IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	Chapter 11
AKORN, INC., et al.,	Case No. 20-11177 (KBO)
Debtors.	(Jointly Administered)
	Objections due by: August 14, 2020 Hearing Date: December 11, 2020 Time: 11:00 a.m. EST

DECLARATION OF ANTHONY DZIABO IN SUPPORT OF OBJECTION OF PRIMAPHARMA, INC. TO THE MOTION OF DEBTORS FOR THE ASSUMPTION AND ASSIGNMENT OF CERTAIN EXECUTORY CONTRACTS AND LEASES

I, Anthony Dziabo, declare as follows:

I make the following declaration of facts based upon my own knowledge and, if called upon, can testify competently thereto except where the same are stated upon my information and belief, as to which facts I believe them to be true.

1. I am the Vice President of Product Development, Quality & Regulatory Affairs of PrimaPharma, Inc., a California corporation ("PrimaPharma"). I make this declaration in support of PrimaPharma's objection to the Motion of Debtors for the Assumption and Assignment of the "PrimaPharma contract" between Akorn, Inc. ("Ak.om") and PrimaPharrn, Inc. ("PrimaPharm").

2. I am a custodian of records of PrimaPharrna. Attached to my declaration as exhibits is a true and correct copy of various documents that I either obtained from the

public record, documents that were sent to PrimaPharma or documents that were prepared in the regular course of business of PrimaPharma. The documents were made at or near the time of the act, condition, or event described in the documents. The documents were prepared from information transmitted by a person with knowledge of the act, condition or event described therein or were prepared by a person with knowledge of the act, condition or event described therein. At the time the documents were prepared it was a regular practice of the business to prepare documents in connection with the business activity.

3. On or about July 1, 2015, PrimaPharma acquired certain contract rights of PrimaPharma.

4. I am informed and believe that on May 20, 2020 (the "Petition Date"), Akorn, Inc. ("Akorn") and certain of its affiliates (together, the "Debtors") filed voluntary petitions for relief under chapter 11 of Title 11 of the United States Code.

5. Prior to the Petition Date, Akorn and PrimaPharm entered into that certain Asset Purchase Agreement dated as of June 16, 2011 (the "APA"). PrimaPharma subsequently acquired the contract rights and is now the owner of PrimaPharm's contract rights under the APA. A true and correct copy of the APA is attached hereto as Exhibit A and is incorporated herein by this reference.

6. Pursuant to the APA, PrimaPharm transferred to Akorn the Marketing Authorization which transferred to Akorn the right to make, use and sell Hydase (TM)

(Hyaluronidase Injection, USP) 150 unites/mL in the United States of America, including all of its territories and possessions, including Puerto Rico, for diagnostic, therapeutic and over the counter products for ophthalmic use. PrimaPharma retains all other rights.

7. Paragraph 6.3 of the APA provides:

> From and after the Effective Date, Akorn shall be responsible for and shall satisfy all obligations and liabilities arising from or relating to the Marketing Authorization, including, without limitation, all applicable regulatory obligations regarding the sale of the Product within the Field of Use and in the Territory under the Marketing Authorization.

8. On or about July 8, 2011, Mark T. Livingston, as President of PrimaPharm, Inc. sent a letter to Dr. Amy Rosenberg, Director of the Division of Therapeutic Proteins, Office of Biotechnology Products, U.S. Food and Drug Administration ("FDA"), wherein the FDA was notified of the transfer to Akorn of the Hydase Marketing Authorization the subject of the APA A true and correct copy of Mr. Livingston's the July 8, 2011 letter to the FDA is attached hereto as Exhibit A and is incorporated herein by this reference for all purposes.

9. On or about August 2, 2011, Sam Boddapati, Ph. D., Sr, Vice President, of Regulatory Affairs for Akorn, sent a letter, together with his executed FDA form 356h to the Director of the Division of Therapeutic Proteins, Office of Biotechnology Products, FDA, wherein Akorn notified the FDA of the transfer to Akorn of the Hydase Marketing Authorization the subject of the APA, effective as of July 8, 2011, and to transmit the executed FDA form 356h regarding same. A true and correct copy of Dr. Boddapati's August 2, 2011 letter to the FDA is attached hereto as Exhibit B and is incorporated herein by this reference for all purposes.

10. On or about August 9, 2011, I sent a letter to Alonza Cruse, Director, Los Angeles District Office of the FDA, wherein I notified the Los Angeles District Office of the FDA, on behalf of PrimaPharm, of the transfer to Akorn of the Hydase

Marketing Authorization the subject of the APA A true and correct copy of my August 9, 2011 letter to the Lo Angeles District Office of the FDA is attached hereto as Exhibit C and is incorporated herein by this reference for all purposes.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 11 day of ~~October~~ November, 2020 at San Diego, California.

11/11/20

Anthony Dziabo

EXHIBIT A

PrimaPharm, Inc.
9940 Mesa Rim Road
San Diego, CA 92121 USA

Tel: 858.964.0240 Fax 858.964.0250
E-mail: ppi@msn.com

July 8, 2011

Dr. Amy Rosenberg
Director
Division of Therapeutic Proteins
Office of Biotechnology Products
HFD 122
5901-B Ammendale Road
Beltsville, MD 20705

RE: NDA No. 21-716
Hydase™ (Hyaluronidase Injection, USP) 150 units/mL

TRANSFER OF RIGHTS

Dear Dr. Rosenberg:

In accordance with 21CFR 314.72, please be advised that effective July 8, 2011 the following rights to the above mentioned NDA 21-716 for Hydase™ (Hyaluronidase Injection, USP) 150 units/mL will be transferred from PrimaPharma, Inc. to Akorn, Inc., 1925 West Field Court, Suite 300, Lake Forest, IL 60045.

Transfer of the Marketing Authorization. PrimaPharm has transferred to Akorn the right to make, use, and sell **Hydase™ (Hyaluronidase Injection, USP) 150 units/mL** in the United States of America, including all of its territories and possessions, including Puerto Rico for diagnostic, therapeutic and over the counter products for ophthalmic use.

PrimaPharm, Inc. will provide a copy of the application, including all supplements and records to Akorn, Inc. that are required to be kept under 21 CFR 314.81. A letter of acceptance of ownership from Akorn, Inc. will be provided under separate cover by Akorn, Inc. PrimaPharm, Inc. is submitting this Transfer of Ownership correspondence in duplicate (Archival and Review).

All correspondence after June 16, 2011 should be forwarded to Akorn Inc. at:

Name:	Sam Boddapati, Ph.D.
Title:	Senior Vice President Regulatory Affairs
Address:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, IL 60045
Telephone:	847-353-4909
Fax:	847-279-6196

Should additional information be required, please contact me at the number below.

Sincerely,

Mark T. Livingston
President
858-259-0969, ext. 148

EXHIBIT B

1925 West Field Court ▼ Lake Forest, IL 60045
847-279-6100 ▼ Fax: 847-279-6196

August 2, 2011

The Director
Division of Therapeutic Proteins
Office of Biotechnology Products, HFD122
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Rd.
Beltsville, MD 20705

NDA TRANSFER OF OWNERSHIP

RE: NDA 021716
Hydase™ (Hyaluronidase Injection, USP) 150 units/mL
Transfer of NDA Ownership to Akorn, Inc.

Dear Sir:

PrimaPharm, Inc. transferred the ownership of the above listed NDA 021716 for Hydase™ (Hyaluronidase Injection, USP) 150 units/mL to Akorn, Inc. as per the letter addressed to FDA, dated July 8, 2011 (see enclosed). The date of this transfer will be effective as of July 8, 2011. Akorn, Inc. requests the Agency to direct all the correspondence regarding this NDA to the following address:

Sam Boddapati, Ph.D.
Sr. Vice President, Regulatory Affairs
Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, IL 60045

Phone: 847-353-4909
Fax: 847-279-6196
Email: sam.boddapati@akorn .com

Akorn, Inc. hereby, acknowledges that a complete copy of the NDA, including the amendments, supplements and annual reports of the NDA 021716 for Hydase™ (Hyaluronidase Injection, USP) 150 units/mL has been received from PrimaPharm, Inc. that are to be kept under CFR § 314.81.

Akorn
A SPECIALTY PHARMACEUTICAL COMPANY

1925 West Field Court ▼ Lake Forest, IL 60045
847-279-6100 ▼ Fax: 847-279-6196

Akorn commits to inform FDA of any change in the conditions in the approved application under CFR § 314.70, except for a change in the drug product's label or labeling to change the product's brand or name of its manufacturer, packer or distributor, which will be reported in the next annual report.

Should you require any additional information, please contact the undersigned at 847-353-4909.

Sincerely

S. Boddapati

Sam Boddapati, Ph.D.
Sr. Vice President, Regulatory Affairs
Phone: 847-353-4909
Fax 847-279-6196
Email: sam.boddapati@akorn.com

cc: PrimaPharm,Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0430
Expiration Date: April 30, 2009
See OMB Statement on page 2.

FOR FDA USE ONLY
APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Akorn, Inc.	08/02/2011
TELEPHONE NO. *(Include Area Code)* 847 - 353 - 4909	FACSIMILE (FAX) Number *(Include Area Code)* 847-279-6196
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):* 1925 West Field Court, Suite 300 Lake Forest, IL 60045	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE N/A

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* NDA 021716

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Hyaluronidase Injection USP	Hydase

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
Hyaluronoglucosominidase	N/A

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Injection	150 Units/mL	Injection

(PROPOSED) INDICATION(S) FOR USE:
To increase absorption and dispersion of other injected drugs

APPLICATION INFORMATION

APPLICATION TYPE *(check one)* ☑ NEW DRUG APPLICATION (NDA, 21 CFR 314.50) ☐ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☑ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug — Holder of Approved Application

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☑ OTHER Transfer of Ownership

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION Change in Ownership Application

PROPOSED MARKETING STATUS *(check one)* ☑ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 — THIS APPLICATION IS ☐ PAPER ☑ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

This application contains the following items: *(Check all that apply)*	
☐	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☐	4. Chemistry section
	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☐	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☑	20. OTHER *(Specify)* Transfer of Ownership

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
S. Boddapati	Sam Boddapati, Sr. Vice President, Regulatory Affairs	08/02/2011

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
1925 West Field Court, Suite 300, Lake Forest, IL 60045	847-353-4909

Public reporting burden for this collection of information is estimated to average 24 hours 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. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (HFD-143)
Central Document Room
5901-B Ammendale Road
Beltsville, MD 207052-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

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.

EXHIBIT C

PrimaPharm, Inc.
3443 Tripp Court, Suite A
San Diego, CA 92121 USA

Tel: 858.259.0969 / 259.0717 Fax: 858.259.8268
E-mail: pp2@msn.com

August 9, 2011

Alonza Cruse,
Director
Los Angeles District Office
US Food and Drug Administration
19701 Fairchild
Irvine, California 92612

RE: Sale of Hydase™ (Hyaluronidase Injection, USP) 150 U/ml NDA #21-716 from PrimaPharm, Inc. to Akorn, Inc.

Dear Director Cruse,

This letter is to inform the FDA Los Angeles District Office of the asset sale of the Hydase™ (Hyaluronidase Injection, USP) 150 U/ml NDA #21-716 to Akorn, Inc. of Lake Forest, IL., (Dr. Sam Boddapati 847 353 4909 sam.boddapati@akorn.com), effective as of July 8, 2011.

PrimaPharm, Inc. and Akorn, Inc. have notified the FDA Center for Drug Evaluation and Research of the ownership transfer of the Hydase™ (Hyaluronidase Injection, USP) 150 U/ml NDA #21-716 as per the attached copies of the letters to the Center and a copy of the Form FDA 356h.

The manufacture of the Hydase™ (Hyaluronidase Injection, USP) 150 U/ml drug product will take place at the Akorn, Inc. designated manufacturing facility after the appropriate site qualification and validation. PrimaPharm, Inc. will not be manufacturing the Hydase™ (Hyaluronidase Injection, USP) 150 U/ml drug product for Akorn or any other distribution at this time. PrimaPharm, Inc. will assist Akorn, Inc. in the manufacture of the Hyaluronidase API if requested in the short term.

If you have any questions or require further information concerning the transfer of the Hydase™ (Hyaluronidase Injection, USP) 150 U/ml NDA #21-716 to Akorn, Inc. please feel free to contact me at my office telephone number 858 259 0969 x147 or by e-mail at tony@primapharm.net.

Sincerely,

Anthony Dziabo
VP Product Development, Quality & Regulatory Affairs

Copies: Dr. S. Boddapati (Akorn, Inc.), M. Jafary (FDA), B. Bevill (FDA)

PrimaPharm, Inc.
9940 Mesa Rim Road
San Diego, CA 92121 USA

Tel: 858.964.0240 Fax 858.964.0250
E-mail: ppi@msn.com

July 8, 2011

Dr. Amy Rosenberg
Director
Division of Therapeutic Proteins
Office of Biotechnology Products
HFD 122
5901-B Ammendale Road
Beltsville, MD 20705

RE: NDA No. 21-716
Hydase™ (Hyaluronidase Injection, USP) 150 units/mL

TRANSFER OF RIGHTS

Dear Dr. Rosenberg:

In accordance with 21CFR 314.72, please be advised that effective July 8, 2011 the following rights to the above mentioned NDA 21-716 for Hydase™ (Hyaluronidase Injection, USP) 150 units/mL will be transferred from PrimaPharma, Inc. to Akorn, Inc., 1925 West Field Court, Suite 300, Lake Forest, IL 60045.

Transfer of the Marketing Authorization. PrimaPharm has transferred to Akorn the right to make, use, and sell **Hydase™ (Hyaluronidase Injection, USP) 150 units/mL** in the United States of America, including all of its territories and possessions, including Puerto Rico for diagnostic, therapeutic and over the counter products for ophthalmic use.

PrimaPharm, Inc. will provide a copy of the application, including all supplements and records to Akorn, Inc. that are required to be kept under 21 CFR 314.81. A letter of acceptance of ownership from Akorn, Inc. will be provided under separate cover by Akorn, Inc. PrimaPharm, Inc. is submitting this Transfer of Ownership correspondence in duplicate (Archival and Review).

All correspondence after June 16, 2011 should be forwarded to Akorn Inc. at:

Name:	Sam Boddapati, Ph.D.
Title:	Senior Vice President Regulatory Affairs
Address:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, IL 60045
Telephone:	847-353-4909
Fax:	847-279-6196

Should additional information be required, please contact me at the number below.

Sincerely,

Mark T. Livingston
President
858-259-0969, ext. 148

1925 West Field Court ▼ Lake Forest, IL 60045
847-279-6100 ▼ Fax: 847-279-6196

August 2, 2011

The Director
Division of Therapeutic Proteins
Office of Biotechnology Products, HFD122
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Rd.
Beltsville, MD 20705

NDA TRANSFER OF OWNERSHIP

RE: NDA 021716
Hydase™ (Hyaluronidase Injection, USP) 150 units/mL
Transfer of NDA Ownership to Akorn, Inc.

Dear Sir:

PrimaPharm, Inc. transferred the ownership of the above listed NDA 021716 for Hydase™ (Hyaluronidase Injection, USP) 150 units/mL to Akorn, Inc. as per the letter addressed to FDA, dated July 8, 2011 (see enclosed). The date of this transfer will be effective as of July 8, 2011. Akorn, Inc. requests the Agency to direct all the correspondence regarding this NDA to the following address:

Sam Boddapati, Ph.D.
Sr. Vice President, Regulatory Affairs
Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, IL 60045

Phone: 847-353-4909
Fax: 847-279-6196
Email: sam.boddapati@akorn .com

Akorn, Inc. hereby, acknowledges that a complete copy of the NDA, including the amendments, supplements and annual reports of the NDA 021716 for Hydase™ (Hyaluronidase Injection, USP) 150 units/mL has been received from PrimaPharm, Inc. that are to be kept under CFR § 314.81.

Akorn
A SPECIALTY PHARMACEUTICAL COMPANY

1925 West Field Court ▼ Lake Forest, IL 60045
847-279-6100 ▼ Fax: 847-279-6196

Akorn commits to inform FDA of any change in the conditions in the approved application under CFR § 314.70, except for a change in the drug product's label or labeling to change the product's brand or name of its manufacturer, packer or distributor, which will be reported in the next annual report.

Should you require any additional information, please contact the undersigned at 847-353-4909.

Sincerely

S. Boddapati

Sam Boddapati, Ph.D.
Sr. Vice President, Regulatory Affairs
Phone: 847-353-4909
Fax 847-279-6196
Email: sam.boddapati@akorn.com

cc: PrimaPharm,Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0430
Expiration Date: April 30, 2009
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Akorn, Inc.	08/02/2011
TELEPHONE NO. *(Include Area Code)* 847 - 353 - 4909	FACSIMILE (FAX) Number *(Include Area Code)* 847-279-6196
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*: 1925 West Field Court, Suite 300 Lake Forest, IL 60045	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE: N/A

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* NDA 021716

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Hyaluronidase Injection USP	Hydase

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
Hyaluronoglucosominidase	N/A

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Injection	150 Units/mL	Injection

(PROPOSED) INDICATION(S) FOR USE:
To increase absorption and dispersion of other injected drugs

APPLICATION INFORMATION

APPLICATION TYPE *(check one)* ☑ NEW DRUG APPLICATION (NDA, 21 CFR 314.50) ☐ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☑ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug — Holder of Approved Application

TYPE OF SUBMISSION *(check one)* ☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☑ OTHER Transfer of Ownership

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: _____

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION Change in Ownership Application

PROPOSED MARKETING STATUS *(check one)* ☑ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 — THIS APPLICATION IS ☐ PAPER ☑ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

This application contains the following items: *(Check all that apply)*	
☐	1. Index
☐	2. Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3. Summary (21 CFR 314.50 (c))
☐	4. Chemistry section
	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
	B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
	C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
☐	6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	7. Clinical Microbiology (e.g., 21 CFR 314.50(d)(4))
☐	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15. Establishment description (21 CFR Part 600, if applicable)
☐	16. Debarment certification (FD&C Act 306 (k)(1))
☐	17. Field copy certification (21 CFR 314.50 (l)(3))
☐	18. User Fee Cover Sheet (Form FDA 3397)
☐	19. Financial Information (21 CFR Part 54)
☑	20. OTHER *(Specify)* Transfer of Ownership

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
S. Boddapati	Sam Boddapati, Sr. Vice President, Regulatory Affairs	08/02/2011

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
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Food and Drug Administration
Center for Drug Evaluation and Research (HFD-143)
Central Document Room
5901-B Ammendale Road
Beltsville, MD 207052-1266

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Center for Biologics Evaluation and Research (HFM-99)
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Rockville, MD 20852-1448

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FORM FDA 356h (4/06)

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re	:	**Chapter 11**
	:	
AKORN, INC., *et al.*	:	**Case No. 20-11177 (KBO)**
	:	
Debtors.	:	**(Jointly Administered)**
		Hearing Date: December 11, 2020
		Time: 11:00 a.m. EST

CERTIFICATE OF SERVICE

I, BRUCE W. McCULLOUGH, hereby certifies that on this date a copy of the foregoing DECLARATION OF ANTHONY DZIABO IN SUPPORT OF OBJECTION OF PRIMAPHARMA, INC. TO THE MOTION OF DEBTORS FOR THE ASSUMPTION AND ASSIGNMENT OF CERTAIN EXECUTORY CONTRACTS AND LEASES was served via CM/ECF on the following:

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Dated: November 12, 2020

/s/ Bruce W. McCullough
Bruce W. McCullough, (Del ID #3112)