1 MIU or 0.02 mL of Interferon alfa-2b. The 30 MIU or 18 MIU multidose pen deliver don't require the click method; use the standard doses

The product's box labeling is also confusing, so use this table:

Pen Strength	Labeled as....	Contains
60 MIU	10 MIU Multidose Pen	Six 10 MIU doses
30 MIU	5 MIU Multidose Pen	Six 5 MIU doses
18 MIU	3 MIU Multidose Pen	Six 3 MIU doses

How much should you order? Order four packages of the 60 MIU, five packages of the 30 MIU, or 4 packages of the 18 MIU to cover 8 weeks. And please.....Each multidose pen is for one SINGLE patient only; record it as such on the DAR.

Merci et à Bientôt!!!

Calling, calling, +co calling, banana fanna fo falling, *fe fi mo malling

Call-LING! * +

Àve the appropriate investigator number readily available.
Àbe prepared for the technical receptionist to ask, "May I tell him what this concerns?" if you ask for an employee by name. Sharon's not nosy - she's the nicest lady in the world! But some of you get a favorite PMB contact and call that person for everything, and you may think you know who handles alemtuzumab, but Jeannette passed that hot potato to Ravie a month ago!
Àneed information for more than 3 investigator statuses? Please fax the request to (301) 402-4870 so we don't tie up the line.
Às your question about a blinded study? Yell it out! "I need to know about ST1571 on a blinded study!"

We're Expectin'!



+ A new 15 mg vial size of BMS-247550 will be available in early 2005. Information on this product is already in all BMS-247550 protocols.

+ Lyophilized powder oxaliplatin will have a sibling soon! A liquid oxaliplatin injection formulation (no reconstitution needed before dilution in D5W) will be available in early 2005. Several, but not all, trials are will include both formulations.

+ Initially, both 5 mg and 25 mg CC-5013 will be available in 21 caps per bottle. Bottles containing 28 caps each will be available in the future.

Riddle: What do McDonald's and Genentech have in common?



No more "biggie" or supersized portions; bevacizumab (bev-A-sci-z[as in C]-zoo-mab; Avastin®; NSC 704865) 1000 mg vials have been discontinued.!

Detest retests?

Why does PMB use "retest" dates?

The US Food and Drug Administration (FDA) mandates that commercial drugs in the United States be labeled with an expiration date. Investigational drugs are exempt from this requirement if periodic stability studies demonstrate product integrity during their investigational use.

The "retest period" is the time interval during which the agent can be considered within specifications as long as it has been stored properly. The "retest date" is the date when the manufacturer must reexamine the agent to ensure its suitability for use. If the agent is within specifications, this date can be extended. This process continues until the agent fails testing. Specifications often include factors relating to chemical, physical, and microbial stability such as the following: identification (HPLC analysis), dissolution, related impurities, uniformity, and microbial burden.

Since the retest date changes, our IND agents often omit the retest date on the product label. Those products are labeled with a prep date to provide a clue as to the age of the product. In accordance with FDA regulations, we notify both Investigators and Shipping Designees when a particular lot of the agent will expire soon.

CANCER PATIENTS & COOTIE BOOSTERS

In severely immunocompromised people (ICP), administration of live, attenuated-virus vaccines may be risky: virus replication can be enhanced. In general, do not administered live vaccines to severely ICP. Killed or inactivated vaccines do not represent a danger to ICP: administer as you would to healthy people.

ICP frequently have a reduced antibody response to immunization and may require a higher dose, additional boosters, or post immunization serologic testing for immunity. The immune response may be suboptimal, regardless. Patients vaccinated while on immunosuppressive therapy (or in the 2 weeks before starting) should be considered unimmunized and should be revaccinated at least 3 months after therapy discontinuation.

The American Council of Immunization Practices recommends the following for non-HIV related ICP:

H. influenzae B	Recommended
Pneumococcal	Recommended
Influenzae	Recommended
MMR (MR/M/R)	Contraindicated
Tetanus	Use if indicated
Hepatitis B	Use if indicated
Meningococcal	Use if indicated

BCG, OPV, vaccinia, and yellow fever are contraindicated. (Other cooties? See CDC MMWR 1993;42:1-18.)

THE END

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