So What’sa Matta Wicha?!
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!

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:
U Make note in the comments section of any holidays in your country that may delay delivery to you. Plan ahead.
A Note 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!”
U Send boxes of your traditional holiday cookies to us to sample!

Look for INSIDE PMB quarterly! Next issue: February, 2005
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 60 MIU multidose pens deliver don’t require the click method; use the standard doses.

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

<table>
<thead>
<tr>
<th>Pen Strength</th>
<th>Labeled as:...</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 MIU</td>
<td>10 MIU Multidose Pen</td>
<td>Six 10 MIU doses</td>
</tr>
<tr>
<td>30 MIU</td>
<td>5 MIU Multidose Pen</td>
<td>Six 5 MIU doses</td>
</tr>
<tr>
<td>18 MIU</td>
<td>3 MIU Multidose Pen</td>
<td>Six 3 MIU doses</td>
</tr>
</tbody>
</table>

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!!!

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.

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 (TCP), administration of live, attenuated-virus vaccines may be risky: virus replication can be enhanced. In general, do not administered live vaccines to severely TCP. Killed or inactivated vaccines do not represent a danger to TCP: 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:

<table>
<thead>
<tr>
<th>VACCINE/CONTRAINDICATIONS</th>
<th>RECOMMENDATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>H. influenzae B</td>
<td>Recommended</td>
</tr>
<tr>
<td>Pneumococcal</td>
<td>Recommended</td>
</tr>
<tr>
<td>Influenza</td>
<td>Recommended</td>
</tr>
<tr>
<td>MMR (MR/MR)</td>
<td>Contraindicated</td>
</tr>
<tr>
<td>Tetanus</td>
<td>Use if indicated</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Use if indicated</td>
</tr>
<tr>
<td>Meningococcal</td>
<td>Use if indicated</td>
</tr>
<tr>
<td>BCG, OPV, vaccinia</td>
<td>Contraindicated</td>
</tr>
</tbody>
</table>

(Other cooties? See CDC MMWR 1993;42:1-18.)

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

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