



1940 124TH AVE NE  
STE A105  
Bellevue, WA 98005

Phone: 877-630-9198  
Fax: 425-451-8964  
Web: www.HyGenPharma.com

## Vendor Application Wholesaler / Distributor – Checklist

Thank you for choosing to do business with HyGen Pharmaceuticals, Inc. Please take a few minutes to fill out and fax or scan and email over the following items.

<b>Description</b>	
<input type="checkbox"/>	<b>Completed &amp; Signed New Vendor Application Form – <u>Required</u></b> Completely filled out.
<input type="checkbox"/>	<b>Completed &amp; Signed Guaranty &amp; Indemnification Form – <u>Required</u></b>
<input type="checkbox"/>	<b>Completed &amp; Signed Pharmaceutical Pedigree Agreement – <u>Required</u></b>
<input type="checkbox"/>	<b>Copy of Resident State Wholesale License – <u>Required</u></b>
<input type="checkbox"/>	<b>Copy of Washington State Wholesale License – <u>Required</u></b>
<input type="checkbox"/>	<b>Copy of Federal DEA registration (if applicable)</b>
<input type="checkbox"/>	<b>Copy of Resident State Controlled Substance License (if applicable)</b>
<input type="checkbox"/>	<b>Copy of Most Recent Facility Inspection Reports (if applicable)</b>
<input type="checkbox"/>	<b>Copy of VAWD License (if applicable)</b>
<input type="checkbox"/>	<b>List of Other State(s) of Licensure including Registration/Permit Numbers</b>



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## New Vendor Application Form

### Company Information

Legal Company Name: \_\_\_\_\_

DBA: \_\_\_\_\_

Year established: \_\_\_\_\_ Ownership Type (Check One):

Corporation  Partnership  Sole Proprietorship  LLC  Other: \_\_\_\_\_

State of incorporation (if LLC or Corporation): \_\_\_\_\_

Shipping Address: \_\_\_\_\_ Billing Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Office Phone: \_\_\_\_\_ Toll Free: \_\_\_\_\_ Fax: \_\_\_\_\_

Remittance Address: \_\_\_\_\_

\_\_\_\_\_

Accounting Contact:

Name: \_\_\_\_\_ E-mail: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Sales Contact:

Name: \_\_\_\_\_ E-mail: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Company Contact & Title: \_\_\_\_\_ Email: \_\_\_\_\_

Warehouse Contact: \_\_\_\_\_ E-mail: \_\_\_\_\_

State Wholesale License #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Federal DEA Lic#: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

WA Out of State Wholesale License #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Federal Tax ID #: \_\_\_\_\_ Dunn & Bradstreet# \_\_\_\_\_

Please list all owners with 10% or more ownership

\_\_\_\_\_

\_\_\_\_\_

Terms: \_\_\_\_\_ Credit Limit: \_\_\_\_\_ HyGen Cust #: \_\_\_\_\_

**Licensing**

When was the last inspection by the State Board of Pharmacy?  
\_\_\_\_\_

Were any deficiencies noted? If so, have they been corrected? \_\_\_\_\_  
\_\_\_\_\_

When was the last inspection by the DEA (if applicable)?  
\_\_\_\_\_

Were any deficiencies noted? If so, have they been corrected? \_\_\_\_\_  
\_\_\_\_\_

Has the company ever had any disciplinary actions by a local, state, or federal authority with regards to pharmaceutical storage, handling, and distribution? YES  NO

If yes, please explain: \_\_\_\_\_  
\_\_\_\_\_

**Facility**

What is the size of the facility (in sq. feet): \_\_\_\_\_

Is the facility VAWD Certified? YES  NO  APPLIED  If yes, please include a copy of VAWD License.

Does the company have temperature and humidity monitoring equipment? YES  NO

Does the company record temperature and humidity readings? YES  NO

Does the company have adequate refrigeration equipment with temperature humidity monitoring in place for refrigerated pharmaceuticals? YES  NO

Does the company have a list of excluded vendors? YES  NO

Does the company have an Authorized Distributor list (AD list)? YES  NO

The undersigned certifies that all the information provided herein is true and correct. Further the company agrees to promptly notify HyGen Pharmaceuticals, Inc. if any of the information provided should change. The undersigned must be an officer/owner of the company.

Date: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_



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### **Guaranty & Indemnification Agreement**

It is both the desire and goal of HyGen Pharmaceuticals, Inc. (hereinafter "HyGen") to comply with all Federal State and local laws and to comply with applicable provisions of the Prescription Drug Marketing (hereinafter "PDMA") Act of 1987 including amendments of 1992 and all subsequent revisions, amendments, regulations and guidelines which have been promulgated by the Food and Drug Administration. Accordingly, HyGen requires that all vendors represent and warrant that the following statements are true and correct.

1. All products offered for sale to HyGen are owned free and clear of any encumbrances or restrictions on title at the time of said sale. In addition, all products offered for sale are not adulterated or misbranded within the meaning of the Food, Drug and Cosmetic Act and are not articles which may not be introduced into interstate commerce under the Act.
2. Any products offered for sale to HyGen have not been obtained through fraud, misrepresentation or concealment of any material facts.
3. That Vendor shall comply fully with all Federal, State and local laws applicable to the purchase, handling, sale or distribution of the products sold to HyGen.
4. That Vendor shall provide prompt notice to HyGen of any civil, criminal or administrative action by Federal, State or local authorities regarding the Vendor, its employees, or its officers with respect to alleged violations of Federal, State or local ordinances or regulations and to provide HyGen with full and complete information regarding the disposition of any such action.
5. That Vendor shall provide to HyGen a copy of the Vendor's Sales Tax Exemption Certificate, whether it be a resale certificate, blanket exemption or direct payment exemption, and to notify HyGen promptly of any changes which affects the Vendor's exemption status.
6. Vendor represents and warrants that it has authorized distribution status for product sold to HyGen or, for those products as to which it does not have authorized status shall establish such internal controls and maintain such records as will assure compliance with its obligations under this Agreement and permit it to maintain the appropriate paper trails and pedigrees which must be provided to HyGen with every sale of RX product to HyGen.
7. Any products offered for sale to HyGen have no restrictions on their sale to HyGen or their resale by HyGen.
8. Any products offered for sale to HyGen are not in violation of the PDMA of 1987, the PDMA Amendments of 1992, or any other Federal, State or local ordinance or regulation.
9. The Vendor, to the extent that the Vendor may lawfully do so, hereby consents to the exclusive jurisdiction of the Courts of the State of Washington and the United States District Court for the District of Washington, as well as to the jurisdiction of all Courts to which an appeal may be taken from such courts, for the purpose of any suit, action or other proceeding arising out of any of the creditor's obligations arising hereunder or with respect to the transactions contemplated hereby, and expressly waives any and an objections it or he may have as to venue, including, without limitation, the inconvenience of such forum, in any of such Courts.
10. Vendor shall provide to HyGen a list of all manufacturers with which Vendor has a direct status, as defined by PDMA.
11. Any products that are damaged in the course of shipment from Vendor to HyGen shall be the sole responsibility of Vendor.

THE UNDERSIGNED VENDOR HEREBY CERTIFIES THAT THEY HAVE READ, UNDERSTAND AND AGREE TO THE ABOVE AND THAT THE STATEMENTS CONTAINED HEREIN ARE TRUE AND CORRECT AND THAT THEY ARE AUTHORIZED TO EXECUTE THIS AGREEMENT.

BY:

Signature: \_\_\_\_\_ Company Name: \_\_\_\_\_

Print Name: \_\_\_\_\_ Vendor's Federal Tax ID#: \_\_\_\_\_

Title: \_\_\_\_\_ Date: \_\_\_\_\_



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### Pharmaceutical Pedigree Agreement

Due to the recent discoveries of counterfeit product, HyGen Pharmaceuticals, Inc. is committed to insuring that the products that we represent were obtained with the highest integrity.

Pursuant to section 503 (e) (1) of the Federal Food, Drug, and Cosmetic Act ("The Act") as amended, 21

U.S.C. & 353 (e) (1) \_\_\_\_\_ (vendor) hereby guarantees to HyGen Pharmaceuticals Inc.

(1) That no article sold to HyGen Pharmaceuticals, Inc.

(a) is adulterated or misbranded within the meaning of Act, 21 U.S.C. & 310 et seq., as amended;

(b) is an article which may not, under the provisions of section 404, 505, or 512 of the Act be introduced in interstate commerce;

(c) is an article which was re-imported in violation of section 801

(d) is a drug sample; or (e) is a drug that was previously sold to a hospital, health care entity or charitable organization, which may not, under the provision of section 503

(c) of the Act be sold, traded, purchased or otherwise exchanged; and

(2) That it is an "Authorized Distributor of Record (ADR)" for the following manufacturers (attach if necessary) subject to section 503 (b) of the Act:

Manufacturer:	Acct #	Manufacturer:	Acct#
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

In the event the Vendor ceases to be an ADR for the above referenced manufacturers, **OR** if Vendor becomes an ADR for additional manufacturers Vendor agrees to provide prompt notice to HyGen Pharmaceuticals, Inc. of such change.

**Statement Identifying Pharmaceutical Sales (Pedigree/Paper Trail)** (sample form included) must accompany all products sold to HyGen Pharmaceuticals, Inc. It may be shipped with product or faxed to us at 425-451-8964. This listing **MUST** trace the product back to a verified distributor with dates of purchase for each transaction and completed physical addresses for all suppliers listed.

**The pedigrees that HyGen Pharmaceuticals, Inc. receives from it's non manufacturing vendors will be randomly verified/validated to ensure the integrity of the product it receives. If the pedigree is unable to be verified, HyGen Pharmaceuticals, Inc. reserves the right to send product back to vendor.**

**Any product shipped to HyGen Pharmaceuticals, Inc. that does not include proper paperwork will be quarantined for 5 business days. Our receiving department will notify the vendor and request paperwork. If the proper invoice and pedigree are not received in by the 5th business day, the product will be sent back to vendor.**

**If any of the vendors continually fail to provide the complete and acceptable paper work for any product shipped to them, their status with will be put on hold until that vendors complies with all paperwork requirements.**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Company Name: \_\_\_\_\_

Name of company Owner/Officer: \_\_\_\_\_ Title: \_\_\_\_\_

Wholesaler: HyGen Pharmaceuticals, Inc.

### PRESCRIPTION (LEGEND) DRUG PEDIGREE

History of Drug Sales and Distributions

Legend Drug Name, Strength, Dosage Form, Container Size:

GLIPIZIDE ER 5MG, TB, 1000CT

This is a repackaged drug (requires repackager's pedigree information and authentication of repackager's pedigree)

NDC (optional): 00591-0844-10

Lot Number	Quantity	Unique Serial #
ABC1234	24	

Reference* Number:	111111
Document Type:	Invoice
Reference* Date:	2/10/2008
<i>(related to the sale by the wholesaler identified above)</i>	

**Manufacturer's Name:** Watson Laboratories, Inc. Phone: 800-272-5525

**Manufacturer's information for authentication:** 39 MT EBO ROAD SOUTH BREWSTER, NY 10509

#### OWNERSHIP HISTORY

1. Bought from Manufacturer of (from a Repackager which requires authentication form 2135 as well)

Name: XYZ Pharmaceutical Suppliers  
Address: 123, Pharmaceutical Way,  
Pharmatown, NA 00000  
Date Purchased & Ref \* #: 02/05/08 12345 PO  
Print Name of Recipient: name  
Signature of Recipient: \_\_\_\_\_  
Name of Authenticator: name  
Signature of Authenticator: \_\_\_\_\_  
To authenticate a subsequent transaction, contract:  
Name: XYZ Authenticator  
Telephone Number: 123-456-7890  
Email address: authenticator@XYZ.com

#### PHYSICAL DISTRIBUTION HISTORY

(if different from the order information)

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
Date Purchased & Ref \* #: \_\_\_\_\_  
Print Name of Recipient: \_\_\_\_\_  
Signature of Recipient: \_\_\_\_\_  
Name of Authenticator: \_\_\_\_\_  
Signature of Authenticator: \_\_\_\_\_  
To authenticate a subsequent transaction, contract:  
Name: \_\_\_\_\_  
Telephone Number: \_\_\_\_\_  
Email address: \_\_\_\_\_

2. #1 Above SOLD TO:

Name: HyGen Pharmaceuticals, Inc.  
Address: 1940 124th Ave NE; Suite A-105  
Bellevue, WA 98005  
Date Purchased & Ref \* #: 02/08/08 99999 INV  
Print Name of Recipient: John Doe  
Signature of Recipient: \_\_\_\_\_  
Name of Authenticator: \_\_\_\_\_  
Signature of Authenticator: \_\_\_\_\_  
To authenticate a subsequent transaction, contract:  
Name: Jane Doe  
Telephone Number: 425-451-9178  
Email address: janedoe@hygen.com

SHIPPED TO:

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
Date Purchased & Ref \* #: \_\_\_\_\_  
Print Name of Recipient: \_\_\_\_\_  
Signature of Recipient: \_\_\_\_\_  
Name of Authenticator: \_\_\_\_\_  
Signature of Authenticator: \_\_\_\_\_  
To authenticate a subsequent transaction, contract:  
Name: \_\_\_\_\_  
Telephone Number: \_\_\_\_\_  
Email address: \_\_\_\_\_

3. #2 Above SOLD TO:

Name: Retail Pharmacy  
Address: 1234, Pharma AVE,  
Drugtown, NO 00000  
Date Purchased & Ref \* #: 02/10/08 111111 INV  
Print Name of Recipient: \_\_\_\_\_  
Signature of Recipient: \_\_\_\_\_  
Name of Authenticator: \_\_\_\_\_  
Signature of Authenticator: \_\_\_\_\_  
To authenticate a subsequent transaction, contract:  
Name: \_\_\_\_\_  
Telephone Number: \_\_\_\_\_  
Email address: \_\_\_\_\_

SHIPPED TO:

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
Date Purchased & Ref \* #: \_\_\_\_\_  
Print Name of Recipient: \_\_\_\_\_  
Signature of Recipient: \_\_\_\_\_  
Name of Authenticator: \_\_\_\_\_  
Signature of Authenticator: \_\_\_\_\_  
To authenticate a subsequent transaction, contract:  
Name: \_\_\_\_\_  
Telephone Number: \_\_\_\_\_  
Email address: \_\_\_\_\_

I swear of affirm that the information contained on this pedigree is accurate and complete and that prior sales and distributions have been authenticated, if required.

Signature (authorized to bind the company) Nishit Mehta Print Name and Title Nishit Mehta, CEO Date 2/10/2008

\*Reference Number should be identified as an invoice, purchase order, shipping document number or similar unique identifier.

Prescription (Legend) Drug Pedigree DH 2129, 7/06 (obsoletes previous editions)