*Akebia Therapeutics, Inc. ("Akebia")**

Auryxia

Akebia DTP Sample Fulfillment Program

Business Rules

BRD #: AKEB-BR-0522

Version #: **1.0**

Created: 04/01/2020

Created by: Pamela Liddell

Program Manager

Client Business Rules – AKEB-BR-0522

Version 1.0

* On December 12, 2018, Keryx Biopharmaceuticals, Inc. ("Keryx") and Akebia Therapeutics, Inc. ("Akebia") completed a merger, whereby Keryx became Akebia's wholly owned subsidiary. The Labeler Name for Auryxia is under Keryx Biopharmaceuticals, Inc.

Table of Contents

1 Document Approval

I understand that from the information supplied in this Business Rule Document (BRD), J. Knipper and Company, Inc. ("Knipper") will establish and administer the "Akebia DTP Sample Fulfillment Program Name" program as specified by Akebia Therapeutics, Inc. ("AKEBIA" or "Client"). Client approval of this BRD may be in the form of a digital signature or email communication in lieu of the handwritten signature entered below. Evidence of signature approval must be attached to the end of this document.

Party representative's signature indicates approval of all information provided.

AKEBIA – APPROVAL SIGNATURES

DocuSigned by:
Jamie Manning
7D4C43269373409...

27-Oct-2020 | 4:11 PM EDT

Jamie Manning, Director, Commercial Operations — Date

Knipper – Approval Signatures

Pamela Liddell
Digitally signed by Pamela Liddell
DN: cn=Pamela Liddell, o, ou, email=pamela.liddell@knipper.com, c=US
Date: 2020.10.27 16:17:47 -04'00'

10/27/2020

Pamela Liddell, Program Manager, Professional Services — Date

Susan Lala
Digitally signed by Susan Lala
Date: 2020.10.28 10:14:51 -04'00'

Susan Lala, Associate Director, Professional Services — Date

Barbara Neumann
Digitally signed by Barbara Neumann
DN: cn=Barbara Neumann, o=J. Knipper and Company, ou, email=Barbara.neumann@knipper.com, c=US
Date: 2020.10.28 12:43:31 -04'00'

Barbara Neumann, Compliance Manager, Regulatory Affairs and Compliance — Date

2 Definitions

ACA	Affordable Care Act (ACA 6004)
AMA	American Medical Association
AOC	Acknowledgement of Contents
AOD	Acknowledgement of Delivery
BRD	Business Rule Document
BRE	Business Reply Envelope
COB	Close of Business 5:00 PM EST
DEA	Drug Enforcement Administration
DG	Digital Campaign for Sample Request Form
DIA	Data Interface Agreement
DM	Direct Mail Campaign for Sample Request Form
DO	Doctor of Osteopathy
Drug Sample	Unit of a prescription drug that is not intended to be sold but is intended to promote the sale of the drug.
DTP	Direct to Practitioner
eAOC	Electronic Acknowledgement of Contents
FDA	US Food and Drug Administration
HCP	Health Care Provider
IB	Inbound Call Campaign for Sample Request Form
INCA	Knipper Inventory Check and Adjustment Sheet
Licensed Practitioner	Any person licensed or authorized by State law to prescribe drugs. However, a licensed practitioner who is prohibited by State law from receiving samples of certain drugs is not permitted to do so under the PDMA, even though he/she is licensed or authorized to prescribe those drugs (e.g., some Nurse Practitioners or Physician Assistants).
MD	Medical Doctor
MSC	MySampleCloset.com
MSDS	Material Safety Data Sheet
NABP	National Association of Boards of Pharmacy
NDC	National Drug Code
NP	Nurse Practitioner
NTIS	National Technical Information Service
OB	Outbound Call Campaign for Sample Request Form
OIG	Office of Inspector General
PA	Physician Assistant
PDMA	Prescription Drug Marketing Act of 1987 and all amendments
QER	Knipper Quality Event Report
SFA	Sales Force Automation
sFTP	Secure File Transfer Protocol
SLA	Service Level Agreement
SLN	State License Number
SOP	Standard Operating Procedure

SRF	Sample Request Form
SVL	Signature Verification Letter
TDDD	Terminal Distributor Dangerous Drugs
VAWD	Verified-Accredited Wholesale Distributors
VPN	Virtual Private Network

3 References

1	Akebia Veeva Knipper Interface Agreement V4.0

4 Scope

The requirements in this document apply to the program development, guideline and maintenance for AKEBIA's direct to practitioner program. It also applies to the practices and services provided to AKEBIA by Knipper specific to the program. Sample requests are received electronically through the Veeva platform or via a paper Sample Request Form (SRF) outside of the Veeva platform.

Knipper Professional Services personnel who support the functions outlined in this document will be appropriately trained to ensure compliance with the business rules and/or laws applicable to the service offering.

5 Change Management Process

Any changes to the documented process described in work instructions or business rules will require a Change Request. The Change Request is documented and routed through Knipper's Change Management System. Once change requirements are gathered, the change is defined and quoted. Knipper will then provide the project cost associated with the particular change for AKEBIA's approval. Upon approval of the quoted change, a timeline for the changes will be supplied to AKEBIA. Knipper will complete the changes in the specified timeline unless otherwise noted to AKEBIA.

6 New Inventory Management

a) Vendors will need to follow Knipper's inbound shipping procedures by making a delivery appointment forty-eight (48) hours in advance before the material arrives. AKEBIA will be responsible for distributing the inbound shipping procedures document to their vendors, as it provides clear and concise standards for inbound shipments to Knipper.

b) If any vendor arrives prior to setting up a delivery appointment, Knipper Receiving will do their best to accommodate the shipment, but extended wait times may be encountered while waiting for an open dock.

c) For all new inventory, Knipper Professional Services will complete a New Item Notification (NIN) form. If available, AKEBIA will supply an image of the item in .JPEG format. Knipper Professional Services will manage the image process.

d) When a new item is received without a prior NIN form, the inventory will be held in the receiving area until the New Item number is set up.

7 Contact Information

7.1 Client of Record

Akebia Therapeutics, Inc. ("AKEBIA")
245 First Street
Cambridge, MA 02142

7.2 Distributor/Manufacturer of Record

Manufactured by: Keryx Biopharmaceuticals, Inc.
245 First Street
Cambridge, MA 02142

Distributed by: Keryx Biopharmaceuticals, Inc.

7.3 Client Contacts

Primary project points-of-contact:

Name	Title/Role	Phone	Email
Jamie Manning	Director, Commercial Operations	617.466.3475	Jmanning@akebia.com
Sean Brennan	Analyst, Commercial Operations	857-777-4525	Sbrennan@akebia.com
Doug Adourian	Senior Director, Commercial Operations and Analytics	617.466.3514	DAdourian@akebia.com
Kenneth Kobus	Senior Director, Supply Chain	617.466.3526	Kkobus@akebia.com
Molly Shea	VP, Regulatory Affairs	857.777.6584	mshea@akebia.com

7.4 Healthcare Marketing Support Contact Information

J. Knipper and Company, Inc. ("Knipper")

Corporate Headquarter
(Letter Fulfillments)
One Healthcare Way, Lakewood, NJ 08701
Knipper Phone #: 732-905-7878
Knipper Fax #: 732-905-0469
Website: www.knipper.com

Lyndhurst, NJ Facility
(Professional Services)
160 Chubb Ave, Ste. 305, Lyndhurst, NJ 07071

Knipper Fax #: 201-514-7286

Knipper Contact Center
1009 Lenox Drive, Lawrenceville, NJ08648
Knipper Phone #: 1-609-803-7096

Charlestown, IN Facility
(Drug Sample Fulfillments)
1250 Patrol Road, Charlestown, IN 47111
Knipper Phone #: 1-888-KNIPPER

7.5 Knipper Contacts

Primary project points-of-contact:

Name	Title/Role	Phone	Email
Tommy King	Vice President, National Accounts	732.595.9887	Thomas.King@knipper.com
Pamela Liddell	Program Manager, Professional Services	201.514.7066	Pamela.Liddell@knipper.com
Susan Lala	Associate Director, Professional Services	201.514.7017	Susan.Lala@knipper.com
Teresita Weiss	Senior Vice President, Regulatory Affairs & Compliance	732.987.7124	Teresita.Weiss@knipper.com

7.6 Knipper Hours of Operation*

8:30a.m. – 5:00p.m. EST, Monday – Friday
8:00a.m. – 4:30p.m. EST, Monday – Friday (Fulfillment Center)

*Excluding holidays

8 Reporting of Suspicious Criminal Activity for VAWD

As required under the National Association of Boards of Pharmacy's ("NABP") VAWD Accreditation Program, the following assurances related to reporting of suspicious criminal activities and suspicious orders are established:

a) AKEBIA assures that it will authenticate its drug products, and if applicable its contract manufacturers and distributors from which KNIPPER will be receiving AKEBIA's drug products. This verification includes annual confirmation of the appropriate pharmaceutical licenses directly with the licensing agency. If a license cannot be verified and criminal activity is suspected, notification by AKEBIA is made to the relevant licensing agency and the FDA within three (3) business days. Notification by AKEBIA will be made to the DEA if controlled substances are involved.

b) As required by the NABP, KNIPPER assures that the drug sample orders are verified prior to delivering said drug samples to prescribers. Validation involves prescriber license verification against the state agency license record and if requested by AKEBIA, whether prescriber requestor is eligible as per AKEBIA's program business rules. KNIPPER is to validate the drug sample orders prior to fulfillment.

c) As required by the NABP AKEBIA and KNIPPER assure that if a drug product cannot be authenticated by either party, AKEBIA will report the adulteration, misbranding, and suspected or known counterfeiting to the appropriate state regulatory agency and FDA within three (3) business days, provided that once KNIPPER becomes aware that a drug product cannot be authenticated, KNIPPER shall notify AKEBIA immediately and in any case no later than twenty-four (24) hours after such discovery. KNIPPER shall endeavor to complete a preliminary investigation within seven (7) days of such discovery. KNIPPER shall provide any investigational findings to AKEBIA in support of the report to the agencies when they make such notification to AKEBIA and throughout their investigation. Additionally the drug product will be quarantined and retained by KNIPPER on behalf of AKEBIA until disposition is authorized by the applicable board of pharmacy and/or FDA. The final investigation shall be completed as quickly as possible.

9 Program Components and Information

9.1 Type of Program

Req. #	Program Description
BR9.1-1	Knipper will fulfill AURYXIA® samples to valid HCPs for orders received electronically via VEEVA and via paper sample request forms (SRF). **See ATTACHMENT #1.**
BR9.1-2	AURYXIA® is indicated for the control of serum phosphorus levels in adults with chronic kidney disease on dialysis and for the treatment of iron deficiency anemia in adults with chronic kidney disease, not on dialysis.

9.2 Product List

Req. #	Product Name	NDC	Storage
BR9.2-1	Auryxia® (ferric citrate) Tablets 210 mg 25 tablets	59922-631-93	Ambient

9.3 New Product or Material

Req. #	Description
BR9.3-1	Prior to a new Item being sent to Knipper, product information including NDC, Description, Strength, MSDS should be passed to Knipper so the Item can be setup in Knipper's Warehouse Management System.
BR9.3-2	Akebia inventory team makes the determination, based on Knipper provided inventory reports, of when inventory replenishment is required.
BR9.3-3	Professional Services Team at Knipper will track inventory levels and will provide Akebia with updates on a weekly basis.

9.4 Program Dates

Req. #	Effective Date	MSA End Date	Launch Date
BR9.4-1	01/01/2020	12/31/2023	01/01/2020

9.5 Program Volume

Req. #	Description
BR9.5-1	Program volume is estimated to be 12,000-15,000 orders annually.

9.6 Program Audience

Req. #	Description
BR9.6-1	MDs and DOs who are eligible to receive prescription drug samples based on valid state license numbers as outlined in the PDMA.
BR9.6-2	NPs and PAs who are eligible to receive prescription drug samples based on valid state license numbers and the regulations for NPs and PAs in their state.

9.7 Program Telecommunications

Req. #	Description
BR9.7-1	Toll Free Fax Number: 1-844-822-8918
BR9.7-2	HCP Support Line: 1-888-537-9348
BR9.7-3	Akebia@Knipper.com

9.8 Knipper Internal Job Numbers

Req. #	Job Numbers
BR9.8-1	• On-going: 33877002 • AOC: 33877004 • SVL: 33877005 • Teleservices Support: 33877006 • SRF Fulfillment: 33877016

10 Order Processing

10.1 Order Limits

Req. #	Order Limits
BR10.1-1	For Electronic orders, all Allocation limits will be handled in Veeva; no checks by Knipper
BR10.1-2	For Sample Request Forms (SRFs), practitioners are allowed 5 orders per calendar month.
BR10.1-3	For SRFs, the sample offer consists of up to 48 Sample Units.

10.2 Electronic Files

Req. #	Description
BR10.2-1	Electronic order data pulled by Knipper via direct integration with VEEVA.
BR10.2-2	Knipper shall pull Sample Request Files –based on electronic signature capture.
BR10.2-3	Prescriber Sample Eligibility Validation shall be handled by Knipper on inbound requests. *See the Prescriber Validation Services section below for details
BR10.2-4	The parties will agree to a AKEBIA-specific DIA detailing the file layouts and timing.
BR10.2-5	If there are any issues loading data, all escalation procedures outlined in the DIA will be followed.
BR10.2-6	Knipper will scrub and load an outbound call target file provided quarterly by Akebia in a Knipper specified layout.

10.3 Prescriber Validation Services

Req. #	Service	Description
BR10.3-1	State License Number (SLN) Verification	Checks that the state license number and name matches to a practitioner (State Board and AMA).
BR10.3-2	SLN Expiration Check	Checks to ensure the state license number is not expired.
BR10.3-3	SLN Status (MD/DO)	Checks the status of the state license number to ensure the license is active and in good standing with the state board.
BR10.3-4	SLN Status (Mid-Level)	Checks the status of the state license number to ensure the license is active and in good standing with the state board and checks against mid-level sampling eligibility rules by state.
BR10.3-5	Specialty Exclusions (electronic)	Specialty restrictions will be handled by Veeva
BR10.3-6	Specialty Exclusions (SRF)	Knipper will accept the specialty provided by the HCP based on their SRF attestation.
BR10.3-7	OH State Restriction	**Sampling in Ohio** Due to regulations enacted by the Ohio Board of Pharmacy, HCPs are required to have an active Terminal Distributor of Dangerous Drugs ("TDDD") license in order to receive samples. Upon receipt of electronic and paper requests for samples from HCPs located in Ohio, Knipper will take the following steps: • The mitigation team will look up the HCP's address on the list received weekly from the Ohio Board of Pharmacy • Orders found to have a ship to address with a valid TDDD license will be released for shipping • For orders whose ship to address is not found on the aforementioned list; the mitigation team will make an outbound call to the HCP's office (3 attempts will be made) o If the HCP's office claims that they are exempt (i.e. a sole practitioner) Knipper will update their records accordingly and the order will be released for shipping. o If the HCP claims to have a current TDDD license, Knipper will request that a copy be faxed to Knipper; upon receipt the order will be released for shipping. Document will be appropriately retained by Knipper. o If the HCP's office does not have a valid TDDD license Knipper will provide information as to where to go to obtain a license and will reject the order.

10.4 Sample Request Forms

Req. #	Description
BR10.4-1	The SRF design will be provided by Knipper with input and approval from Akebia.
BR10.4-2	Paper forms will include the following: • HCP name (first, middle initial, last) • HCP address (Building Number, Street Name, City, State, Zip Code and if available, Suite Number) • HCP state license number • HCP professional designation • HCP specialty • Form ID (unique identifier for the form) • HCP signature and date (date of request) • Product name and description (including dosage form and dosage strength) • Product quantity requested (as defined by program requirements) • Distributor/manufacturer information • Campaign Code (IB, DM, DG, OB)
BR10.4-3	If the HCP inserts a quantity greater than the quantity offered on the SRF, Knipper will default to the pre-determined quantity.

10.5 Other Tactics -"This section does not apply to the client's current drug sampling program"

Req. #	Description
BR10.5-1	N/A

10.6 MySampleCloset -"This section does not apply to the client's current drug sampling program"

Req. #	Description
BR10.6-1	N/A

10.7 Inbound Sample Request Forms (SRFs)

Req. #	Description
BR10.7-1	SRFs will be sent to Knipper via Fax.
BR10.7-2	Knipper shall process all incoming SRFs.
BR10.7-3	Knipper shall capture the following information from the SRFs: • Scanned image • Form id • HCP name (first, middle initial, last) • HCP address (Building Number, Street Name, City, State, Zip Code and if available, Suite Number) • HCP state license number • HCP professional designation • HCP specialty • Phone • Fax • Email • Product name/description • Product quantity • Signature (Y/N) • Signature stamped (Y/N) • Signature mismatch (Y/N) • Signature date • Modifications to pre-printed fields • Practitioner comments written on form • Campaign Code (IB, DM, DG, OB)

10.8 Sampling Limitations – Electronic Orders

Req. #	Description
BR10.8-1	For Electronic orders, all rejection statuses will be reported via the daily Order Status data push into Veeva.
BR10.8-2	For any missing required information (name, and or address), the order shall be rejected.
BR10.8-3	For missing state license number, the order shall be rejected.
BR10.8-4	Any requests where P.O. Box is the only address, the order shall be rejected.
BR10.8-5	If the practitioner's state license number is invalid or inactive, the order shall be rejected.
BR10.8-6	If the practitioner's ship to name does not match the state license name, the order shall be rejected.

Req. #	Description
BR10.8-7	If the practitioner's ship to state does not match the state license state, the order shall be rejected.
BR10.8-8	If the practitioner's professional designation is not valid for the program, the order shall be rejected.
BR10.8-9	If the practitioner's professional designation and state combination are not valid to receive samples, the order shall be rejected.
BR10.8-10	If an order is received with an invalid quantity, the order shall be rejected.
BR10.8-11	If the practitioner did not sign the request, the order shall be rejected.
BR10.8-12	If the practitioner has an open acknowledgment of contents (AOCs) for 45 days from delivery date, the HCP will be placed on hold and will not be able to receive samples. An order will remain on hold for 30 days, if the outstanding AOC has not been returned the order will be rejected.
BR10.8-13	If the practitioner's sample request is for the state of Ohio a TDDD license is required. Refer to section 10.3-6.

10.9 Sampling Limitations – Sample Request Form Orders

BR10.9-1	For SRFs, orders are rejected, with no communication sent to the HCP, for the following reasons: • The form is a duplicate of a previously submitted SRF and cannot be processed. • The Last name is missing from the request form. • A valid street address is missing from the request form. • The city is missing as part of the address from the request form. • The state is missing as part of the address from the request form. • The ZIP Code is missing as part of the address from the request form. • The ZIP Code is invalid.
BR10.9-2	The HCP shall be sent an Exception Letter with a copy of the SRF to complete and return for processing/fulfillment for the following reasons: *See Attachment # 2 for Exception Letter • The first name is missing on the request. • The state license number (SLN) is missing on the request. • The signature is missing from the request. • The signature date listed on the request is in the future and cannot be processed. • No product and/or quantity was selected on the form.

BR10.9-3	Data Entry may mitigate forms where the HCP information on the SRF has been pre-printed by Knipper, however some information may be illegible due to fax print quality. Data Entry may perform a look up in Knipper system to confirm HCP information under these conditions: An Exception Letter will not be sent in these instances. • The first name is illegible on the request. • The professional designation is missing and/or illegible on the request. • The state license number (SLN) is illegible on the request.
BR10.9-4	The HCP shall be sent a *Denial Letter for the following reasons: *See Attachment 3 for Denial Letter • The professional designation on the request is not permitted to receive the sample(s) requested. • Sample(s) cannot be shipped to an address that only includes a PO Box. • Signature provided does not match the practitioner's name on the request. • Stamped signatures are not permissible. • A signed packing slip or Acknowledgment of Contents for a previous shipment exceeding 45 days from delivery has not been received. • The state license number listed on the request form cannot be located in our records. • According to our records, the first name listed on the request does not match the name associated with the state license number and the order cannot be processed. • According to our records, the last name listed on the request does not match the name associated with the state license number and the order cannot be processed. • According to our records, the state listed on the request does not match the state associated with the state license number and the order cannot be processed. • According to our records, the state license number listed on the request is inactive and the order cannot be processed. • Unauthorized form change.
BR10.9-5	If the practitioner's sample request is for the state of Ohio a TDDD license is required. Refer to section 10.3-6.

10.10 Order Validation Rules

Req. #	Description
BR10.10-1	See **Attachment #4 (Order Validation Rules Matrix)** for all exception and denial rules.

10.11 Sample Shipments

Req. #	Description
BR10.11-1	All sample shipments from the Manufacturer (see below) shall be sent to Knipper labeled "Sample Not for Sale", "Drug Sample" or "Professional Courtesy Unit Sample". • Manufactured by Keryx Biopharmaceuticals, Inc.
BR10.11-2	Product is not to ship 30 days prior to expiration date.
BR10.11-3	All electronic requests shall be processed and shipped within 1 business days from receipt of the valid request.
BR10.11-4	All paper requests shall be processed and shipped within 5 business days from receipt of the valid request.
BR10.11-5	Orders received and processed after 2:00 PM CST shall be considered received the next business day.
BR10.11-6	Electronic orders shall consist of at least 1 unit.
BR10.11-7	Paper orders shall consist of 10 units.
BR10.11-8	Orders shall ship to all states in the US except the state of Vermont.
BR10.11-9	Orders shall not ship to Puerto Rico.
BR10.11-10	Orders shall ship Monday thru Friday via UPS Ground, signature required, Knipper account #9F72W0.
BR10.11-11	All orders shall include an AOC packing slip. *See **Attachment #5 (AOC Packing Slip)** for packing slip template.
BR10.11-12	The AOC packing slip and/or the electronic AOC record must be signed and returned by the practitioner or the designee to confirm the contents of the delivery.
BR10.11-13	If there is not enough inventory in stock, the entire order shall be held until additional inventory has been supplied.

10.12 Allocation Portal – "This section does not apply to the client's current drug sampling program"

Req. #	Volume
BR10.12-1	N/A

10.13 Mitigation

Req. #	Volume
BR10.13-1	The following order statuses will be sent to the Knipper Mitigation team for review: • The Professional Designation is on a restricted list. • Ship to first name does not equal state license first name. • Ship to last name does not equal state license last name. • Ship to state does not equal state license state. • Ship to state license is inactive. • Ship to state license is not found. • Ship to state requires TDDD license (OH). Knipper will attempt to resolve these orders. If the issue cannot be mitigated, the order will be rejected and a letter will be sent to the HCP, as described above.

10.14 Contact Center

Req. #	Volume
BR10.14-1	**Inbound Support Phone Line:** Contact Center will receive Inbound Calls from practitioners and Reps for various reasons including to check on order status, to fax open AOC Letters, returns and to issue a call tag etc. Contact Center will utilize an Inbound Call Script that will include Frequently Asked Questions (FAQs). Where the FAQ is not covered, Contact Center will escalate their question to Professional Services.
BR10.14-2	**Inbound Sample Requests:** Knipper will receive Inbound Calls or emails requesting samples. Knipper will confirm if the practitioner is eligible, based on the following allowed specialties, endocrinologists, PCPs, hematologists, oncologists, including a nurse practitioner or physician assistant related to these specialties. If the requesting practitioner is a nephrologist, Knipper will take their name and contact information to be escalated to Akebia for direction. If the requesting practitioner has any other specialty they will be advised that samples are not available.
BR10.14-3	**Outbound Call Program:** Knipper will make monthly outbound calls offering Auryxia samples to Akebia targeted HCPs utilizing a Akebia approved call script. Up to 3 call attempts will be made per call cycle when target files are provided

11 Post Order Processing

11.1 AOD Processing

Req. #	Description
BR11.1-1	Knipper shall receive AOD information including delivery status, delivery date and signature information on a daily basis.
BR11.1-2	Knipper Professional Services shall review an Exception Report daily to determine any shipments that have not delivered within the carrier specified Service Level Agreement (SLA).
BR11.1-3	If the order is still tracking with the carrier, no further action will be required.
BR11.1-4	Knipper Professional Services shall contact the carrier to start an investigation when there is no additional information from the tracking history. *See the Lost in Transit section of this document for details.

11.2 AOC Processing

Req. #	Description
BR11.2-1	An AOC packing slip is sent with each shipment.
BR11.2-2	The packing slip should be signed by the practitioner or the office designee and faxed or mailed or emailed back to Knipper to close the AOC. *Reminder: The office designee name and title must be captured for Federal reporting.
BR11.2-3	If the AOC packing slip is not returned in 15 calendar days from the delivery date the first AOC follow up letter will be sent to the practitioner requesting a signature. *See **Attachment #6 (AOC Letter)** for the letter template.
BR11.2-4	A final letter will be sent at 30 calendar days from the delivery date, if the AOC is still pending. *See **Attachment #6 (AOC Letter)** for the letter template.
BR11.2-5	If an AOC packing slip or follow up letter is returned but is not signed, the AOC shall be processed as invalid, and a follow up AOC letter will be sent at the next scheduled time (15, 30 days).

Req. #	Description
BR11.2-6	If an AOC packing slip or follow up letter is returned but is a stamped signature, the AOC shall be processed as not complete and a follow up AOC letter will be sent at the next scheduled time (15, 30 days).
BR11.2-7	If the AOC packing slip or follow up letter is signed by someone else in the office ("office designee"), the AOC shall be honored as complete and closed.
BR11.2-8	If the practitioner has an open acknowledgment of contents (AOCs) for 45 days from delivery date, the HCP will be placed on hold and will not be able to receive samples.
BR11.2-9	If the practitioner has been placed on hold, once the practitioner signs the AOC and returns it to Knipper he/she will be eligible to receive samples.
BR11.2-10	AOCs will also be available to Reps via their Veeva system.. The eAOC will be available in Veeva one (1) day after delivery has been confirmed. Sample status will go on hold after an AOC is outstanding for 45 days.
BR11.2-11	If date is missing, date of fax transmittal will be used.

11.3 AOC Discrepancies

Req. #	Description
BR11.3-1	If an AOC is returned with a discrepancy, Knipper shall investigate, and if necessary issue a Quality Event Report (QER).
BR11.3-2	The AOC will be processed, and future requests will not be denied pending the investigation.
BR11.3-3	Once the investigation is complete, the AOC will be managed as appropriate based on the findings. As necessary (see below), Knipper shall issue an Inventory Check and Adjustment Sheet (INCA).
BR11.3-4	If the indicated quantity received is higher than what was shipped, Knipper shall issue an INCA to have the in-stock quantity counted and adjusted, if needed. *See **Attachment #7 (INCA Process**) for an outline of the INCA process
BR11.3-5	If the indicated quantity received is lower than requested, Knipper shall issue an INCA to have the in-stock quantity counted and adjusted, if needed. Investigation of the loss or potential diversion will be initiated by Knipper.
BR11.3-6	If the INCA is completed and the warehouse inventory is confirmed with an overage, Knipper shall process an additional request to fulfill the shorted quantity.
BR11.3-7	If the INCA is completed and the warehouse inventory is confirmed as accurate, Knipper shall notify Senior Manager, Trade & Managed Markets that a Lost-in-Transit is suspected. *The procedure in section, "Lost in Transit/Damaged Shipment" will be followed.
BR11.3-8	If the AOC indicates an incorrect product was shipped, Knipper shall issue an INCA on the incorrect product that the practitioner stated he/she received.

Req. #	Description
BR11.3-9	If an incorrect product is shipped, Knipper shall issue a call tag to the Carrier and an Quality Event Report (QER) will be opened by Knipper.
BR11.3-10	The Knipper Carrier shall pick up the product, which will be returned per the Knipper Return SOP.
BR11.3-11	The incorrect product shall be returned and placed in quarantine.
BR11.3-12	Knipper shall send out a replacement shipment with the correct product.

11.4 Negative AOC

Req. #	Description
BR11.4-1	A Negative AOC consists of the following: • Practitioner requested samples but did not receive the product; or • Practitioner did not request samples but received the product.
BR11.4-2	If a Negative AOC is discovered by Professional Services during their weekly Inbound AOC evaluation, the following actions will take place within 3 business days from the date of awareness: • Pull the SRF and Carrier tracking information. • Confirm with the Carrier whether the shipment was delivered (AOD), if practitioner states the product was not received. • At the request of Professional Services, Knipper Contact Center will contact the Carrier and the practitioner. [PS will contact if no Contact Center setup for program]. o Knipper will fax a copy of the SRF and the corresponding Carrier information to the practitioner to try and confirm delivery. o If confirmed, a new AOC will be faxed to the practitioner for signature. o If not confirmed, Knipper Professional Services will document findings in accordance with SOP RA-032 , AOD and AOC Monitoring and Investigation. All information such as proof of delivery, negative AOC, QIR, etc., if needed, will be emailed to AKEBIA 3 business days of the date of awareness. o See Lost in Transit section for additional details.

11.5 Signature Verification Process

Req. #	Description
BR11.5-1	A Signature Verification Letter (SVL) is sent as a random audit to confirm and verify that the practitioner's signature on the original sample request is authentic and belongs to the practitioner who requested the samples. *See **Attachment #8 (Signature Verification Letter, electronic)** for the letter template. *See **Attachment #9 (Signature Verification Letter, SRF)** for the letter template.
BR11.5-2	Knipper shall generate signature verification letters monthly.
BR11.5-3	Knipper shall pull 10% (with a minimum of 1 letters) of all requests that have resulted in a confirmed delivery (AOD has been received) within the previous month.
BR11.5-4	The Signature Verification Letter shall be sent to each selected practitioner with a copy of the original sample request. A practitioner will only receive one letter per year unless there is reason to believe that further investigation is necessary.
BR11.5-5	As deemed necessary by AKEBIA, as well as for FDA reporting for possible falsification of record, any SVL response indicating an invalid signature is deemed as a Negative SVL response and shall be forwarded to Director, Commercial Operations & the Sr. Director of Quality Operations for follow-up investigation immediately and in any case no later than twenty-four (24) hours after said SVL response. If upon receipt of the Negative SVL response, AKEBIA determines additional investigation steps are required and chooses to engage the support of Knipper to conduct the investigation on its behalf, Knipper shall endeavor to complete a preliminary investigation within seven (7) days of said first contact attempt. Knipper shall provide any investigational findings to AKEBIA in support of any report by AKEBIA to any relevant agencies when they make the foregoing notification to AKEBIA and throughout their investigation. The final investigation should be completed as quickly as possible. If AKEBIA elects to conduct the investigation itself, Knipper will cooperate in all respects with AKEBIA's investigation.

11.6 Lost-In-Transit

Req. #	Description
BR11.6-1	Lost in Transit is defined as: • A shipment reported as lost by the Carrier. • A Practitioner notifying Knipper or AKEBIA via a method other than an AOC that s/he did not receive the requested samples. • A Practitioner responding to an open AOC reminder letter that s/he did not receive the requested samples. • A shipment is identified as LIT as part of the daily AOD monitoring process.

Req. #	Description
BR11.6-2	If a shipment is deemed Lost-In-Transit by either the shipping Carrier or a confirmed non-delivery status, Knipper shall notify Director, Commercial Operations immediately and in any case within twenty-four (24) hours of becoming aware of the possible loss. • Within 3 days of date of awareness Knipper shall provide client in writing additional information in the form of an LIT Memo in accordance with the Knipper SOP RA-032, AOD and AOC Monitoring and Investigation • Knipper shall also issue a claim with the shipping Carrier.
BR11.6-3	As above, Knipper shall notify Director, Commercial Operations immediately upon becoming aware that a shipment is Lost-In-Transit, and in any case no later than twenty-four (24) hours thereafter, and that Knipper is proceeding with an investigation. Knipper will perform the following: o Send an e-mail notification to Director, Commercial Operations within 24 hours of date of awareness of the potential reportable incident. o On day 3 based on date of awareness and preliminary investigation, Knipper shall provide in writing via a LIT Memo to Akebia, a formal notification of the potential reportable incident. This will allow AKEBIA to meet the 5 day reporting requirement if AKEBIA determines the event to be reportable to the FDA/State agency. o Knipper shall endeavor to complete a preliminary investigation, follow-ups and updates within seven (7) days of the initial notification. An updated Memo will be provided to AKEBIA. The final investigation shall be completed as quickly as possible. o Knipper shall provide any investigational findings to AKEBIA in support of the report to the agencies when they make such notification to AKEBIA and throughout their investigation. AKEBIA will be responsible for any 5 day and 30 day final FDA/State reporting, unless Knipper Compliance is retained by AKEBIA to submit on behalf of AKEBIA, in which case Knipper Compliance will consult with AKEBIA regarding the response to any final FDA/State reporting and will allow AKEBIA at its discretion to control and/or participate in any further contacts or communications relating to such FDA/State reporting. Knipper Compliance will comply with all reasonable requests and comments by AKEBIA with respect to all contacts and communications relating to any FDA/State reporting. AKEBIA shall be responsible for all federal and state reporting.

11.7 Damaged Shipments

Req. #	Description
BR11.7-1	When Knipper becomes aware of a damaged shipment, they shall issue a call tag with the shipping carrier to have the package returned.
BR11.7-2	Akebia will received weekly Returns Reports.
BR11.7-3	Once the damaged shipment has been returned, Knipper shall send out a replacement shipment. The replacement order shipment information will be reported in the daily Veeva Order Status files.

11.8 Concealed Shortages

Req. #	Description
BR11.8-1	If Knipper becomes aware of a concealed shortage during packing, Knipper shall perform the following: • Document the shortage, • Take pictures of corresponding case, • Contact Director, Commercial Operations, and • Make adjustment in inventory management system.

11.9 Notification of Questionable Activities

Req. #	Description
BR11.9-1	Knipper employees that have reason to believe that: (1) any person has falsified drug sample requests, receipts, or other Drug Sample records; (2) there has been significant loss or known theft of drug samples; or (3) any person is diverting drug samples shall immediately, and in any case no later than twenty-four (24) hours after becoming aware of any of the foregoing, notify AKEBIA.
BR11.9-2	If Knipper discovers questionable activities, Knipper shall notify the Director, Commercial Operations, the VP of Regulatory Affairs and the VP of Quality at AKEBIA immediately and in any case no later than twenty-four (24) hours after discovery. Director, Commercial Operations will notify Legal, Compliance, the VP of Quality and Supply Chain at AKEBIA. AKEBIA will be responsible for notifying any federal, state or local agency regarding a violation. Knipper shall endeavor to complete a preliminary investigation within seven (7) days of becoming aware of the questionable activities. Knipper shall provide any investigational findings to AKEBIA in support of the report to the agencies when they make such notification to AKEBIA and throughout their investigation. The final investigation should be completed as quickly as possible.

Req. #	Description
BR11.9-3	Knipper shall be responsible for notifying Akebia of any questionable activities, including investigation and closure as it relates to any investigations related to questionable activities. In accordance with Knipper's Investigations procedure, SOP QA 011 Quality Investigations, Knipper will document the details of the identified event, the root cause, corrective and preventive actions, where applicable.
BR11.9-4	Senior Director, Supply Chain, VP, Regulatory Affairs and Senior Director of Supply Chain at AKEBIA will confirm if any additional actions or investigation by Knipper should be taken regarding the violation. AKEBIA shall be responsible for all federal and state reporting.

11.10 Notification of Business Rules Non-compliance Events

Req. #	Description
BR11.10-1	If Knipper discovers any other instances of non-compliance that would not otherwise fall under this Section 11 or elsewhere in the Business Rules, Knipper shall notify Director, Commercial Operations at AKEBIA immediately and in any case no later than twenty-four (24) hours after discovery. Knipper shall endeavor to complete a preliminary investigation within seven (7) days of becoming aware of the questionable activities and provide a report to AKEBIA in support of such investigation. The final investigation shall be completed as quickly as possible.

11.11 Returns

Req. #	Description
BR11.11-1	If a practitioner requests to have the product returned, Knipper shall issue a call tag to have the product picked up.
BR11.11-2	As returns are received, Knipper shall log all returns, including the reason for the return, if available.
BR11.11-3	The AOC for this order shall be closed and noted that the shipment was returned.
BR11.11-4	All returns shall be stored in the Returns department until it is time to destroy.
BR11.11-5	Knipper shall issue a destruction notice and an estimated cost to AKEBIA for approval to have the product destroyed by a Knipper-supplied vendor.

Adverse Events, Product Quality Complaints, and Medical Inquiries

Any customer provided comment that is written on any inbound correspondence will be documented by Knipper and forwarded to AKEBIA via email as follows:

Req. #	Description
BR11.12-1	Medical comments will be scanned, documented on Knipper's **Adverse Event and Product Quality Complaint Form (TS-006A) Attachment 10**, or a client provided form, and sent via email to AKEBIA and the following Adverse Event contact within 1 business day of receipt. • Phone: 1-844-445-3799 • Email: pvg@akebia.com • Fax: 1-617-466-3507 Medical Inquiries will be transferred to the following number: • Phone: 1-844-445-3799

11.12 Severe Weather Protocol

Req. #	Description
BR11.13-1	Knipper's Business Continuity Plan includes detailed procedures for each recovery scenario addressing potential natural and man-made disasters that can occur at Knipper's facilities. There is an established team and detailed plans for each recovery scenario. These plans focus on facilities, services, and people. Our approach involved an extensive risk analysis evaluating natural and man-made disasters. Knipper's Business Continuity Plan was put into effect during the preparation for and after Hurricane Sandy in October 2012. Severe Weather SOP is available for review at J. Knipper & Co, Lakewood facility at any time.

11.13 Regulatory Document Requests

Req. #	Description
BR11.14-1	Availability of request and receipt forms, reports, lists, and records. Any Knipper person required to create or maintain request and receipt forms, reports, lists, or other records under PDMA or otherwise required by FDA, or these business rules shall make them available, upon request, in a form that permits copying or other means of duplication, to FDA or other Federal, State, or local regulatory and law enforcement officials, with a copy to AKEBIA, for review and reproduction (or, if such request has come from AKEBIA, these documents shall be sent directly to AKEBIA immediately and in any case no later than twenty-four (24) hours after such request in order for Akebia to supply to the FDA within two (2) business days). If the request has come from the FDA to Knipper directly, Knipper shall immediately notify Akebia and make the records available to the FDA, with a copy to Akebia, within two (2) business days of said request. For clarity, Knipper shall not submit any receipt forms, reports, lists, or other records to the FDA unless and until Akebia's Regulatory Department has reviewed and approved prior to submission to the FDA.

12 Reporting

12.1 Reports

Req. #	Description
BR12.1-1	**AKEBIA shall receive the following reports from Knipper weekly (Monday):** o Standard Inventory Report o Product Ship Report o Mitigation Report **AKEBIA shall receive the following reports from Knipper monthly (2nd Business Day):** o Open AOC Report o Signature Verification Report o Mitigation Report o Returns Report o Standard Inventory Report o Product Ship Report
BR12.1-2	Kadabra Reporting Tool will be set up for this program.

12.2 Document Retention

Req. #	Description
BR12.2-1	Knipper shall retain documentation for 5 years for all states in order to comply both with the Prescription Drug Marketing Act of 1987 retention requirement and the retention requirement of those states that require greater time than PDMA.
BR12.2-2	When 5 years is met, Knipper shall request AKEBIA direction and approval for disposition of the documentation.

12.3 Program Materials

Req. #	Description
BR12.3-1	**AKEBIA shall supply:** • Product • Files • Approval to letters and Inbound Call Script • Approval of the Business Rules Document
BR12.3-2	**Knipper shall supply:** • Business Rules • Project Timeline • Product storage and shipment services in accordance with appropriate business rules • Fax line for inbound correspondence • Letter copy for AOC Packing Slip verbiage, Signature Verification Letter and AOC follow up letters • Production of AOC Reminder Insert • #10 Window Envelopes to Mail Letters (AOCs and SVL)

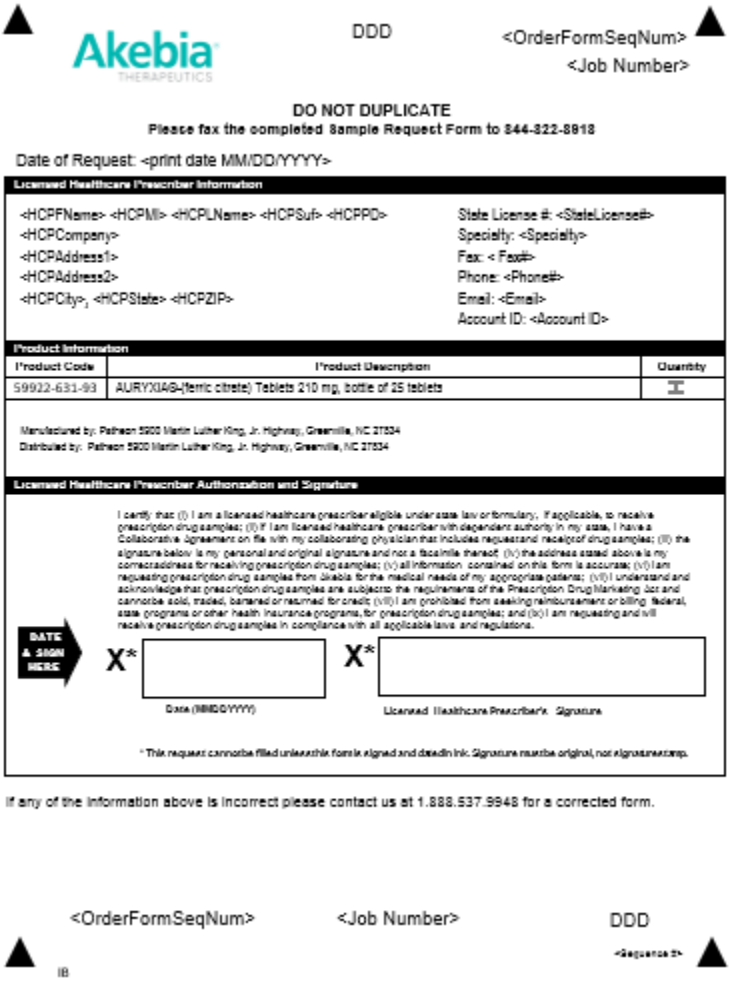
13 Business Rules Revision History

Date	Revision	Description	Author
09.02.2020	V 1.0	Initial	Pamela Liddell

14 Attachments

Attachment #	Name
1.	Sample Request Form
2.	Exception Letter
3.	Denial Letter
4.	Order Validation Rules Matrix
5.	AOC Packing Slip
6.	AOC Letter
7.	INCA Process
8.	Signature Verification Letter –Electronic Version
9.	Signature Verification Letter – Paper Version
10.	Adverse Event and Product Quality Complaint Form (TS-006A)

Attachment 1: Sample Request Form



Akebia THERAPEUTICS

DDD

<OrderFormSeqNum>
<Job Number>

DO NOT DUPLICATE

Please fax the completed Sample Request Form to 844-822-8918

Date of Request: <print date MM/DD/YYYY>

Licensed Healthcare Prescriber Information

<HCPFName> <HCPMI> <HCPLName> <HCPSuf> <HCPPD>
<HCPCompany>
<HCPAddress1>
<HCPAddress2>
<HCPCity>, <HCPState> <HCPZIP>

State License #: <StateLicense#>
Specialty: <Specialty>
Fax: < Fax#>
Phone: <Phone#>
Email: <Email>
Account ID: <Account ID>

Product Information

Product Code	Product Description	Quantity
59922-631-93	AURYXIA® (ferric citrate) Tablets 210 mg, bottle of 25 tablets	

Manufactured by: Patheon 5900 Martin Luther King, Jr. Highway, Greenville, NC 27834
Distributed by: Patheon 5900 Martin Luther King, Jr. Highway, Greenville, NC 27834

Licensed Healthcare Prescriber Authorization and Signature

I certify that: (i) I am a licensed healthcare prescriber eligible under state law or formulary; if applicable, to receive prescription drug samples; (ii) if I am licensed healthcare prescriber with dependent authority in my state, I have a Collaborative Agreement on file with my collaborating physician that includes request and receipt of drug samples; (iii) the signature below is my personal and original signature and not a facsimile thereof; (iv) the address stated above is my correct address for receiving prescription drug samples; (v) all information contained on this form is accurate; (vi) I am requesting prescription drug samples from Akebia for the medical needs of my appropriate patients; (vii) I understand and acknowledge that prescription drug samples are subject to the requirements of the Prescription Drug Marketing Act and cannot be sold, traded, bartered or returned for credit; (viii) I am prohibited from seeking reimbursement or billing federal, state programs or other health insurance programs, for prescription drug samples; and (ix) I am requesting and will receive prescription drug samples in compliance with all applicable laws and regulations.

DATE & SIGN HERE

X* _____ Date (MM/DD/YYYY)

X* _____ Licensed Healthcare Prescriber's Signature

* This request cannot be filled unless this form is signed and dated in ink. Signature must be original, not signature stamp.

If any of the information above is incorrect please contact us at 1.888.537.9948 for a corrected form.

<OrderFormSeqNum> <Job Number> DDD

<Sequence 2>

IB

Attachment 2: Exception Letter

<<Month Day, Year>>

<<JobNumber>>
<KnipperParentOrderId>
<KnipperOrderId>

<ShipToFirstName> <ShipToLastName>, <ShipToDesignation>
<ShipToCompanyName>
<ShipToAddress1>
<ShipToAddress2>
<ShipToAddress3>
<ShipToCity>, <ShipToState> <ShipToZip>

Dear <ShipToFirstName> <ShipToLastName>, <ShipToDesignation>:

Thank you for your interest in AURYXIA® (ferric citrate). Unfortunately, we are not able to fulfill your request at this time, as it does not meet the necessary regulatory requirements due to the following reason(s):

- Sample Request Form is missing required information (name, address, state license number, etc.)
- Signature of the requesting practitioner is missing or a stamped signature was provided.
- Signature provided does not match the practitioner's name on the request.

Please correct the information requested in its entirety on the enclosed Sample Request Form and fax back to 844-822-8918. Once we receive this information, your request will be fulfilled without further delay.

Thank you for your anticipated cooperation.

Sincerely,

Akebia, Inc.

<KnipperParentOrderID> **<<JobNumber>>** - <SequenceID>

Attachment 3: Denial Letter

<<Month Day, Year>>

<<JobNumber>>
<KnipperParentOrderId>
<KnipperOrderId>

<ShipToFirstName> <ShipToLastName>, <ShipToDesignation>
<ShipToCompanyName>
<ShipToAddress1>
<ShipToAddress2>
<ShipToAddress3>
<ShipToCity>, <ShipToState> <ShipToZip>

Dear <ShipToFirstName> <ShipToLastName>, <ShipToDesignation>:

Thank you for your interest in AURYXIA® (ferric citrate). Unfortunately, we are not able to fulfill your request at this time, as it does not meet the necessary regulatory requirements due to the following reason(s):

- Invalid or duplicate form id.
- Request does not meet program requirements.
- Unauthorized changes made to the Sample Request Form.
- The professional designation on the request does not meet program requirements.
- The state on the request does not meet program requirements.
- Address provided is a PO Box. Samples must ship to a physical address.
- Acknowledgement of content for previous orders not yet returned or was not signed.

Sincerely,

Akebia, Inc.

KnipperParentOrderID **JobNumber** - *SequenceID*

Attachment 4: Order Validation Rules Matrix

KFIS Rule Code	KFIS Rule Description	Failure Action	Is Applicable when prior rules pass	Reject Reason Printed on Reject Letters (Parameter ERROR_MESSAGE)	Parameters
ShpToCityMissing	Ship To City missing.	Reject	Continue Processing	Your City is missing as part of your address from the request form and is required.	
ShpToStateMissing	Ship To State missing.	Reject	Continue Processing	Your State is missing as part of your address from the request form and is required.	
ShpToZipMissing	Ship To Zip missing.	Reject	Continue Processing	Your ZIP Code is missing as part of your address from the request form and is required.	
ShpToZipInvalid	Ship To Zip Invalid	Reject	Stop Processing	The zip code on the request is incomplete and therefore, cannot be processed.	
ShpToStLicNmbrMissing	Ship To State License missing.	Reject	Continue Processing	Your state license number (SLN) is missing from the request form and is required.	
ShpToProfDesgMissing	Ship To Professional Designation Missing.	Reject	Continue Processing	Your professional designation is missing from the request and is required.	
ShpToPOBox	Ship To Address contains PO Box.	Reject	Continue Processing	Item(s) cannot be shipped to an address that only includes a PO Box. Please ensure your physical street address is present and includes a route identifier (Avenue, Street, etc).	**Scope:** Valid street addresses with PO Box are allowed. Only reject order request where PO Box is the only provided address.
CannotSampleShipToState	Cannot sample to the provided Ship To State.	Reject	Continue Processing	The ship to state on the request is not permitted to receive the sample(s) requested.	**Valid States:** AL|AK|AZ|AR|CA|CO|CT|DE|DC|FL|GA|HI|ID|IL|IN|IA|KS|KY|LA|ME|MA|MD|MI|MN|MS|MO|MT|NE|NV|NH|NJ|NY|NM|NC|ND|OH|OK|OR|PA|RI|SC|SD|TN|TX|UT|VA|WA|WV|WI|WY
CannotSampleProfDesg	Cannot sample to the provided Professional Designation.	Investigate/ Reject	Continue Processing	The professional designation on the request is not permitted to receive the sample(s) requested.	**Allowed Designations:** MD, DO, NP, PA, APN, DDS, DVM, PAC, RPA, OD, PA-C, CPA, LNP, CNP, CRNP, ANP, APN, RNP, ARNP, APRN, APRN/PMH
NonAOCCompliantPractitioner	The practitioner is non compliant on his/her AOC	Hold/ Reject	Continue Processing	The HCP is deemed non compliant to the open AOC rule. Please have the HCP close one or more open AOCs for this request to be processed.	
ShpToStLicNotFound	Ship To State License invalid as it is not found in master data.	Investigate/ Reject	Stop Processing	Your state license number listed on the request form cannot be located in our records.	
ShpToStLicInactive	Ship To State License inactive.	Investigate/ Reject	Continue Processing	You may have recently renewed your State License information and the change has not yet reflected in our records.	
ShpToFNNotEqualToStLicFN	Ship To First Name is not same as State License First Name.	Investigate/ Reject	Continue Processing	According to our records, your first name listed on the request does not match the name associated with your State License Number and the order cannot be processed. Please ensure this is correct upon signing a new request.	
ShpToLNNotEqualToStLicLN	Ship To Last Name is not same as State License Last Name.	Investigate/ Reject	Continue Processing	According to our records, your last name listed on the request does not match the name associated with your State License Number and the order cannot be processed. Please ensure this is correct upon signing a new request.	
ShpToStateNotEqualToStLicState	Ship To State is not equal to the State License State.	Investigate/ Reject	Continue Processing	According to our records, the state listed on the request does not match the state associated with your State License Number and the order cannot be processed. Please ensure this is correct upon signing a new request.	

Attachment 5: AOC Packing Slip

RETURN ADDRESS
Akebia Therapeutics
1250 Patrol Road
Charlestown, IN 47111

PICK / PACK SLIP

Acknowledgment of Contents
Date: 03/13/2020 Time: 3:04:14 a.m.

ORDER ID: KFIS000695-00000198

33877004 CCC

INVOICE:
SCHEDULED SHIP DATE: 03/06/2020
NEED BY DATE: 03/13/2020

SHIP TO
RIDHMI RAJAPAKSE MD
3615 NW SAMARITAN DRIVE STE 203
CORVALLIS, OR 97330

ORDERED BY
RIDHMI RAJAPAKSE MD
3615 NW SAMARITAN DRIVE STE 203
CORVALLIS, OR 97330

Order ID	Job Number	Order Date	Carrier & Shipping Method	Shipment ID	Purchase Order #
KFIS000695-00000198	33877016	03/13/2020	UPS Ground Commercial Sig	12427887	

Item Location	Item ID Container ID	Description	Lot Number	Expiry Date	Quantity UOM
KMI-PM-B3-125-B	59922-631-03 | 40000000052769168	AURYXIA® (ferric citrate) Tablets 210 mg 25 tablets	AL4220X	12/31/2020	10 EA
KMI-PM-B3-127-C	KERYXAOCFLYER | 40000000052769168	Keryx AOC Reminder Flyer			1 EA

ACKNOWLEDGMENT OF CONTENT (AOC)

FDA Regulations require pharmaceutical manufacturers to obtain the acknowledged receipt of products. Please sign, date and fax this form to 1-844-822-8918.
It is important that you compare this AOC to the samples that you received. If the samples received match the amount indicated on this AOC, simply sign, date and fax this form to 1-844-822-8918. If the samples received do not match the information on this AOC, please note the discrepancy on this AOC before signing and faxing this form.
No stamp signatures are permitted. Violation of the Prescription Drug Marketing Act is a federal offense.

- Are you signing as an approved designee of the practitioner above? Yes ❑ No ❑
- If yes, you must print your name and title, then sign below per Prescription Drug Marketing Act (PDMA) requirements.
- If no, please sign below, confirming as the requesting practitioner.

Field required only if approved designee.

Printed Name of Approved Designee | Professional Title of Approved Designee

By signing this form, I certify that I am either the requesting practitioner listed above or an approved designee of the requesting practitioner listed above. Also, I verify that the above sample products were requested and received; acknowledge the receipt of the sample product(s) listed above with the manufacturer, Patheon, and the authorized distributor of record, Patheon; and confirm the quantities listed on this AOC accurately reflect the sample quantities received. Further, I certify that I am currently licensed with the appropriate authorities to request and receive the product(s) listed above; the samples provided will be used for the medical needs of my patients; I will not bill for these samples nor will they be sold; and these samples are not for personal use by me, family members, friends, or office staff.

X

Acknowledgment of Receipt Signature (Licensed Practitioner or Approved Designee) | Date

CCC

Please sign, date and fax this form to 1-844-822-8918.
If this order is NOT what you requested, please call the Akebia Sampling Information Line at 1-888-KERYX4U (1-888-537-9948).

Akebia THERAPEUTICS

Attachment 6: AOC Letter

AAA

March 12, 2020

Shipment Order ID: KFIS000544-00043570
Order ID: KFIS000553-00025910
State License: MD.13799

Shipment ID: 12382155
Job Number: 33877004

Rafael Lopez, MD
229 Camden Byp
Camden, AL 36726

Dear Rafael Lopez, MD :

On behalf of Akebia Therapeutics, please allow this letter to serve as a request for a signed RECEIPT for the drug samples recently delivered to you (Acknowledgement of Content ("AOC")). Our records indicate that you received a sample shipment on 02/20/2020 for which we have not yet received a signed receipt (AOC).

Qty	Code	Description	Lot No.
1	59922-631-93	AURYXIA® (ferric citrate) Tablets 210 mg 25 tablets	AL1364X 11/30/2020

Federal regulations require that we obtain a signed receipt for all prescription drug samples requested and shipped. It is necessary for us to maintain accurate tracking records in order to continue to offer prescription drug samples. *Therefore, in order to comply with the federal sampling regulations, please acknowledge below receipt of these samples, sign, date, and fax this letter to 1-844-822-8918.*

If you have any questions, please call the Akebia Sampling Information Line at 1-888-KERYX4U (1-888-537-9948).

Thank you for your anticipated cooperation.

Sincerely,

Akebia Therapeutics

Prescriber OR Authorized Designee Must Sign and Date Below

Prescriber Signature	**Authorized Designee Signature**
X _____ Prescriber's Signature / Date	X _____ Authorized Designee Signature / Date
Rafael Lopez, MD	X _____ Authorized Designee Printed First and Last Name /Title
33877004 - 12382155 - 001U000000ZWDPLIAU	☐MD ☐DO ☐NP ☐PA ☐Office Manager ☐Other____
	NOTE: Name AND Professional Designation or Job Title Must Be Provided and Must Be Legible in order to be accepted. ***By signing this Acknowledgment of Contents, I certify that I am a designee of this Prescriber and have been authorized by this Prescriber to sign for drug samples.***

AAA

1

Attachment 7: INCA Process

Knipper internal SOP IN-005 Inventory Investigation, Reconciliations, and Adjustments

1. At the request of Professional Services, Inventory will perform a physical count of a product.
2. The INCA (Inventory check and adjustment) form is filled out detailing the scope and nature of the request.
3. The form includes Client Name, Product ID and description, lot # if applicable and reason for the investigation.
4. The Inventory Department acknowledges the receipt of the form, assigns a control # and performs a physical count. The results of the count are passed to Professional Services.
5. Any adjustment to product quantities requires approval and signoff by Quality Assurance.
6. Supporting documentation (transaction histories, signed count sheets, prior adjustments) is filed with the INCA form upon completion.

Attachment 8: Signature Verification Letter - Electronic

BBB

Akebia THERAPEUTICS

Letter Order ID: KFIS000555-00003866
Order ID: KFIS000544-00042875
Project Number: 33877005
State License: 1104033504

March 12, 2020

Clement Nwosu, MD
959 17th St
Columbus, GA 31901

Dear Clement Nwosu, MD:

According to our records, we have shipped prescription drug samples of one or more of our prescription products to you per your request. To comply with the Prescription Drug Marketing Act of 1987 ("PDMA"), we conduct periodic audits to determine whether the signature on the sample requests is authentic and belongs to the practitioner requesting the samples.

Complete the section below to confirm that you ordered the samples referenced below and the digital signature displayed is your signature. Please sign, date and return this letter to us via fax to 1-844-822-8918.

Qty	Code	Description	Lot No.
24	59922-631-93	AURYXIA® (ferric citrate) Tablets 210 mg 25 tablets	AL1355X 10/31/2020

_____ Yes, I ordered Auryxia® (ferric citrate) Tablets sample(s) and provided the e-signature on file.

_____ No, office personnel ordered Auryxia® (ferric citrate) Tablets sample(s) and provided the e-signature on file.

Name of person who provided the e-signature: _____

Title: _____

_____ No, neither I nor any office personnel ordered Auryxia® (ferric citrate) Tablets sample(s).

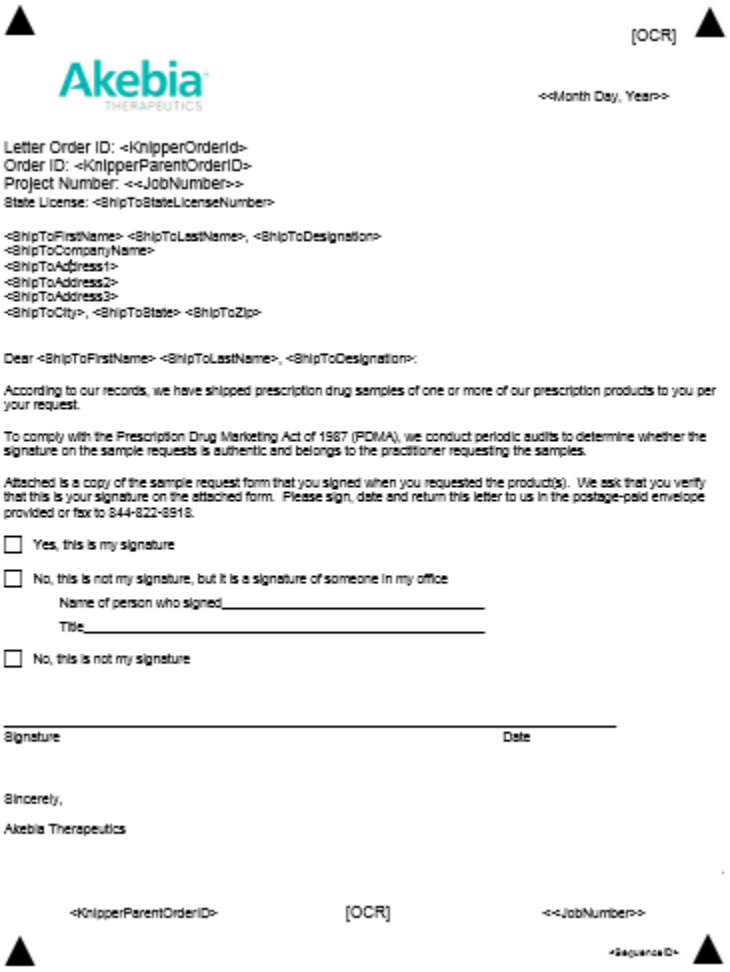
_____ _____
Signature Date

Sincerely,

Akebia Therapeutics

KFIS000544-00042875 BBB 33877005 40

Attachment 9: Signature Verification Letter – Paper



[OCR]

Akebia THERAPEUTICS

<<Month Day, Year>>

Letter Order ID: <KnipperOrderId>
Order ID: <KnipperParentOrderID>
Project Number: <<JobNumber>>
State License: <ShipToStateLicenseNumber>

<ShipToFirstName> <ShipToLastName>, <ShipToDesignation>
<ShipToCompanyName>
<ShipToAddress1>
<ShipToAddress2>
<ShipToAddress3>
<ShipToCity>, <ShipToState> <ShipToZip>

Dear <ShipToFirstName> <ShipToLastName>, <ShipToDesignation>:

According to our records, we have shipped prescription drug samples of one or more of our prescription products to you per your request.

To comply with the Prescription Drug Marketing Act of 1987 (PDMA), we conduct periodic audits to determine whether the signature on the sample requests is authentic and belongs to the practitioner requesting the samples.

Attached is a copy of the sample request form that you signed when you requested the product(s). We ask that you verify that this is your signature on the attached form. Please sign, date and return this letter to us in the postage-paid envelope provided or fax to 844-822-8918.

☐ Yes, this is my signature

☐ No, this is not my signature, but it is a signature of someone in my office

Name of person who signed_____

Title_____

☐ No, this is not my signature

_____

Signature Date

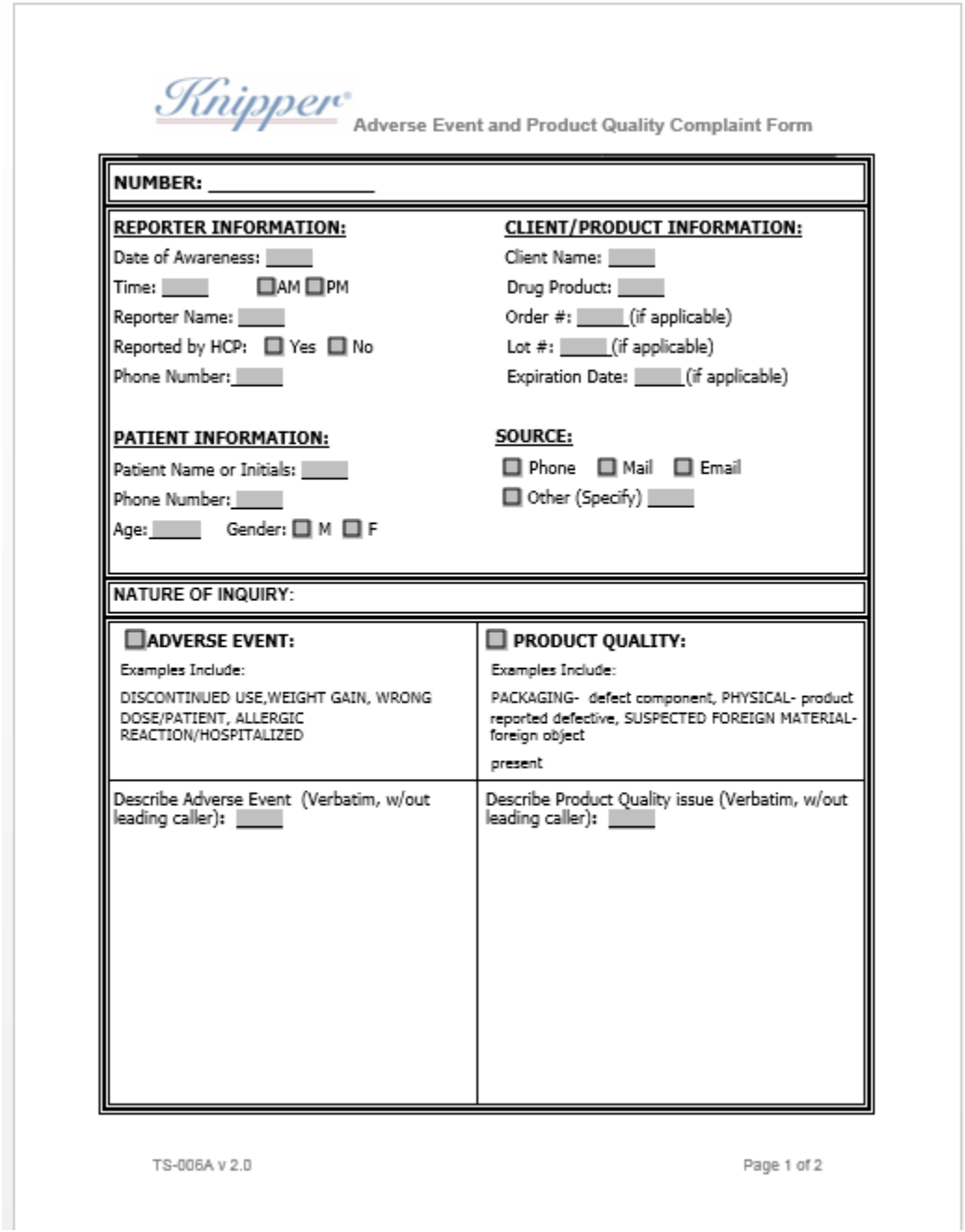
Sincerely,

Akebia Therapeutics

<KnipperParentOrderID> [OCR] <<JobNumber>>

<SequenceID>

Attachment 10: Adverse Event and Product Quality Complaint Form (TS-006A)



Knipper®

Adverse Event and Product Quality Complaint Form

NUMBER: _____

REPORTER INFORMATION:

Date of Awareness: _____

Time: _____ ☐AM ☐PM

Reporter Name: _____

Reported by HCP: ☐ Yes ☐ No

Phone Number: _____

CLIENT/PRODUCT INFORMATION:

Client Name: _____

Drug Product: _____

Order #: _____ (if applicable)

Lot #: _____ (if applicable)

Expiration Date: _____ (if applicable)

PATIENT INFORMATION:

Patient Name or Initials: _____

Phone Number: _____

Age: _____ Gender: ☐ M ☐ F

SOURCE:

☐ Phone ☐ Mail ☐ Email

☐ Other (Specify) _____

NATURE OF INQUIRY:

☐ **ADVERSE EVENT:**	☐ **PRODUCT QUALITY:**
Examples Include: DISCONTINUED USE,WEIGHT GAIN, WRONG DOSE/PATIENT, ALLERGIC REACTION/HOSPITALIZED	Examples Include: PACKAGING- defect component, PHYSICAL- product reported defective, SUSPECTED FOREIGN MATERIAL- foreign object present
Describe Adverse Event (Verbatim, w/out leading caller): _____	Describe Product Quality issue (Verbatim, w/out leading caller): _____

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ACTIONS TAKEN:	
☐ CALL TRANSFER COMPLETED TO: Name____ Phone# ____ Date/Time ____ ☐AM ☐PM	☐ EMAIL TO:____
☐ FAXED TO: Client____ Fax # ____	☐ OTHER ____ Knipper Investigation Required ☐ Yes ☐ No Knipper Incident Report Number: ____

AE/PQC REVIEW:
Prepared by: _____ Date: _____ Approved by: _____ Date: _____