Termination of Emergency Use Authorization

On June 23, 2010 the Commissioner of the Food and Drug Administration terminated the Emergency Use Authorizations for the following:

- Tamiflu (oseltamivir) – unapproved use of an approved product
- Relenza (zanamivir) – unapproved use of an approved product
- Peramivir IV – unapproved product

In accordance with FDA guidance and pursuant to section 564(b)(2)(C) and (b)(3) of the Federal Food, Drug, and Cosmetic Act unapproved products and product information for an unapproved use must be disposed of. Notwithstanding any such termination, under section 564(f)(2) an authorization shall continue to be effective to provide for continued use in any patient who began treatment before termination (to the extent found necessary by the patient’s attending physician).

What You Need To Do

Properly dispose of or return the following pharmaceuticals you received from the Division of Public Health or the CDC. Return information is below:

<table>
<thead>
<tr>
<th>Pharmaceutical Name</th>
<th>Lot #</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peramivir IV</td>
<td>All</td>
<td>All</td>
</tr>
<tr>
<td>Tamiflu 75mg Capsules</td>
<td>Lot: U2011</td>
<td>Expiry: 30-Sep-10</td>
</tr>
<tr>
<td></td>
<td>Lot: U2012</td>
<td>Expiry: 30-Sep-10</td>
</tr>
<tr>
<td>Tamiflu Oral Suspension</td>
<td>Lot: B1048</td>
<td>Expiry: 31-Aug-10</td>
</tr>
<tr>
<td>12mg/ml 25ml</td>
<td>Lot: B1050</td>
<td>Expiry: 31-Aug-10</td>
</tr>
<tr>
<td></td>
<td>Lot: B1053</td>
<td>Expiry: 31-Aug-10</td>
</tr>
<tr>
<td></td>
<td>Lot: B1185</td>
<td>Expiry: 31-May-11</td>
</tr>
</tbody>
</table>

If returning please mark these lots as "Returned for Disposal"

You may keep or return all other lots of Tamiflu and Relenza. If you return these products please mark "Returned to Stockpile". If you choose to keep these products you are responsible for proper disposal at expiry.

Dispose of all “Emergency Use Authorization Fact Sheets”

On June 24, 2010 you must follow all FDA labeling requirements when dispensing Tamiflu and Relenza and comply with the FDA approved labeling for the use of Tamiflu and Relenza.
Return of Pharmaceuticals

If you received Tamiflu and/or Relenza from the Division of Public Health you may send any unused products back to the Division of Public Health before July 26, 2010 marked as "Return for Disposal" (See lot numbers on page 1) or "Return to Stockpile" for all other lots.

Ship to:

DPH/H1N1
1 W WILSON ST
RM B251
MADISON WI 53703

If it is easier for you to dispose of these pharmaceuticals at your facility you may do so at your own expense.

If you received Peramivir IV from the CDC you are responsible for the proper disposal and reporting of doses disposed of to the CDC. Guidance is available at: [www.cdc.gov/h1n1flu/eua](http://www.cdc.gov/h1n1flu/eua)

Please send pharmaceutical questions to: [DHSSstockpile@wisconsin.gov](mailto:DHSSstockpile@wisconsin.gov)

Return of H1N1 Vaccine

Sanofi multi-dose vials of H1N1 Monovalent vaccine (NDC 49281-0640-15) do not expire until June 2011 you may keep or return this vaccine to DPH. If you choose to return this vaccine it is important to maintain the cold chain during shipment. Information on maintaining the cold chain can be found here: [http://www.immunize.org/catg.d/p3049.pdf](http://www.immunize.org/catg.d/p3049.pdf)

Vaccine should be sent before July 26, 2010 and should only be shipped Monday through Wednesday.

Ship to:

DPH/IMMUNIZATIONS
1 W WILSON ST RM B354
MADISON WI 53703

If you choose to keep this vaccine you are responsible for proper disposal at expiry.

Disposal of H1N1 Vaccine

Guidance for the return and disposal of all other H1N1 vaccines is located at: [pandemic.wisconsin.gov](http://pandemic.wisconsin.gov) on the Vaccine Information for Providers page

Please send vaccine questions to: [DHSH1N1Vaccine@wisconsin.gov](mailto:DHSH1N1Vaccine@wisconsin.gov)