
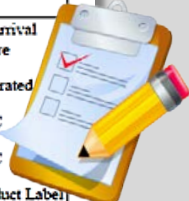



Welcome to this video tutorial on Agent Receipt in the PMB Investigational Drug Accountability series.

This video will review the NCI investigational agent shipment record and proper accountability when agent is received by a Control Dispensing Area.

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PM.Bafterhours@mail.nih.gov		SHIPMENT RECORD OF CLINICAL DRUG REQUEST  Date Authorized: 08/12/2014 Date Needed: 08/26/2014		Courier: Account # Acct Ref # Order # 2014224-0043 Order Ref # O-1039409	
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1111	724772	Sorafenib (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	4	BAY CT1931/32
33333 (0) Sissy Applesmith, M.D. C/O Wonder RPh, R.Ph. Pharmacy Training Center Pharmacy Mail Code 000 11DS Blvd NE Grand Hall, DE 49500 Phone: (303) 111-2222			Storage Information Upon Arrival <input type="checkbox"/> Store at Room Temperature <input type="checkbox"/> On Blue Ice-Store Refrigerated <input type="checkbox"/> On Dry Ice-Store at -20°C <input type="checkbox"/> On Dry Ice-Store at -70°C <input type="checkbox"/> Store as Specified on Product Label		
RETAIN WITH YOUR ACCOUNTABILITY RECORDS					




Each agent shipment will contain a shipping record. Upon receipt of the agent, it's important to verify the contents of the agent shipment against each shipping record.


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NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1111	724772	Sorafenib (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	4	BAY CT1931/32
33333 (0) Sissy Applesmith, M.D. C/O Wonder RPh, R.Ph. Pharmacy Training Center Pharmacy Mail Code 000 11DS Blvd NE Grand Hall, DE 49500 Phone: (303) 111-2222			Storage Information Upon Arrival <input type="checkbox"/> Store at Room Temperature <input type="checkbox"/> On Blue Ice-Store Refrigerated <input type="checkbox"/> On Dry Ice-Store at -20°C <input type="checkbox"/> On Dry Ice-Store at -70°C <input type="checkbox"/> Store as Specified on Product Label		
RETAIN WITH YOUR ACCOUNTABILITY RECORDS					

The shipping record has three main sections.


The top section of the shipping record pertains to the shipper. This section contains the PMB's address, Date Authorized or the date that PMB processed the drug request, and the Date Needed. It will also provide specific details about the courier, an order number and its reference number.

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NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1111	724772	Sorafenib (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	4	BAY CT1931/32
		33333 (0) Sissy Applesmith, M.D. C/O Wonder RPh, R.Ph. Pharmacy Training Center Pharmacy Mail Code 000 11DS Blvd NE Grand Hall, DE 49500 Phone: (303) 111-2222		Storage Information Upon Arrival <input type="checkbox"/> Store at Room Temperature <input type="checkbox"/> On Blue Ice-Store Refrigerated <input type="checkbox"/> On Dry Ice-Store at -20°C <input type="checkbox"/> On Dry Ice-Store at -70°C <input type="checkbox"/> Store as Specified on Product Label	
RETAIN WITH YOUR ACCOUNTABILITY RECORDS					

The bottom section of the shipping record contains shipping information consisting of the ordering investigator's name, the shipping designee, and the shipping address. This section also contains the recommended storage temperature of the agent upon arrival. It is possible that the shipping conditions of an agent may differ from the storage conditions of that agent.

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NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1111	724772	Sorafenib (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	4	BAY CT1931/32
33333 (0) Sissy Applesmith, M.D. C/O Wonder RPh, R.Ph. Pharmacy Training Center Pharmacy Mail Code 000 11DS Blvd NE Grand Hall, DE 49500 Phone: (303) 111-2222			Storage Information Upon Arrival <input type="checkbox"/> Store at Room Temperature <input type="checkbox"/> On Blue Ice-Store Refrigerated <input type="checkbox"/> On Dry Ice-Store at -20°C <input type="checkbox"/> On Dry Ice-Store at -70°C <input type="checkbox"/> Store as Specified on Product Label		
RETAIN WITH YOUR ACCOUNTABILITY RECORDS					

And in the middle section, the NCI protocol number, the NSC number, the agent name, strength & formulation, quantity, the manufacturer's abbreviated name and the Lot number. Please note that we will refer to the Lot number as the identifier throughout this presentation.

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NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1111	724772	Sorafenib (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	4	BAY CT1931/32
33333 (0) Sissy Applesmith, M.D. C/O Wonder RPh, R.Ph. Pharmacy Training Center Pharmacy Mail Code 000 111DS Blvd NE Grand Hall, DE 49500 Phone: (303) 111-2222			Storage Information Upon Arrival <input type="checkbox"/> Store at Room Temperature <input type="checkbox"/> On Blue Ice-Store Refrigerated <input type="checkbox"/> On Dry Ice-Store at -20°C <input type="checkbox"/> On Dry Ice-Store at -70°C <input type="checkbox"/> Store as Specified on Product Label		
RETAIN WITH YOUR ACCOUNTABILITY RECORDS					

Standard Order vs. Patient-Specific Order

Information in this section also varies according to the type of agent order, either Standard Order or Patient Specific Order.

Standard Order Shipping Record

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PMBafterhours@mail.nih.gov		SHIPMENT RECORD OF CLINICAL DRUG REQUEST Date Authorized: 08/12/2014 Date Needed: 08/26/2014		Courier: Account # Acct Ref # Order # 2014224-0043 Order Ref # O-1039409	
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1111	724772	Sorafenib (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	4	BAY CT1931/32




Patient-Specific Order Shipping Record

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PMBafterhours@mail.nih.gov		SHIPMENT RECORD OF CLINICAL DRUG REQUEST Date Authorized: 08/12/2013 Date Needed: 08/26/2013		Courier: Account # Acct Ref # Order # 2014224- 0008-BLI Order Ref # O-1039409	
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
E1111	724772	Sorafenib 200 mg or Placebo	bottle 140 Tablets	4	?
PATIENT ID: 1212121		PATIENT INITIAL: A, XX		←	

Note the differences between the two shipping records. The Patient Specific Order shipping record does not have the Manufacturer or identifier. However, it lists the patient ID number and the patient initials.

Identifier



Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PMBafterhours@mail.nih.gov		SHIPMENT RECORD OF CLINICAL DRUG REQUEST  Date Authorized: 08/12/2014 Date Needed: 08/26/2014		Courier: Account # Acct Ref # Order # 2014224-0043 Order Ref # O-1039409	
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1111	724772	Sarafem (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	4	BAY CT1931/32
33333 (0) Sissy Applesmith, M.D. C/O Wonder RPh, R.Ph. Pharmacy Training Center Pharmacy Mail Code 000 11DS Blvd NE Grand Hall, DE 49500 Phone: (303) 111-2222			Storage Information Upon Arrival <input type="checkbox"/> Store at Room Temperature <input type="checkbox"/> On Blue Ice-Store Refrigerated <input type="checkbox"/> On Dry Ice-Store at -20°C <input type="checkbox"/> On Dry Ice-Store at -70°C <input type="checkbox"/> Store as Specified on Product Label		
RETAIN WITH YOUR ACCOUNTABILITY RECORDS					

Now let's discuss the identifier. In this shipping record, the identifier is CT1931/32.

Multiple Identifiers



BAY 43-9008 / NSC #724772
200 mg BAY 43-9008 as free base / tablet (Formulated as the tosylate salt)
140 tablets / bottle Take as directed.

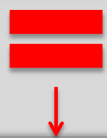
Pack Batch No.: CT1931/32
Bulk Batch No.: SG002LHT

Date of Manufacture (bulk tablets): 15/Oct/2012
**CAUTION: NEW DRUG LIMITED BY FEDERAL (OR UNITED STATES) LAW
TO INVESTIGATIONAL USE**
Do not store above 25°C (77°F). Store in the original package.
Distributed By: National Cancer Institute, Bethesda, MD 20892
Mfg. By: Bayer HealthCare AG, D-51368 Leverkusen, Germany m754

However, upon receipt of the agent, you also checked the bottles and found that the label of the bottle has 2 identifiers: a Pack Batch identifier and a Bulk Batch identifier. So which identifier should be recorded on the Oral DARF?

Standard Order Shipping Record

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PMBafterhours@mail.nih.gov		SHIPMENT RECORD OF CLINICAL DRUG REQUEST  Date Authorized: 08/12/2014 Date Needed: 08/26/2014		Courier: Account # Acct Ref # Order # 2014224-0043 Order Ref # O-1039409	
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1111	724772	Sorafenib (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	4	BAY CT1931/32



Agent Label

<p>BAY 43-9006 / NSC #724772 200 mg BAY 43-9006 as free base / tablet [Formulated as the tosylate salt] 140 tablets / bottle Take as directed. Pack Batch No.: CT1931/32 Bulk Batch No.: SG002LHT Date of Manufacture (bulk tablets): 15/Oct/2012 CAUTION: NEW DRUG LIMITED BY FEDERAL (OR UNITED STATES) LAW TO INVESTIGATIONAL USE Do not store above 25°C (77°F). Store in the original package. Distributed By: National Cancer Institute, Bethesda, MD 20892 Mfg. By: Bayer HealthCare AG, D-51368 Leverkusen, Germany m754</p>

You should use the agent label identifier that matches the identifier on the shipping record.

Standard Order Oral DARF

Print Form Save As Reset Form

Collection of this information is authorized under 21 CFR 312.57. This information is collected to ensure compliance with Food and Drug Administration (FDA) requirements for NCI as an IND sponsor and that investigational agents are under the control and accounted for by competent authority. The information may be disclosed to researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the applicable Institutional Review Board, NCI, FDA and Department of Health and Human Services. Submission of this information is voluntary, however, in order for you to conduct a study in accordance with relevant, current protocols, you must complete all fields.

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: COM, Project Clearance Branch, 4330 Rockledge Drive, MSC, 7932, Bethesda, MD 20892-7932, at the OIRA (0425-0043). Do not return the completed form to this address.

Form Approved OMB No. 0925-0013 Expires 03/31/2016

Investigational Agent Accountability Record
Oral agents ONLY

National Institutes of Health
National Cancer Institute
Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

PAGE NO. 1
CONTROL RECORD
SATELLITE RECORD

Name of Institution: Pharma Training Center Investigator Name: Dr. Applesmith CTEP Investigator ID: 33333

Protocol Title: Phase VII IDS NCI Protocol No: IDS1111 Local Protocol No: N/A Dispensing Area: IDS pharmacy

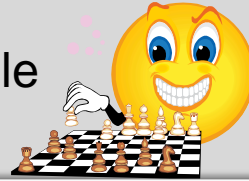
Agent Name: Soreafenib (BAY 43-9006); NSC 724772 Dose Form and Strength: 200 mg Tablet Bottle size (e.g., #tablets/bottle): 140 tablets/bottle


Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials



Record that identifier on the DARF in the Manufacturer and Lot Number Column. It's important to record the correct identifier on the DARF because stock recovery letters and recall letters are tracked using this identifier.

Single Agent Strength with Multiple Identifiers



Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PMBAfterhours@mail.nih.gov		SHIPMENT RECORD OF CLINICAL DRUG REQUEST  Date Authorized: 08/07/2014 Date Needed: 08/27/2014		Courier: Federal Express Account # XXXXX Acct Ref # XXXXX Order # 2014219-0013 Order Ref # O-1039140	
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS- 1111	724772	Sorafenib (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	2	BAY CT1931/32
IDS- 1111	724772	Sorafenib (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	1	BAY CT1931/31

Sometimes, there are multiple identifiers on the same shipping record for the same agent strength. In this example, you received 2 bottles of identifier CT1931/32 and 1 bottle of identifier CT1931/31. Thus, carefully verify the shipping record against what you received.

Expiration Date on Agent Label

Print Form Save As Reset Form

Collection of this information is authorized under 21 CFR 312.57. This information is collected to ensure compliance with Food and Drug Administration (FDA) requirements for NCI as an IND sponsor and that investigational agents are under the control and accounted for by competent authority. The information may be disclosed to researchers for investigative purposes, sponsors of clinical trials and their company collaborators, the applicable Institutional Review Board, NCI, FDA and Department of Health and Human Services. Submission of this information is voluntary, however, in order for you to conduct a study in accordance with research, patient protocols, you must complete all fields.

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Paperwork Project Director, Paperwork Project, Washington, DC 20503-2048, ATTN: 0120-0045-0011. Do not send the completed form to this address.

Form Approved OMB No. 0725-0113 Expires 03/31/2016

Investigational Agent Accountability Record
Oral agents ONLY

National Institutes of Health
National Cancer Institute
Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

PAGE NO. 1
CONTROL RECORD
SATELLITE RECORD

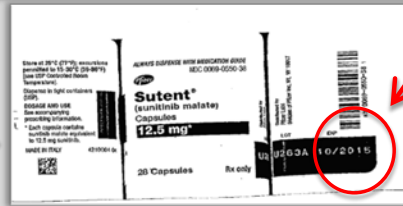
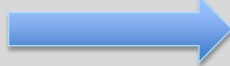
Name of Institution: Pharma Training Center Investigator Name: Dr. Applesmith CTEP Investigator ID: 33333

Protocol Title: Phase 2 of sunitinib IDS NCI Protocol No: IDS0001 Local Protocol No: N/A Dispensing Area: IDS pharmacy

Agent Name: Sunitinib (Sutent); NSC 736511 Dose Form and Strength: 12.5 mg/capsule Bottle size (e.g., # tablets/bottle): 28 Capsules/bottle


Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward		Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1	8/15/14	Received from FMB/NCI			+4 bottles	4 bottles		PFZ/U263A	PS	10/2015			

Agent Label




Also upon receipt, you may discover that the agent is labeled with an expiration date. Record that expiration date on the Oral DARF in the Expiration Date Column. If the expiration date is not available, leave the Expiration Date Column blank.

“DG”= Dangerous Goods

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PMBafterhours@mail.nih.gov		SHIPMENT RECORD OF CLINICAL DRUG REQUEST  Date Authorized: 07/28/2014 Date Needed: 07/30/2014		Courier: Federal Express Account # XXXXXX Acct Ref # XXXXXX Order # 2014209-0037 Order Ref # O-1038533	
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1212	683864	Temsirolimus (CCI-779)	25 mg For Injection 1.2 mL Vial dual pack	4	WYP AIBV/1G
DG Affix Excepted Quantity Label for each shipment					


The middle section of the shipping record may contain special notes such as DG. A DG means Dangerous Goods. Certain agents will be labeled as DG because they require special handling and packaging for the transport. Expired or recalled DG agents need approval from the PMB for local destruction when the agent cannot be returned to the NCI Clinical Repository for proper disposal.

Manufacture Date and Shipped Quantity

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PMBafterhours@mail.nih.gov			SHIPMENT RECORD OF CLINICAL DRUG REQUEST  Date Authorized: 08/12/2014 Date Needed: 08/19/2014		Courier: Account # Acct Ref # Order # 2014224-0049 Order Ref # O-1039416	
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #	
IDS-9999	761968	XL184 (Cabozantinib)	60 mg Tablets 30 Tablets/Bottle	1	PATHI P001287	
The eight week supply for this protocol is 2 bottles per patient.						
IDS-9999	761968	XL184 (Cabozantinib)	60 mg Tablets 30 Tablets/Bottle	1	PATHI P000787	

Other special notes that will be populated in the middle section could be a manufacture date when the agent label does not have it or a change in ordering quantity from what was originally requested, usually an eight week supply.

Patient-Specific Shipping Record

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PMBafterhours@mail.nih.gov		SHIPMENT RECORD OF CLINICAL DRUG REQUEST  Date Authorized: 08/12/2013 Date Needed: 08/26/2013		Courier: Account # Acct Ref # Order # 2014224- 0008-BLI Order Ref # O-1039409	
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
E1111	724772	Sorafenib 200 mg or Placebo	bottle 140 Tablets	4	?
PATIENT ID: 1212121 PATIENT INITIAL: A, XX <div style="display: flex; justify-content: center; gap: 100px; margin-top: 10px;"> ↑ ↑ </div>					
33333 (0) Sissy Applesmith, M.D. C/O Wonder RPh, R.Ph. Pharmacy Training Center Pharmacy Mail Code 000 11DS Blvd NE Grand Hall, DE 49500 Phone: (303) 111-2222			Storage Information Upon Arrival <input type="checkbox"/> Store at Room Temperature <input type="checkbox"/> On Blue Ice-Store Refrigerated <input type="checkbox"/> On Dry Ice-Store at -20°C <input type="checkbox"/> On Dry Ice-Store at -70°C <input type="checkbox"/> Store as Specified on Product Label		
RETAIN WITH YOUR ACCOUNTABILITY RECORDS					

Now, let's look at an example of a Patient Specific shipping record.
 As discussed previously, the Manufacturer and the identifier of the agent are not available, but the patient ID and the patient initials are provided.

Patient-Specific Oral DARF



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Form Approved
OMB No. 0925-0613
Expires: 03/31/2016

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Investigational Agent Accountability Record Oral agents <u>ONLY</u>				National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program				PAGE NO. 1 CONTROL RECORD <input checked="" type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>			
Name of Institution: Pharmacy Training Center				Investigator Name: Dr. Applesmith				CTEP Investigator ID: 33333			
Protocol Title: Randomized Placebo IDS				NCI Protocol No: E1111		Local Protocol No: N/A		Dispensing Area: IDS pharmacy			
Agent Name: Sorafenib or Placebo				Dose Form and Strength: 200 mg Tablet/placebo				Bottle size (e.g., # tablets/bottle): 140 tablets/bottle			

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1							?					
2												
.												

However, you need to record an identifier on the DARF upon receipt of the shipment. Since it is not available on the shipping record for Patient Specific Orders, how or where can you obtain an identifier?

Patient-Specific Agent Label



RETURN THIS PACKAGE AND ANY UNUSED MEDICATION		DETACH THIS LABEL AND RETAIN FOR RECORDS	
<small>AVOID TAKING LONGER THAN PRESCRIBED</small>	E1111 Bottle 1 of 1 140 tablets 14189-0008	<small>AVOID TAKING LONGER THAN PRESCRIBED</small>	E1111 Bottle 1 of 1 140 tablets 14189-0008
<small>ADMINISTRATIVE USE ONLY</small>	Patient ID: 1212121 A, XX	<small>ADMINISTRATIVE USE ONLY</small>	Patient ID: 1212121 A, XX
	SORAFENIB 200mg or PLACEBO		SORAFENIB 200mg or PLACEBO
	NAME: _____		NAME: _____
	Take _____ tablets by mouth daily.		Take _____ tablets by mouth daily.
	Store at controlled room temperature, not to exceed 25°C.		Store at controlled room temperature, not to exceed 25°C.
	In case of emergency, call 773-702-6800, option 1, pager ID 8625.		In case of emergency, call 773-702-6800, option 1, pager ID 8625.
	Distributed by: Pharmaceutical Management Branch, CTEP, DCTD, National Cancer Institute, Bethesda, MD 20892.		Distributed by: Pharmaceutical Management Branch, CTEP, DCTD, National Cancer Institute, Bethesda, MD 20892.

The identifier for the Patient Specific supplies can be found in the upper right hand corner of the agent label. The number contains 9 digits.

Agent Label Patient-Specific

DETACH THIS LABEL AND RETAIN FOR RECORDS

E1111 Bottle 1 of 1 140 tablets 14189-0008

Patient ID: 1212121 A, XX

SORAFENIB 200mg or PLACEBO

NAME: _____


Take _____ tablets by mouth daily.

Store at controlled room temperature, not to exceed 25°C.

In case of emergency, call 773-702-6800, option 1, pager ID 8625.

Distributed by: Pharmaceutical Management Branch, CTEP, DCTD;
National Cancer Institute; Bethesda, MD 20892.

Patient-Specific Shipping Record

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PMBAfterhours@mail.nih.gov		SHIPMENT RECORD OF CLINICAL DRUG REQUEST  Date Authorized: 08/12/2013 Date Needed: 08/26/2013		Courier: Account # Acct Ref # Order # 2014224-0008-BLI Order Ref # O-1039409	
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
E1111	724772	Sorafenib 200 mg or Placebo	bottle 140 Tablets	4	

The first 5 digits are the Julian Date followed by 4 digits, which are the last 4 digits of the order number on the shipping record.

Oral DARF for Patient-Specific

Print Form
Save As
Reset Form

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Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Norm Smallwood Clearance Branch, 8777 Rockledge Drive, MDC 7074, Bethesda, MD 20895-7074, 4776-064 (02/25/09). Do not return this completed form to this address.

Form Approved
 OMB No. 0925-0013
 Expires 03/31/2016

Investigational Agent Accountability Record Oral agents ONLY	National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program	PAGE NO. 1 CONTROL RECORD <input checked="" type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>
Name of Institution: Pharmacy Training Center	Investigator Name: Dr. Applesmith	CTEP Investigator ID: 33333
Protocol Title: Randomized Placebo IDS	NCI Protocol No: E1111	Local Protocol No: N/A
Agent Name: PL ID# 1212121 Sorafenib or Placebo (NSC 724772)	Dose Form and Strength: 200 mg/placebo tablet	Bottle size (e.g., # tablets/bottle): 140 tablets/bottle

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1	8/26/13	A, XX	recived from	PIMB/NCI	+4 bottles	4 btls	14189-0008	A-J				
2												



Now you can record that identifier on the DARF in the Manufacturer and Lot Number Column.

SHIPMENT RECORD OF CLINICAL DRUG REQUEST

Pharmaceutical Management Branch
 Cancer Therapy Evaluation Program, DCTD, NCI
 9609 Medical Center Drive
 Room 5N228, MSC 9723
 Bethesda, MD 20892-9725
 Phone (240) 276-6575 Fax (240) 276-7893
 Email: PM@fda.hhs.gov or mail: nci.gov

SHIPMENT RECORD OF CLINICAL DRUG REQUEST
 Date Authorized: 08/12/2014
 Date Needed: 08/26/2014

Course:
 Accession #
 Acct Ref #
 Order # 2014234-043
 Order Ref # Q-1029409

NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1111	724772	Sorafenib (BAY 43-9006; Nexavar) Nexavar	200 mg Tablets 140 Tablets/Bottle	4	BAY CT193132

33333 (0)
 Stacy Applesmith, M.D.
 C/O Wonder Rph, R.Ph.
 Pharmacy Training Center
 Pharmacy
 Mail Code 000
 11EGS Blvd NE
 Grand Hall, DE 49500
 Phone: (303) 111-2222

Storage Information Upon Arrival
 Store at Room Temperature
 On Blue Ice-Store Refrigerated
 On Dry Ice-Store at -20°C
 On Dry Ice-Store at -70°C
 Store as Specified on Product Label

RETAIN WITH YOUR ACCOUNTABILITY RECORDS

Print Form **Save As** **Reset Form**

Investigational Agent Accountability Record
 Oral agents ONLY

Name of Institution: Pharmacy Training Center
 Investigator Name: Dr. Applesmith
 CTEP Investigator ID: 33333

Protocol Title: Phase 1/2 IDS
 NCI Protocol No: IDS-1111
 Local Protocol No: N/A
 Dispensing Area: IDS pharmacy


Agent Name: Sorafenib (BAY-43-9006; Nexavar)
 Date Form and Strength: 200 mg Tablet
 Bottle size (e.g. # tablets/bottle): 140 Tablets

Line No.	Date	Prep'd Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward Balance	Manufacturer and Lot No.	Receiver's Initials	Expiration Date if Available	Date Patient Returned	Quantity Patient Returned	Receiver's Initials
1												
2												

Finally, ensure that you received the correct agent. Carefully cross verify the agent shipment contents against the shipping records and the information on the DARF. If there is a discrepancy, contact the PMB immediately at 240-276-6575.

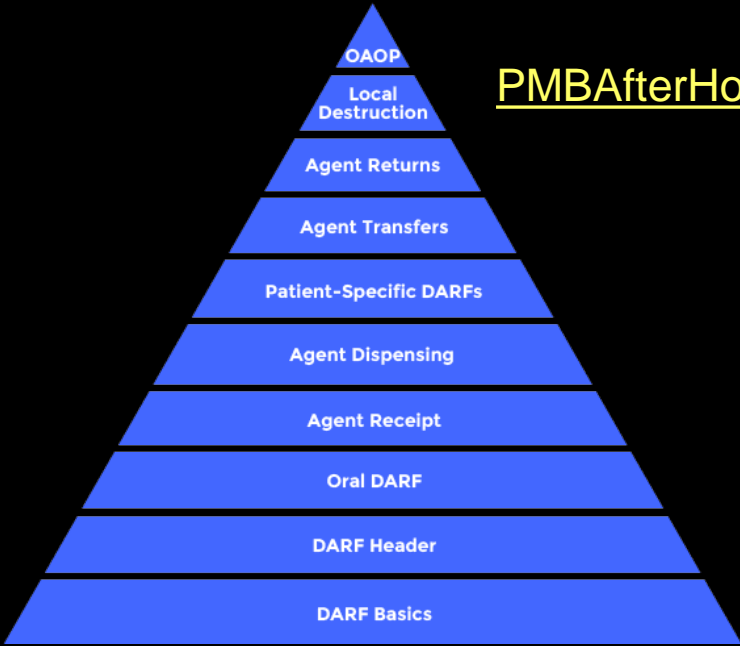
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Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PMBar@nih.gov		SHIPMENT RECORD OF CLINICAL DRUG REQUEST  Date Authorized: 08/12/2014 Date Needed: 08/26/2014		Courier: Account # Acct Ref # Order # 2014224.0043 Order Ref # O-1039409	
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1111	724772	Sorafenib (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	4	BAY CT1931/32
33333 (0) Sissy Applesmith, M.D. C/O Wonder RPh, R.Ph. Pharmacy Training Center Pharmacy Mail Code 000 11ES Blvd NE Grand Hall, DE 49500 Phone: (303) 111-2222			Storage Information Upon Arrival <input type="checkbox"/> Store at Room Temperature <input type="checkbox"/> On Blue Ice-Store Refrigerated <input type="checkbox"/> On Dry Ice-Store at -20°C <input type="checkbox"/> On Dry Ice-Store at -70°C <input type="checkbox"/> Store as Specified on Product Label		
RETAIN WITH YOUR ACCOUNTABILITY RECORDS					

As you put away your agents, make sure to retain a copy of the shipping record with your accountability records. Store the agents according to the Policy and Guidelines for Accountability and Storage of Investigational Agents.

Pharmaceutical Management Branch, CTEP, NCI



Email
PMBAfterHours@mail.nih.gov
Phone
(240) 276-6575

NCI YouTube
<https://www.youtube.com/user/NCIgov/>

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Please note that the video and any items displayed within the videos are subject to change. Check back periodically for updates.

Questions can be directed to the Pharmaceutical Management Branch, CTEP, NCI by phone Monday through Friday from 8:30am to 4:30pm Eastern Time or by email any time.

U.S. Department of Health and Human Services
National Institutes of Health | National Cancer Institute

<http://ctep.cancer.gov/>

1-800-4-CANCER

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