



Pharmaceutical Management Branch/Cancer Therapy Evaluation Program/Division of Cancer Treatment and Diagnosis/National Cancer Institute
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FAQ: What is a satellite? Or, is it OK for us to send drug that we have ordered from the PMB to one of our other offices/sites?

Answer: It depends!

And again: IT DEPENDS!

A "Satellite Location" is a local site away from the control area or primary storage area (that is, the place to which PMB shipped the agent). Any transportation of PMB-supplied agents between the control location and satellite location must remain in the institution's immediate control. If delivery of an agent requires use of a secondary carrier (e.g. US postal service, Fed-EX, UPS), the other location is not a satellite.

When investigational agents are received at the control location, they may be transported to satellite locations (originally conceived as within walking distance, sharing staff, and covered by the same IRB). Any transportation must be in the receiving institution's direct control, and a third party shipper may not be used. Local satellite institutions or affiliates must be serviced by institution-employed couriers or central pharmacy staff. CTEP-supplied agents must not be repackaged or forwarded by mail or express courier. The NCI has established policy

- to maintain validated shipping conditions (and therefore product integrity) for agents used for clinical research
- to ensure that PMB can track all product immediately should there be a recall
- to be able to convey other important pharmaceutical information quickly when necessary, and
- to assist in agent accountability.

Any transportation of investigational agents outside the direct control of the institution receiving the agent is considered secondary distribution. Secondary distribution violates NCI policy and procedures.

Proceed to page 2 if your situation isn't congruent with this description...

And if my situation doesn't fit that description, what should we do?

If your situation doesn't exactly fit this description, call PMB and ask to speak to a manager. She or he will ask some questions including the following:

- How far away is the satellite in both distance and travel time? How many patients will need this accommodation?
- Can we work together to develop a mechanism that works for you that will allow us to directly ship agent to your satellite?
- Does the staff member who will transport the agent know that it is considered a dangerous substance by the Department of Transportation if that is the case?
- How will you address the following?
 - agent stability issues both during transportation and for any storage at the local site.
 - safety issues (dangerous substance, how to handle a spill)
 - preparation of the patient's dose under appropriate conditions by appropriately trained staff
 - the need to have someone that can appropriately administer the medication at the site
 - a method for proper disposal of the waste, empty IV bags, etc.
 - a plan for returning unused medication to the central location
 - a back up plan for those instances where a replacement dose may be needed (product damaged, treatment had to be emergently interrupted, etc.) particularly if treatment has been started
 - confirmation that the medication was given (while not a PMB requirement, it is an investigational study requirement)
 - a plan for handling missed doses
 - a plan for multiple day therapies (are doses driven up each day)
 - agent accountability via a DARF

PMB always prefers to ship to the site where the patient is going to be treated. E-mail any questions to ctepmbmgmt@mail.nih.gov (PMB Management), or call 301-496-5725

September 11, 2008

*Prepared and distributed by the Pharmaceutical Management Branch, CTEP, NCI.
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Information in this FAQ is subject to change without notice; check periodically for updates.
Please contact PMB at (301) 496-5725 if you have questions.*