Validus PHARMACEUTICALS	**Patient Assistance Program 2023** ENROLLMENT APPLICATION	**ENROLLMENT APPLICATION** **ALL FIELDS REQUIRED** Mail completed application to: **Validus Pharmaceuticals LLC** **90 East Halsey Rd. Suite 210** **Parsippany, NJ 07054**

INSTRUCTIONS

AM I ELIGIBLE?

- Patient must meet specific program criteria. **Not everyone who applies will qualify for enrollment.**
- Patient must be a legal resident of the United States.
- Patient cannot be covered by or eligible for any government prescription programs, such as Medicaid, Medicare Part D, Veteran's Administration, or any State or local programs, either directly or indirectly (through other household members).
- Patient cannot have any insurance that will reimburse or otherwise pay for the medication.
- Patient's household income must not exceed 200% of the 2023 Federal Poverty Level (FPL) as shown in the chart below. Household income is defined as all sources listed in Section E, Eligibility, on page 1 of the Enrollment Application. **Proof of household income is required with patient's first application and annually thereafter.**

Family Size	200% of 2023 FPL
1	$29,160
2	$39,440
3	$49,720
4	$60,000
5	$70,280
6	$80,560
7	$90,840
8	$101,120

HOW DO I APPLY?

First Application in a Calendar Year

Patient Instructions:

- Complete and sign pages 1 and 2 of the attached Enrollment Application (Section 1: Patient Information). This must be done by the patient or the patient's personal representative.
- Attach a copy of the patient's most recent household Federal tax return and all supporting documentation listed in Section E, Eligibility, on page 1 of the Enrollment Application (W-2/1099, social security, disability statement, pension, unemployment, child support statement, etc.) **Updated proof of household income is required annually**.
- If the patient does not file taxes, the patient should submit form 4506-T ("Request for Transcript of Tax Return") **to the IRS** requesting Verification of Non-filing (item # 7). DO NOT SEND FORM 4506-T TO VALIDUS. The IRS will then send a letter back to the patient/taxpayer (usually within 10 days) verifying non-filing of taxes. Once the IRS reply letter is received, mail a copy to Validus as proof of non-tax filing.

Practitioner Instructions:

- Complete and manually sign the page 3 of the attached Enrollment Application (Section 2: Practitioner Information). This must be completed by an authorized practitioner.
- Attach an original prescription of the medication, written for a **three-month supply, NO REFILLS**.

Submission Instructions:

- Mail the completed, original Enrollment Application with all attachments and supporting documentation, including the original prescription, to Validus's address listed above.
- Both the patient and the practitioner will be advised in writing of denied applications or additional information requests.
- Incomplete applications will be returned to the practitioner.

Additional Applications in a Calendar Year

- Both patient and practitioner should follow the instructions above, ***except*** patient does not have to resend copies of patient's most recent household Federal tax return and supporting documentation (or proof of non-tax filing in lieu).

* Medications available through the Patient Assistance Program may change at any time *

* Eligibility criteria for the Patient Assistance Program may change at any time *

* The Patient Assistance Program may be terminated at any time *

Validus PHARMACEUTICALS	**Patient Assistance Program** ENROLLMENT APPLICATION	IF ALL INFORMATION IS NOT CLEAR AND COMPLETE, THIS FORM WILL BE RETURNED **Page 1 of 3**

SECTION 1: PATIENT INFORMATION

Patient Name: _____ SS#: _____
(Last) (First) (M.I.)

Date of Birth: _____

Street Address: _____

Marital Status: _____

City: _____ State: _____ Zip: _____

Phone: _____

ELIGIBILITY

A.	Is the patient a legal U.S. resident?	☐ Yes	☐ No
B.	Is the patient directly or indirectly (through other household members) covered or eligible for prescription coverage in any government program (i.e., Medicaid, Medicare Part D, VA or any other state or local program)?	☐ Yes	☐ No
C.	Is the patient enrolled in Medicare Part D?	☐ Yes	☐ No
D.	Is the patient directly or indirectly (through other household members) covered or eligible for prescription coverage with any private programs (i.e., private insurance HMO plan, PPO plan)?	☐ Yes	☐ No
E.	List all Sources of Income, **gross <u>MONTHLY</u> amounts**:		
	Salary/Wages $_____ Social Security $_____ Social Security Disability $_____ Pension/Retirement $_____ Child Support/Alimony $_____ Unemployment/Workers Comp $_____ Investment Income $_____ Other $_____		
	Attach documentation of all Sources of Income to this Enrollment Application.		
F.	Total **<u>ANNUAL</u>** household income, including social security and pension benefits: For eligibility, annual household income must not exceed **200% of Federal Poverty Level** -- see chart under Program Eligibility on the cover page of this Enrollment Application)	$_____	
G.	Number of persons residing in household (including patient)	_____	
H.	List all Prescription Drug Coverage (check box)		
	Private/Commercial Insurance ***(If yes, provide insurance information below)***	☐ Yes	☐ No
	Medicaid Drug Coverage	☐ Yes	☐ No
	Medicare Drug Coverage / Medicare Part D*	☐ Yes	☐ No
	State Drug Assistance	☐ Yes	☐ No
	* If you are eligible for Medicare Drug Coverage / Medicare Part D: Medicare Part D enrollees must have applied for and been denied the Low-Income Subsidy (LIS) from the Social Security Administration (SSA) before submitting this Enrollment Application. To apply for LIS, contact the SSA at (800) 772-1213 or go to www.socialsecurity.gov/prescriptionhelp.		
	Attach a photocopy of LIS denial letter to this Enrollment Application.		
I.	List all Private / Commercial insurance Information:		
	Primary Insurance Plan Name: _____ Group Number: _____		
	Policy Holder Name: _____ Policy ID: _____		
	What is the co-pay/reimbursement for the requested medication?	$_____	
	Has your insurer denied coverage for the requested medication?	☐ Yes	☐ No
	Secondary Insurance Plan Name: _____ Group Number: _____		
	Policy Holder Name: _____ Policy ID: _____		
	What is the co-pay/reimbursement for the requested medication?	$_____	
	Has your insurer denied coverage for the requested medication?	☐ Yes	☐ No

PATIENT DECLARATION

I authorize Validus Pharmaceuticals LLC ("Validus") to use this information to assess my eligibility for participation in the Patient Assistance Program ("Program"), including the audit of my medical records and/or by contacting my health care provider, my insurance company and/or me directly to confirm my eligibility or receipt of the requested medication ("Program Drug") or matters related to the Program. I understand that this assistance is temporary and that the Program may be discontinued or changed at any time. I understand that Validus will use my personal information in connection with the operation of the Program and issues related to the Program. I certify that I am a U.S. resident, do not have the ability to pay for Program Drug, earn less than 200% of the current Federal Poverty Level, and have no government or private insurance to pay for Program Drug. I certify that I do not have other sufficient financial resources or assets to pay for Program Drug or that paying for Program Drug from my own resources or assets would cause me severe financial hardship. I understand that I am expected to seek any available government assistance before applying or reapplying to the Program. I agree to notify Validus if my insurance coverage or financial situation changes. I agree not to submit an insurance claim or any other claim for payment to any third party payor (private or government) for Program Drug. I understand and agree that, if I am a Medicare Part D enrollee, I will not apply or claim any Program Drug towards True-Out of Pocket (TROOP) costs. If I am enrolled in a Medicare Part D Plan, the Program will not deny my re-application during a Medicare Part D plan year based on a change relating to availability of Medicare Part D coverage (except LIS eligibility). I agree not to resell, offer for sale, trade or barter any Program Drug and certify that it will be utilized solely for my personal use. I understand that Program Drug may not be returned for credit. I understand that I will be deemed ineligible to participate in the Program if I provide any incorrect or false information to Validus or violate any of the terms of the Program. I have read, understood and agree to all terms of this Patient Declaration. **I attest the foregoing is true and that the information provided in this Enrollment Application is accurate, correct and complete.**

PATIENT SIGNATURE (*must be original – no photocopies*): _____ **DATE:** _____

PATIENT ASSISTANCE PROGRAM AUTHORIZATION FORM

This Patient Assistance Program Authorization Form authorizes your health care provider to disclose your health and medical information to Validus Pharmaceuticals LLC and its employees, representatives, suppliers and agents (collectively, "Validus") in connection with your application to the Patient Assistance Program ("Program") as required by the Health Insurance Portability and Accountability Act of 1996, as amended, and related federal privacy rules and regulations ("HIPAA").

Authorization

I, _____, hereby authorize
(Patient's Last Name) (Patient's First Name) (Patient's M.I.)

_____ ("Health Care Provider")
(Name of Physician or Medical Group)

to disclose my individually identifiable health and medical information described below to Validus solely for the authorized purposes described below.

Description of Health and Medical Information That May Be Disclosed

My Health Care Provider may disclose individually identifiable health, medical and other information that supports my application to the Program, including my name, address, date of birth, social security number, financial information, medical records and the specialty of my Health Care Provider.

Authorized Purposes

The authorized purposes are: (1) to permit Validus to evaluate my eligibility for participation in the Program and (2) if Validus, in its sole discretion, approves my request to participate in the Program, for Validus' administration of my participation in the Program.

Expiration of Authorization

My authorization shall expire on the earliest of: (1) when Validus does not approve my application for participation in the Program or (2) at the conclusion of my participation in the Program or (3) as required by applicable State law.

Acknowledgements

(1) I understand that Validus is not an entity covered by HIPAA and that my health and medical information may be subject to disclosure by Validus and no longer protected by HIPAA. I further understand and agree that Validus may retain my health and medical information disclosed to Validus by my Health Care Provider after my authorization expires for purposes related to the administration of the Program.

(2) I understand that I may refuse to sign this Authorization Form and that, unless allowed by law, my refusal to sign will not affect my ability to obtain treatment from my Health Care Provider or my eligibility for benefits. However, I understand that I may not participate in the Program if I refuse to sign this Authorization Form.

(3) I understand that I may revoke my authorization at any time by providing a written notice of revocation to my Health Care Provider that refers to (or with a copy of) this Authorization Form, or as set forth in my Health Care Provider's Notice of Privacy Practices (if any). I understand that if I revoke this authorization, it will not affect prior disclosures made by my Health Care Provider to Validus in reliance on this authorization.

Patient signature:	Date:
Patient name:	
Patient's personal representative signature (if applicable):	Date:
Patient's personal representative name (if applicable):	Relationship of personal representative to patient:
☐ I acknowledge that I am the personal representative of the patient under applicable state law. CHECK BOX IF SIGNING AS PERSONAL REPRESENTATIVE	

All signatures must be original – no photocopies

Patient Name _____
(Last) (First) (M.I.)

SECTION 2: PRACTITIONER INFORMATION

Practitioner Name: _____
(Last) (First) (M.I.)

Street Address: _____

_____

City:_____ State:_____ Zip:_____

Phone:_____

Fax: _____

NPI #: _____

DEA #:_____
If no DEA# is available, attach a copy of State license.

PRACTITIONER DECLARATION

I certify that the use of the requested medication ("Program Drug") is medically necessary and I will be evaluating the treatment of the above-named patient ("Patient"). To the best of my knowledge, the Patient has no prescription insurance coverage for Program Drug, including Medicaid, Medicare Part D or other public programs, and the Patient has insufficient financial resources to pay for the prescribed therapy. I acknowledge that I may not, and agree not to, submit any insurance claim or other claim for payment to any third-party payor (private or government) for Program Drug or charge a fee for professional services or any other services rendered in association with the prescription of the Program Drug. My signature certifies that Program Drug received under this Patient Assistance Program ("Program") is for the use of the Patient only. The Program Drug will not be resold or offered for sale, trade or barter and will not and cannot be returned for credit.

I understand that Validus Pharmaceuticals LLC ("Validus") reserves the right to, at any time, modify the Program, including the financial and other eligibility criteria, or terminate it. I understand that Validus may refuse to distribute the Program Drug under the Program to any patient or practitioner. I understand that Validus reserves the right to recall the Program Drug if necessary.

I certify that I am in good standing in the State where I hold my medical license and that I have not been excluded from participating in any federally-funded health care program pursuant to 42 U.S.C. § 1320 or any equivalent State program.

I certify that the information contained in this Enrollment Application is complete and accurate to the best of my knowledge.

PRACTITIONER SIGNATURE: _____ **DATE:**_____
(*must be original – no stamps or photocopies)*

Please check all boxes:

- ☐ Health Care Provider has given patient and/or patient's personal representative a signed copy of this Enrollment Application
- ☐ **Health Care Provider has verified the authority of patient's personal representative (if any) to act on patient's behalf**
- ☐ Health Care Provider has attached an original prescription for Program Drug, written for a **three-month supply, NO REFILLS**

All information in this Enrollment Application will be kept confidential to the patient as required by law.