Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI

Policy and Guidelines for INVESTIGATIONAL AGENT ORDERING

Policy:

Active CTEP registered investigators or their authorized shipping designees and ordering designees may order agents from the Pharmaceutical Management Branch (PMB), CTEP for NCI- sponsored or funded clinical trials using PMB-supplied agents.

Active CTEP-registered investigators and investigator-designated shipping designees and ordering designees should submit agent requests through the PMB Online Agent Order Processing (OAOP) application < https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jspx >. Access to OAOP requires the establishment of a CTEP Identity and Access Management (IAM) account < https://eapps-ctep.nci.nih.gov/iam/ > and the maintenance of an "active" account status and a "current" password.

- Routine Orders: Normal PMB processing time is two (2) working days. Orders are shipped by U.S. Postal Service Priority Mail or other ground service. Agents having special storage conditions [e.g., thermo labile agents that require refrigerated or frozen (-20 or -70 degree C) storage conditions] or shipping requirements (e.g., dangerous goods, infectious substances) are shipped Monday through Thursday for next day delivery.
- Urgent Orders: PMB provides next day delivery to registered investigators to meet
 "emergency" or urgent needs. Requests for next day delivery must be received at
 PMB by 2:00 p.m. Eastern Time. The requirement for next day delivery must be
 stated on the order request and an express courier account number provided.
 Submitters will receive a confirmation e-mail of successful order submission.

Guidelines:

 When a number of investigators are participating on a clinical study at the same institution, one investigator should be considered or designated the principal or lead investigator under whom all investigational agents for that protocol should be ordered.

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- Orders will only be shipped to the investigator's designated shipping address.
 Investigators may only have a single shipping address. All changes to the investigator's shipping address must be in writing by submission of an updated Supplemental Investigator Data Form signed by the investigator or by submission of an updated Primary Shipping Address and Designee (PSD) Worksheet if applicable.
- Changes or additions to investigator-designated shipping designees and ordering designees must be in writing by submission of an updated Supplemental Investigator Data Form signed by the investigator or by submission of an updated Primary Shipping Address and Designee (PSD) Worksheet if applicable.
- Submitters will receive a confirmation e-mail of successful order submission. Order status may be viewed at anytime through the OAOP application. Upon shipment, a confirmation e-mail is sent which includes the order details and tracking information (if appropriate).
- Limit agent requests to an eight week supply.

Questions or comments regarding investigational agent ordering should be addressed to the Pharmaceutical Management Branch by telephone (301-496-5725) Monday through Friday between 8:30 am and 4:30 pm (ET) or email PMBAfterHours@mail.nih.gov anytime.

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