Thank you for choosing AXIA!

AXIA Pharmaceutical is an FDA-registered outsourcing facility that works closely with universities, physicians, clinics, and hospitals to create high-quality injectable medications for a variety of markets. With past clients, we have developed a contract manufacturing program that leverages agility with cost. Our state-of-the-art facility contains all the modern technology necessary to provide our clients with pure injectable pharmaceutical agents of the highest quality. Our devotion to providing the highest quality sterile injectable medications and analytical work available in the industry is supported by implementation of

- a cGMP/cGLP facility;
- FDA registration and a DEA license;
- fully validated sterilization procedures;
- a strong aseptic training program and validated media fill processes;
- superior gowning processes and environmental monitoring;
- cutting-edge ScanRDI and BacTAlert sterility testing;
- a state-of-the-art Cleanroom facility with cleaning and disinfection procedures and material segregation;
- routine equipment calibrations to assure proper performance;
- full documentation and recording of materials handling for accountability;
- class-leading Quality Assurance and Control systems to ensure that all our products are completely sterile and safe before distribution to the client.
- our *P*roactive *P*roduction *P*lanning *P*rogram (P^4) to support rapid turnaround times and avoid needing to make costly last-minute changes that lead to delays and expenses.

Thank you for taking the time to fill out the following information, which helps us to maintain compliance with the regulatory bodies to whose high standards we meet. We appreciate the opportunity to act as your Outsourcing Facility. We look forward to hearing from you and to counting you amongst our many satisfied clients!

Thank you,

Your AXIA Team

Rev: 07APR2018

Medical/Clinical Necessity Form

POLICY: It is the policy of FusionIV Pharmaceuticals dba AXIA Pharmaceutical to conduct its business in compliance with applicable federal, state and local laws and regulations, and to adhere to the highest ethical standards.

STANDARD: It is the standard of FusionIV Pharmaceuticals dba AXIA Pharmaceutical to provide only manufactured sterile injectable products which are not essentially copies of one or more approved drugs. However, there are cases in which drugs are determined to be medically/clinically necessary which may seem to be in conflict with this policy. "Medically/clinically necessary" is defined as:

- Consistent with generally-accepted standards in the field of treatment, or other discrete clinical discipline, providing a designated effect;
- Are reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
- Are appropriate to the condition or need set being treated;
- Require the specific level of care or expertise being proposed;
- Are individualized based on the assessed needs of the individual;
- Are provided in the most integrated setting for the given need(s) being addressed;
- Are not conducted for the convenience of the provider, the person receiving the service, family members, payers, or any other parties.

Manufactured sterile injectable products that are "medically/clinically necessary" may be required when:

- Best practice clinical intervention has not been effective;
- Differential diagnosis is indicated to develop a more effective treatment plan;
- The individual has a medical or neurological condition and has been referred by a physician for further assessment after being evaluated by the MD;
- An individual presents with concerns regarding specialized services.

Such products manufactured by FusionIV Pharmaceuticals dba AXIA Pharmaceutical cannot be billed to insurance using an NDC for a similar product produced by any other entity. FusionIV Pharmaceuticals dba AXIA Pharmaceutical will not be held liable for issues arising from how products are billed.

Reason for being medically/clinically necessary (please check all that apply):

☐ Change in administration
☐ Change in strength
☐ Addition/removal of excipient
☐ Is on FDA Drug Shortage list
☐ Is not otherwise available or cannot be easily obtained through other means
☐ other (specify):

_____

My signature on this document signifies that as of _____ (date), I, _____ _____, hereby certify that the products(s) requested is/are medically and/or clinically necessary despite being related to one or more approved drugs, and I do not hold FusionIV Pharmaceuticals dba AXIA Pharmaceutical responsible for any matters related to its/their billing.

AXIA PHARMACEUTICAL

Physician Account Agreement

1990 Westwood Blvd Suite 135 Los Angeles, CA 90025
Tel: 877. 685.8222 Fax: 866.732.4194

☐ **New Customer** ☐**Change of Ownership** ☐ **Changes to Existing Acct**

Business Contact Information

Title:		
Practice Name:		
Phone:	**Fax:**	**E-mail:**
Shipping Address:		
City:	**State:**	**Zip Code:**
Federal Tax Id or SS #:		

Please provide License, DEA, and NPI Numbers for All prescribing Physicians

Name	License	DEA	NPI

To avoid any delays in orders, please provide us with your business hours and any special shipping instructions.

Office Hours: _____

Special Shipping Instructions

Physician Account Agreement

By signing below you agree to pay any and all amounts charged by FusionIV Pharmaceutical d/b/a AXIA Pharmaceuticals to your credit card account specified below, and authorize FusionIV Pharmaceuticals d/b/a AXIA Pharmaceutical to obtain credit approval from said credit card company.

I hereby authorize FusionIV Pharmaceuticals d/b/a AXIA Pharmaceutical to charge my credit card account specified below. I affirm that I am at least 18 years old and that I am legally authorized to use the credit card account number specified below.

Furthermore I understand and agree that any charges made to the account specified below are nonrefundable, and I agree to pay FusionIV Pharmaceuticals d/b/a AXIA Pharmaceutical pursuant to my agreement with said credit card company, any such amounts charged by me both in the past and henceforth. Additionally I agree to hold FusionIV Pharmaceuticals d/b/a AXIA Pharmaceutical fully harmless from and against all claims whatsoever resulting from any charges made to said credit card billed to the credit card shown below.

Signature Date

Printed Name Title

Credit Card Information

Name:	Credit Card #
Exp Date: Security Code:	Billing Zip Code:
Billing Address:	

*Note: All new credit cards are charged $.01 for card verification. If the transaction is declined, you will be contacted to update the credit card information before your application is accepted.

Does your office sell controlled substances?

☐Yes ☐No

AXIA PHARMACEUTICAL

Controlled Substances Agreement

Company:		**DEA # / Exp:**	
Contact:		**Email:**	
Address:		**City, State, Zip:**	
Telephone:		**Fax:**	

Dear Valued Customer: In order to comply with 21 CFR1305.07 and prevent diversion of controlled substances, AXIA identifies and establishes the authorization status of each person seeking to order a controlled substance and only accepts such orders from persons legally authorized to place them.

Privacy Statement: All personal information obtained for this purpose is received in a restricted access area, handled only by authorized personnel and secured to maintain the privacy of your personal information. This information will not be disseminated by AXIA in any form, but must be disclosed to law enforcement personnel upon lawful request.

Authorized Purchasing Agent: (Print) _____

Title: _____ Authorized to Purchase (Specify Schedules): _____ ☐ N/A

Agent Signature: _____Date: _____

Check ONE:

☐ This practice does not use Controlled Substances but is aware of the policies herein.

☐ I am authorized by the above registrant to designate the Authorized Purchasing Agent named above. I hereby authorize the above person to purchase the specified schedules of controlled substances in behalf of the above registrant. This authorization shall include DEA List 1 Chemicals unless I have specified otherwise, above.

Schedule II Orders Only: The person designated above is the same person who signed the above registrant's most recent DEA registration, or holds currently-valid Power of Attorney from that person to execute Order Forms (Forms 222) for Schedule II on behalf of the above registrant, per 21CFR 1305.07.
Initial: _____ Date: _____

Purchasing Company Official:

Name:		**Title:**	
Signature:		**Date:**	

AXIA PHARMACEUTICAL

Controlled Substances Agreement

DEAR CUSTOMER: The DEA has increased its surveillance and scrutiny of manufacturers, wholesalers, and distributors of controlled substances as a matter of public safety to ensure that such items are not diverted or misused. Furthermore, recently enacted legislation places greater responsibility on pharmacies to prevent the illegal distribution and dispensing of controlled substances via online sites. One of the main factors contributing to the nationwide increase in diversion of pharmaceutical controlled substances has been the rise in the number of online sites that sell or facilitate the sale of these drugs for illicit purposes. AXIA requires its customers to complete this three-part form. It ensures customers' orders can be promptly filled. It also is part of AXIA's compliance program to assure that controlled substances will be used for legitimate medical purposes. We thank you for your participation in this joint effort to protect the public safety by preventing diversion of controlled substances.

PART ONE – BUSINESS INFORMATION

Company:		**DEA # / Exp.:**	
Contact:		**Email:**	
Address:		**City, State, Zip:**	
Telephone:		**Fax:**	

1.1 Please select all that apply to your practice:	☐ Independent ☐ Pain Management	☐ Clinic ☐ Veterinarian	☐ Hospital ☐ University

1.2 Approximately what percentage of your practice's business involves dispensing controlled substances?	
1.3 Does your practice ship controlled substances to other states?	YES ☐ NO ☐
1.4 If your response to question 1.3 above is "Yes," is your practice in compliance with the controlled substance laws of the other states to which you ship controlled substances?	YES ☐ NO ☐
1.5 Has any previous registration under the Controlled Substances Act (state or federal) held by any officer or owner ever been surrendered, revoked, suspended, denied or is pending such action? **If "yes," please attach a letter explaining the circumstances of such action.**	YES ☐ NO ☐
1.6 Have any of the officers, owners or pharmacists ever been convicted of a felony or misdemeanor under state or federal law relating to the manufacture, distribution, or dispensing of controlled substances? **If "yes," please attach a letter explaining the circumstances of such action.**	YES ☐ NO ☐

PART TWO – ONLINE PRACTICE INFORMATION

Notice of New DEA Regulations: As a valued AXIA customer, please be aware of newly enacted federal legislation that may affect your current DEA registration. The Ryan Haight Online Practice Consumer Protection Act (Ryan Haight Act), which became effective April 13, 2009, amended the Controlled Substances Act by adding new provisions to prevent the illegal distribution and dispensing of controlled substances via the Internet. The new law was symbolically named in memory of a teenager who died from a drug overdose after obtaining controlled substances online without a valid prescription.

Definition of an Online Practice: The Ryan Haight Act defines an online practice as a person, entity, or Internet site in the U.S. or abroad that knowingly or intentionally delivers, distributes, or dispenses a controlled substance via the Internet, and includes, among other things:

- Any Web site (sic) that sells, or offers to sell, any controlled substance or a prescription to a person in the United States.
- Any person who pays a practitioner to write prescriptions for controlled substances for customers of such a Web site (sic).
- Any person who pays a practice to fill prescriptions for controlled substances that were issued to customers of such a Web site (sic).
- Any practice that knowingly or intentionally fills prescriptions for controlled substances that were issued to customers of a Web site (sic).

What you must do: Most practices are not affected by the new registration requirements. However, every practice must determine whether the provisions of the Ryan Haight Act apply to its business and, if so, must obtain a modification of its DEA registration in order to continue delivering, dispensing, or distributing controlled substances via the Internet. A complete copy of the Ryan Haight Act is available online from the DEA Office of Diversion Control Website at:http://www.deadiversion.usdoj.gov/fed_regs/rules/2009/fr0406.pdf

2.1 Are you aware of the provisions of the Ryan Haight Act, and how they may apply to your practice?	YES ☐ NO ☐
2.2 Is your practice classified as an online practice as defined by the Ryan Haight Act?	YES ☐ NO ☐
2.3 If you responded "YES" to question 2.2 above, has your practice obtained a modified registration from DEA authorizing Online dispensing of controlled substances? **If "yes," please attach a letter explaining the circumstances of such action.**	YES ☐ NO ☐

COMPANY OFFICIAL (Owner, Officer, Pharmacist):

I make these representations for the purpose of obtaining controlled substances. I certify all the information I have provided is true, complete, and correct, and that the business named above operates in compliance with all applicable federal and state regulations. I further certify I am authorized to make these representations on behalf of the organization named above.

Name:		**Title:**	
Signature:		**Date:**	

PART THREE – PRODUCT USAGE INFORMATION:

[Please use a separate PART 3 for each controlled substance]

NOTE: Under 21 CFR 1301.74, AXIA is required to screen each controlled substance order for significant changes in quantities and ordering patterns. AXIA will use the requested information in Part Three to establish purchasing and use profiles for controlled substances. Information previously submitted to AXIA in response to Parts One and Two of the Controlled Substance Questionnaire remains valid for one year from the date of order acceptance. Customers need to complete and submit only Part Three of the Controlled Substance Order Questionnaire for additional orders of controlled substances placed during the one-year period of validity.

3.1 Product Description:

3.2 Catalog Number:

3.3 Size:

3.4 Quantity:

3.5 Dosage form:

3.6 What is the number of
a) prescriptions using this material per month?

b) grams of material used per month?

3.7 Does this order represent a significant increase from past purchases of this controlled substance from AXIA? YES ☐ NO ☐
If "yes," please attach a letter explaining the need for additional material:

3.8 Have you purchased this material from other suppliers? YES ☐ NO ☐

3.9 If you answered **YES** to **3.8** above, what was your **estimated** usage of this material from all suppliers in the past six months?

COMPANY OFFICIAL (Owner, Officer, Pharmacist):
I make these representations for the purpose of obtaining controlled substances. I certify all the information I have provided is true, complete, and correct, and that the business named above operates in compliance with all applicable federal and state regulations. I further certify I am authorized to make these representations on behalf of the organization named above.

Name:		**Title:**	
Signature:		**Date:**	

AXIA PHARMACEUTICAL

Shipping Policy

Thank you for choosing AXIA. Below are the terms and conditions that constitute our Shipping Policy.

Shipment Processing Time

Orders are generally processed within 1-2 business days.

Note: To ensure orders are processed the same day, the order must be received by 12 pm PST.

Shipping Rates & Delivery Estimates

To ensure the quality of our products is not compromised, all orders are shipped via overnight delivery.

Shipment Method	Estimated delivery time	Shipment cost
Standard Overnight (Non Refrigerated Items)	1-2 business days	$20.00
Standard Overnight (Refrigerated Items)	1-2 business days	$25.00

Missed Deliveries: Should your facility not be able to accept a scheduled delivery, the following charges will apply:

Refrigerated Items

Due to strict FDA regulations, all refrigerated items returned to our facility must be discarded and reprocessed. Customers will be billed **50%** of the order cost for replacement orders, along with standard shipping rates.

Non Refrigerated Items

All items returned to our facility due to non-delivery will be reshipped at the customer's expense.

Return Policy: No returns will be accepted for medication.

Name:		**Title:**	
Signature:		**Date:**	