POLICY

This policy establishes processes for accessing medications not currently approved by the Food and Drug Administration (FDA).

A patient at Duke University Hospital (DUH) may not receive non-FDA approved medications while at DUH except:

1.) The patient is receiving a non-FDA approved drug via an investigational new drug (IND) application and has been enrolled in a clinical trial at DUH or has been admitted to DUH and is enrolled in a clinical trial from another institution under an effective IND.

2.) The patient is receiving a non-FDA approved drug via an Emergency Use IND or Single Patient IND (i.e. non-emergency or "expanded access").

3.) The patient has been receiving a non-FDA approved drug prior to admission to DUH under the FDA Policy on Personal Importation of Drugs, and the Chair of the Pharmacy and Therapeutics (P & T) Committee at DUH has approved use of the drug to be continued during the inpatient stay.

OR

4.) In unique circumstances, the attending-level physician wishing to initiate therapy with a non-FDA approved drug not meeting any of the above criteria (#1-3) provides appropriate data supporting its use, in addition to a protocol outlining criteria for use, to the P & T Chair (or designee) or Committee for review and approval prior to initiating the drug.

DEFINITIONS

Drug: According to the Federal Food, Drug, & Cosmetic Act, a drug is defined as “an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease…and an article (other than food) intended to affect the structure or any function of the body in man or other animals.”

Non-FDA Approved Drug: A non-FDA approved drug is a drug which has not had its safety and efficacy formally evaluated and approved by the FDA for any indication.

Life-Threatening: Describes a situation necessitating use of an Emergency Use IND, in which no standard acceptable treatment is available. For the purposes of this policy, “life-threatening” includes the scope of both “life-threatening” and “severely debilitating”, as defined below:

Life-Threatening: Describes diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes,
where the endpoint of clinical analyses is survival. The criteria for life-threatening do not require a condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review of an IRB protocol at a convened IRB meeting is feasible.

**Severely Debilitating:** Describes diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis, or stroke.

**Investigational New Drug (IND) application:** An effective IND allows the use of a drug which has not yet been approved for use in the United States, but is being used in conjunction with a research study or to care for a patient under authorization from the FDA (see Single Patient Use or Emergency Use INDs).

**Emergency Use IND**: Emergency use is defined as the use of an investigational drug or biological product for a human subject “in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain” Duke University Health System (DUHS) Institutional Review Board (IRB) approval. The emergency use provision of the FDA regulations (21 CFR 56.104(c)) is an exemption from prior review and approval by the IRB. The exemption may not be used unless all of the above mentioned conditions exist. In an emergency situation, the request to use the drug may be made via telephone or other rapid means of communication, and authorization to ship and use the drug may be given by the FDA official over the telephone. Shipment of and treatment with the drug may begin prior to the FDA’s receipt of the written IND submission that is to follow the initial request.

To ensure that the emergency use will occur in compliance with FDA regulations and guidance, the investigator must establish and document the following:

1.) The patient is in a life-threatening situation.

2.) No standard acceptable treatment is available.

3.) There is not sufficient time to obtain a review and approval of the proposed use through a convened IRB.

4.) The emergency use will be reported to the IRB within five working days.

5.) Any subsequent use of the investigational product at the organization will have a prospective IRB review and approval.
<table>
<thead>
<tr>
<th>Duke University Hospital</th>
<th>Approved by: Pharmacy Senior Management Group &amp; DUH P&amp;T Committee</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Pharmacy</td>
<td>Orignation Date: 2/2014</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Expiration Date: 5/2022</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Review Date:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Revision Date: 10/2017, 05/2019</td>
<td></td>
</tr>
<tr>
<td>POLICY and PROCEDURE</td>
<td>Archived Date:</td>
<td>Page 3 of 15</td>
</tr>
</tbody>
</table>

6.) The use does not involve a systematic investigation designed to develop or contribute to generalizable knowledge.

7.) Consent will be sought from each prospective participant or the participant’s legally authorized representative, in accordance with and to the extent required by 21 CFR 50 and will be appropriately documented, in accordance with and to the extent required by 21 CFR 50.27, or the situation meets the 21 CFR 50.23 exception to the requirement for consent.

The DUHS IRB will be informed of each Emergency Use IND and can advise physicians on the proper procedures to ensure human subject protections. See section V for the link to the DUHS IRB procedures.

**Single Patient IND (Expanded Access)**: A Single Patient (Expanded Access) IND is intended to provide access to experimental drugs for a seriously ill patient where no comparable or satisfactory alternative treatment is available. This is appropriate only after prior review and approval by the FDA and DUHS IRB. Prior approval and informed consent from the patient or the patient’s legally authorized representative is required.

**Intermediate-Size Patient Population Expanded Access Protocol (EAP)**: Access to an investigational drug (including biologic) for use by more than one patient, but generally fewer patients than are treated under a typical treatment IND or protocol. Submitted as a protocol to an existing IND by the Sponsor of the existing IND. The protocol must be received by the FDA and have IRB approval before treatment may begin.

A protocol may also be submitted to allow access to a treatment with an approved drug (or biologic) or a related product that is not available through marketing channels because of failure to meet the conditions of approval or a drug shortage, provided the drug and the patient meet the general criteria for expanded access as the criteria specific to use in an intermediate-size patient population.

**Dietary Supplement**: The Dietary Supplement Health and Education Act (DSHEA) defines dietary supplements as products intended to supplement the diet that contain vitamins, minerals, herbs or other botanicals, or amino acids. The FDA does not review evidence of efficacy or safety of dietary supplements. A product sold as a dietary supplement which is promoted as a treatment, prevention, or cure for a specific disease or condition would be considered an unapproved (illegal) drug.
**Herbal Supplement:** A type of dietary supplement that contains herbs, either singularly or in mixtures, and are used for therapeutic purposes. The United States FDA regulates herbals as foods. Therefore, the manufacturers of herbal supplements do not have to meet the same regulatory standards as drugs and over-the-counter medications for proof of safety, effectiveness, and Good Manufacturing Practices.

**USP Verified Product:** Process that ensures a manufacturer is producing products according to their specifications, as per USP manufacturing practices. The manufacturer may display the USP verified mark only on specific products that have met all of the requirements of the verification process. USP's Verification Program ensures that supplements contain the ingredients stated on the label, in the stated amounts, and that they meet acceptable limits for contaminants such as heavy metals, pesticides, dioxins, furans, PCBs, and microbes. The program ensures that the products are manufactured using safe, sanitary, and well-controlled procedures. Products certified by USP will be required to dissolve or disintegrate properly. USP manufactured drugs are legally compounded by pharmacies, but do not constitute “FDA approved drugs” as the compounded drug is not reviewed by the FDA.

**FDA Policy on Personal Importation of Drugs**: The United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. section 331) prohibits the interstate shipment (which includes importation) of non-FDA approved drugs. Thus, the importation of drugs that lack FDA approval, whether for personal use or otherwise, violate the Act. However, the FDA goes on to suggest in a policy that refraining from taking action against illegal importation, in the exercise of enforcement discretion, may be appropriate. The following are the conditions under which the FDA may consider not taking enforcement actions against such importation:

1.) The drug must be unapproved and intended for use in a serious medical condition for which there is no effective treatment domestically available.

2.) There must be no commercialization or promotion of the drug in the United States.

3.) The drug is not considered to represent an unreasonable health risk to the patient.

4.) The request must be accompanied by an affirmation that the drug is for the patient’s use only, and by the name and address of the United States-licensed physician responsible for the patient’s treatment.

5.) The request is generally for no more than a 3-month supply of the drug.

It should be noted that the policy is not a license for individuals to import non-FDA approved (and therefore illegal) drugs for personal use into the U.S., and even if all the factors noted in the policy are present, the drugs remain illegal and the FDA may decide that such drugs should be refused entry or seized. The policy is intended to help direct FDA enforcement discretion, and should not be considered binding requirements for the FDA or the public. Physicians wishing to treat patients with drugs that are...
not approved by the FDA are encouraged to complete and submit an IND application for emergency or expanded access.

RESPONSIBILITY
Medical and pharmacy staff

OTHER APPLICABLE POLICIES

1.) Duke University Health System Human Research Protection Program: Emergency Exemption for an Investigational Drug or Biologic or Unapproved Device

2.) Formulary System and the Formulary Policy

3.) Patient Taking Own Medication (PTOM) Policy

PROCEDURES
Requests to utilize an investigational medication via Expanded Access, require review and approval by the DUH Pharmacy and Therapeutics Committee (or designee). The Director, Center for Medication Policy (or designee) will communicate outcome of the review to the requestor(s).

Emergency Use IND Applications: Please refer to the Duke University Health System Human Research Protection Program: Emergency Use Policy for further information. The following is the FDA-outlined procedure for obtaining approval for an emergency use IND. For questions regarding documentation, drug shipment, or drug storage, contact Investigational Drug Services (IDS) via pager at 970-8392.

1.) The physician should contact the manufacturer of the non-FDA approved drug to obtain agreement to provide the drug and a letter of authorization for reference to the IND for emergency use. A template for a letter of authorization is on the FDA website.

2.) The physician should then call the FDA at (855) 543-3784 or (301) 796-3400 during business hours (8:00 AM – 4:30 PM ET Monday through Friday) or at (301) 796-9900 or (301) 796-2210 after-hours to request opening an emergency IND application and obtain FDA authorization for investigational treatment.

3.) The physician shall obtain informed consent from the patient or their legally authorized representative prior to administering the drug.

4.) By post-treatment Day 5, the physician must notify the DUHS IRB of the emergency IND treatment and supply any requested supporting documentation.
5.) By Day 15, the listed primary investigator must:
   a. Document and submit the full emergency IND application to the appropriate Review Division in the Center for Drug Evaluation and Research (CDER) at the FDA, including:
      i. Completed Form FDA 3926. For further information, see "Instructions for Filling out Form FDA 3926"
      ii. Letter of authorization from the IND product’s supplier for the right of reference to the information contained in the existing IND application
      iii. Clinical protocol for emergency treatment of a single patient including:
         1. Rationale for use (including a list of therapies tried prior to IND)
         2. Description of patient disease or condition (including recent medical history and treatments)
         3. Proposed method of administration of drug, dose, and duration of therapy
         4. Description of clinical procedures, laboratory tests, or monitoring necessary to evaluate the effects of the drug and minimize its risks
      iv. Copy of the informed consent
      v. Copy of the Investigator’s Brochure (optional)
   b. The submission must be identified as “Expanded Access Submission: Emergency Treatment for an Individual Patient”.

At the discretion of IDS, the investigational new drug to be utilized shall be shipped to the Pharmacy Procurement, Repackaging, and Distribution Group, or most appropriate pharmacy as deemed otherwise. The address/location of where the drug is to be shipped will be communicated to the primary investigator. The drug will be dispensed from pharmacy subsequent to a physician order via Maestro Care and administered to the patient. All documentation related to drug preparation and accountability should be saved for IDS to pick up and store as needed.

**Single Patient (Expanded Access) IND Applications**³,⁶: This procedure defines the process for obtaining an IND in non-emergency situations, where the non-FDA approved drug is intended for use in a single patient (assuming consent is obtained from the patient or the patient’s legally authorized representative, and DUHS IRB approval is obtained). For questions regarding documentation, drug shipment, or drug storage, contact IDS via pager at 970-8392.

1.) The physician should first ensure that the manufacturer of the non-FDA approved drug is willing to provide both the drug and a letter of authorization for reference to the Expanded Access IND.

2.) A written request for individual patient use of an investigational drug must be received and approved by the FDA before shipment of and treatment with the drug may begin.
3.) The IND application can be completed using Form FDA 3926. This form may be submitted via mail, fax, or email, and must be accompanied by the letter for authorization from the manufacturer of the non-FDA approved drug.

   a. FDA Mailing Address:
      Food and Drug Administration
      Center for Drug Evaluation and Research
      Central Document Room
      ATTN: [appropriate review division]
      "EXPANDED ACCESS SUBMISSION"
      5901-B Ammendale Rd.
      Beltsville, MD 20705-1266
   b. FDA Fax Number: (301) 431-6353 (prior to faxing documents, call or email the FDA)
   c. FDA Email Address: druginfo@fda.hhs.gov

4.) A number will be assigned to the application. The treating physician should provide the IND number to the drug supplier to facilitate shipment of the drug (once the IND is approved).

5.) The FDA will either allow treatment to proceed or put the application on clinical hold. The IND is considered active 30 days after the FDA receives the IND submission, or upon earlier notification of the physician by the FDA.

6.) If the treatment use is not allowed to proceed, the FDA will notify the physician of this decision initially via telephone call (the call will be followed by a written letter providing reasons for the FDA's denial of the request).

7.) Prior to administering the drug, the investigator must obtain DUHS IRB approval per 21 CFR Part 56, and informed consent from the patient or patient’s legally authorized representative per 21 CFR Part 50. The written consent form must be approved by the DUHS IRB.

If the Single Patient (Expanded Access) IND Application is approved by the FDA, the investigational new drug, at the discretion of IDS, shall be shipped to the Pharmacy Procurement, Repackaging, and Distribution Group, or most appropriate pharmacy as deemed otherwise. The address/location of where the drug is to be shipped will be communicated to the primary investigator. After DUHS IRB approval and informed consent, the drug will be dispensed from pharmacy subsequent to a physician order via Maestro Care and administered to the patient. All documentation related to drug preparation and accountability should be saved for IDS to pick up and store as needed.

**Utilization of Non-FDA Approved Products Available in the United States (i.e. Dietary or Herbal Supplements):** As with any medication, attending-level members of the medical faculty may request that entities such as dietary or herbal supplements be reviewed for addition to the formulary.
1.) To initiate a dietary or herbal supplement for a patient:
   a. Any authorized prescriber may prescribe a supplement listed on the DUHS formulary of accepted drugs.
   b. If the supplement is listed as formulary restricted, then the prescriber must follow all required steps listed for the product to prescribe it.
   c. If the supplement is considered non-formulary, then standard non-formulary processes must be followed (see Formulary System and the Formulary policy). If a provider wishes to request a dietary or herbal supplement for addition to formulary, it shall be reviewed in the same manner with which FDA approved medications are evaluated for formulary addition. For these supplements, a DUHS Formulary Request Form shall be filled out by the requesting physician.
   d. Concerns pertaining to safety and effectiveness should be discussed with patients prior to initiation of these products.

2.) For continuation of a dietary or herbal supplement that a patient is taking prior to admission, the pharmacy may procure the supplement or the patient will take his or her own supply. This will be assessed on a case-by-case basis.

3.) The Department of Pharmacy at DUH will procure USP verified supplements when feasible.

**Patient Utilizing Non-FDA Approved Medication(s) Not Available in the United States Prior to Admission (Personal Importation):** If the physician in charge of the patient’s care wishes to continue treatment with a non-FDA approved drug during the patient’s admission to DUH, access to the medication will be granted according to the following procedure:

1.) Data to support the use of the non-FDA approved drug is provided by the treating physician to the Center for Medication Policy and the Chair and Secretary of the DUH P & T Committee for review via the Request for Utilization of a Non-FDA Approved Drug form (see Appendix A).

2.) The medication will be inspected by a pharmacist to ensure, to the extent possible, its amount, identity, and integrity are acceptable. This may involve a pharmacist contacting the original distributing or dispensing pharmacy to ascertain the pedigree of the non-FDA approved drug.

3.) The Chair of the DUH P & T Committee will make the final decision on whether or not the non-FDA approved drug is appropriate to use, and will communicate the decision to the patient’s treating physician.

4.) If use of the medication is approved, the patient will be informed of the risks associated with using medications not supplied by the Department of Pharmacy, and will sign the informed
consent form associated with PTOM use of non-FDA approved drugs if he or she agrees to continue using the non-FDA approved drug while at DUH (see Appendix B).

5.) If these requirements have been satisfied, the patient will utilize the non-FDA approved drug in accordance with the PTOM policy. Upon discharge, the patient will take home any of the remaining non-FDA approved drug.

6.) After use of the non-FDA approved drug is approved, the DUH P & T Committee may request to review utilization data for the agent as necessary.

**Physician Wishes to Initiate a Non-FDA Approved Drug for a Patient (Inpatient or Outpatient):** If a physician wishes to initiate a non-FDA approved drug (including non-FDA approved drug via expanded access), the rationale for utilization must meet one of the first four criteria listed in Section II, or the procedure below must be followed.

1.) Data supporting the use of the non-FDA approved drug (Appendix A), in addition to a protocol outlining utilization criteria of the non-FDA approved drug (if applicable), will be provided by the attending-level physician to the Center for Medication Policy and the DUH P & T Chair (or designee). A method of documenting that the patient has been informed of and acknowledges that the drug has not been validated as safe and effective for any indication by the FDA should also be stated within the protocol.

2.) The Center for Medication Policy, in conjunction with the P & T Chair (or designee) and assigned P & T Committee or, will review the supportive data and protocol for use of the non-FDA approved drug.

3.) The Chair of the P & T Committee will make the final decision on whether or not to approve utilization of the non-FDA approved drug (in the inpatient or outpatient setting), as well as its associated protocol for use.

4.) If use of the non-FDA approved medication is approved by the P&T Committee and the treating physician wishes to initiate the non-FDA approved medication in the inpatient setting, it is preferred that the patient’s admission be scheduled in advance. The non-FDA approved drug would be shipped to the Investigational Drug Pharmacy, patient, or as deemed by the EAP. If the medication being supplied by the patient, pharmacy shall inspect the drug to ensure, to the extent possible, its amount, identity, and integrity are acceptable. The patient would then sign the informed consent form associated with PTOM use of non-FDA approved drugs (Appendix B), and use the agent in accordance with PTOM policy. The patient will take home any remaining non-FDA approved medication upon discharge.
5.) If a patient has already been admitted, and the physician wishes to start a non-FDA approved medication, the same request process to obtain approval will be followed. If utilization of the drug is deemed acceptable, the medication will be shipped to the Pharmacy Procurement, Repackaging, and Distribution Group or the Investigational Drug Pharmacy at DUH, where it will subsequently be dispensed for administration to the patient. When possible, the Pharmacy Procurement, Repackaging, and Distribution Group shall consistently utilize a single supplier of the medication for standardization and quality purposes. Upon discharge, the patient will take home any remaining non-FDA approved medication or the medication will be handled according to the EAP.

6.) If use of the drug is approved, it is the responsibility of the treating physician and/or patient to comply with the FDA Policy on Personal Importation of Drugs, and provide the necessary documentation to the importing entity for examination by U.S. Customs Inspectors when the non-FDA approved medication is imported (if applicable). This may include a letter explaining the intended use of the drug, including the name and address of the United States-licensed treating physician, and affirming the drug will be used only for the individual patient and not distributed to other individuals.

7.) After the non-FDA approved medication is approved for use, the DUH P & T Committee may request to review utilization data for the agent as necessary.

EXCEPTIONS
None

REFERENCES


4.) Expanded Access categories for Drugs (Including Biologics).
   https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm431774.htm Accessed February 22, 2019

5.) Personal Importation. Food and Drug Administration.

APPENDICES

Appendix A: Request for Utilization of a Non-FDA Approved Drug Form

Duke Medicine
Request for Utilization of a Non-FDA Approved Drug

Instructions:
The Duke University Hospital (DUH) Center for Medication Policy, P & T Committee Chair, and P & T Committee Secretary consider requests for non-FDA approved drugs to be used within DUH. For the purposes of this form, non-FDA approved drugs are agents which have not yet been approved/deemed to be safe and efficacious for any indication by the FDA. The data concerning efficacy, safety, tolerability, and cost of an agent will all be considered when determining whether or not it is appropriate to be used at DUH. The Chair of the DUH P & T Committee will make the final decision on whether or not use of the non-FDA approved drug is appropriate.

Please fill out this form completely. This form consists of two parts: Part A – Request for Drug Utilization and Part B – Conflict of Interest Disclosure. You must be an attending-level physician to request a non-FDA approved drug to be used in patients at Duke University Hospital. Additionally, the Physician Chair of the Pharmacy & Therapeutics Committee must countersign this form. Forms that are submitted without the appropriate signatures will be returned to the requester. Please send the completed form via one of the following mechanisms:

Duke Center for Medication Policy
Department of Pharmacy
Duke University Hospital
14221 Trent Drive / Box 3089
Telephone: 919-684-5125 Facsimile: 919-613-7830
Email: ann.scates@duke.edu

Part A – Request for Drug Utilization

Generic name: _____________________________________________________________
Trade name: _____________________________________________________________
Manufacturer: __________________________________________________________
Other nations (if any) where drug is approved: ________________________________
Indication(s) _____________________________________________________________
Dosage form(s) and strength(s) requested for use at DUH:________________________
Why is this medication superior to or significantly better than current formulary agents?

- Improved Safety Profile
- Improved Efficacy
- Less Prone to Med Errors
- More Convenient Dosing Regimen
- Additional Indications
- More Cost Effective
- Other (Please Explain):

Based on the above information, please provide the literature citations to support use in patients at DUH. If this is an EAP, please submit protocol, informed consents, pharmacy manual and/or investigator brochure.

What indication(s) do you intend to use this medication for?

Please provide any additional information you think pertinent to assist in evaluating this agent for utilization at DUH.

Were you involved in the clinical trials for the medications?  _____Yes  _____No

---

**Part B – Conflict of Interest Disclosure**

Note: This information is considered when evaluating your request. A potential conflict of interest does not preclude a person from requesting a non-FDA approved medication for utilization. Duke University Hospital appreciates that physicians with an area of expertise often receive research grants or other support from industry. Duke University Hospital considers it important to disclose these relationships to eliminate any concerns regarding potential conflicts of interest. Please provide the following information to the best of your knowledge:

Companies involved in the development, production and distribution of the requested medication:

Do you, or an immediate member of your family, have a proprietary interest in any of these companies listed?  _____Yes  _____No  If yes, which companies?

Please check all that apply:

- Own stock in one of the above companies (excluding mutual funds).
_____ Serve on the Board of Directors for one of these companies.

_____ Expect to receive (or currently receive) royalties from one of these companies.

_____ Other: _________________________________________________________

Have you received any financial support in the last 12 months from the companies listed?

_____ Yes  _____ No  If Yes, which companies?
_____________________________________________________________________________________

Please check all that apply:

_____ Received more than $5000 in research funding.

_____ Received support for presenting continuing education or professional education programs supported by the company (defined as more than 1 lecture for the same company in a 12-month period).

_____ Received an educational grant of more than $5000.

_____ Received more than $500 in travel support, personal gifts, compensation, or rewards in the past 12 months.

_____ Other: _____________________________________________________________

Requester’s name and specialty (Please Print): __________________________________________________________

Requester’s signature: _____________________________________________________________

Pager# _______

Pharmacy & Therapeutics Committee Physician Chair signature: ____________________________

Pager# _______

Date Form Completed: ___/___/_______

Center for Medication Policy Use Only

Date Request Received: ___/___/_______  Upcoming Letter Sent ___/___/_______  Outcome Letter Sent ___/___/_______
Appendix B: Patient Letter and Informed Consent for Patient Taking Own Medications (PTOM) Not Approved by the FDA

PATIENT USE OF MEDICINES WHICH ARE NOT APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA)

INFORMED CONSENT

My pharmacist has explained to me and I understand that the Duke University Hospital policy on the use of personal medicines is as follows:

POLICY FOR PATIENTS RECEIVING THEIR OWN SUPPLY OF MEDICINES NOT APPROVED BY THE FDA

In order to assure the potency and purity of the medicines administered to patients cared for by Duke University Hospital staff, all medicines will be furnished by the Department of Pharmacy except:

1. Those medicines brought in by the patient, which are part of an ongoing clinical investigation
   OR
2. Medications listed in Appendix A of the Patient Taking Own Medication (PTOM) Policy.
   OR
3. Medications which, by mutual consent of the attending physician and Chief Pharmacy Officer (or his designee), are medically necessary and not otherwise available at Duke University Hospital.

The medicine(s) listed below have NOT been deemed to be safe and effective in humans by the FDA at this time, and do not have an approved use in the United States for prevention or treatment of any disease.

The pharmacist has inspected and reviewed the medicines listed below to determine, as far as possible, that the medicine and dose are labeled correctly. A pharmacist will retrieve your medications and give you a receipt. Your medications may be relabeled or repackaged for use within our medication distribution system. Our nurses will administer the medications as prescribed by your physician. You will not be charged for the medication, but a fee will be charged for drug administration.

I, ___________________________ (Patient or Guardian), acknowledge that Duke University Hospital and its Staff assume no responsibility for the purity or content of the medicines, or for their previous storage. I assume all risks associated with the use of these medicines.

Name of Medicine(s):

Printed Name of the Patient: ____________________________________________________________

Patient or Guardian (signature): ___________________________ Date: _________________________

Witness (signature): ___________________________ Date: ___________________________

Reminder: Please ask your nurse for your remaining medicines upon discharge.