

# ARISTADA INITIO and ARISTADA PROVIDER PRICING PROGRAM

ARISTADA  
INITIO®  
aripiprazole lauroxil  
extended-release injectable suspension

675 mg

ARISTADA®  
aripiprazole lauroxil  
extended-release injectable suspension

441 mg 662 mg 882 mg 1064 mg

## HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) CODE

**ARISTADA** received an updated J-code (J1944) which may be used when ARISTADA is being billed under the medical benefit for dates of service on and after October 1, 2019.

HCPCS Code <sup>1</sup>	Description	Settings of Care
J1944	Injection, aripiprazole lauroxil, (ARISTADA), 1 mg	Most payers and care settings

**ARISTADA INITIO** received a unique J-code (J1943) which may be used when ARISTADA INITIO is being billed under the medical benefit for dates of service on and after October 1, 2019.

HCPCS Code <sup>1</sup>	Description	Settings of Care
J1943	Injection, aripiprazole lauroxil, (ARISTADA INITIO), 1 mg	Most payers and care settings

## IT'S EASY TO ENROLL IN THE ARISTADA INITIO AND ARISTADA PROVIDER PRICING PROGRAM

- Direct-purchase discount available to eligible\* providers through the Alkermes provider distribution partner, Besse Medical
- Extended payment terms of 75 days available to program participants

Product and Dosage Strength	11-Digit NDC Code	Discount Price
ARISTADA INITIO 675 mg	65757-0500-03	WAC - 10%
ARISTADA 441 mg	65757-0401-03	
ARISTADA 662 mg	65757-0402-03	
ARISTADA 882 mg	65757-0403-03	
ARISTADA 1064 mg	65757-0404-03	

To get started with your enrollment in the ARISTADA INITIO and ARISTADA Provider Pricing Program

- Set up an account with Besse Medical by completing the enclosed Besse Medical 2-page account setup form
- Fax the completed form, along with a copy of your state license, to Besse Medical at 1-888-375-0030
- Besse Medical retains sole discretion for opening an account and establishing credit limit
- You can also set up your account online at: <https://www.besse.com/Pages/ProvisionAccount.aspx>

When your Besse Medical account is set up, you are ready to order ARISTADA INITIO and ARISTADA

- Submit your order directly to Besse Medical by phone, fax, or online:

Call: 1-800-543-2111

Fax: 1-888-375-0030

Online: [www.besse.com](http://www.besse.com)



**Once enrolled, your order is shipped overnight for next-day delivery, which will help you provide ARISTADA INITIO and ARISTADA to your patients when they need it.**

\* Contact Besse Medical regarding eligibility for program pricing.

### INDICATION

ARISTADA INITIO® (aripiprazole lauroxil), in combination with oral aripiprazole, is indicated for the initiation of ARISTADA® (aripiprazole lauroxil) when used for the treatment of schizophrenia in adults.

ARISTADA is indicated for the treatment of schizophrenia in adults.

### IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA

#### **WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.



Please see additional Important Safety Information contained on the following pages and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

**INDICATION and IMPORTANT SAFETY INFORMATION for ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) extended-release injectable suspension, for intramuscular use**

**INDICATION**

ARISTADA INITIO, in combination with oral aripiprazole, is indicated for the initiation of ARISTADA when used for the treatment of schizophrenia in adults.

ARISTADA is indicated for the treatment of schizophrenia in adults.

**IMPORTANT SAFETY INFORMATION**

**WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

**Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.**

**Contraindication:** Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

**Cerebrovascular Adverse Reactions, Including Stroke:**

Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities, have been reported in placebo-controlled trials of elderly patients with dementia-related psychosis treated with risperidone, aripiprazole, and olanzapine. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.

**Potential for Dosing and Medication Errors:**

Medication errors, including substitution and dispensing errors, between ARISTADA INITIO and ARISTADA could occur. ARISTADA INITIO is intended for single administration in contrast to ARISTADA which is administered monthly, every 6 weeks, or every 8 weeks. Do not substitute ARISTADA INITIO for ARISTADA because of differing pharmacokinetic profiles.

**Neuroleptic Malignant Syndrome (NMS):**

A potentially fatal symptom complex may occur with administration of antipsychotic drugs, including ARISTADA INITIO and ARISTADA. Clinical manifestations of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

**Tardive Dyskinesia (TD):** The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing antipsychotics should be consistent with the need to minimize TD. Discontinue ARISTADA if clinically appropriate. TD may remit, partially or completely, if antipsychotic treatment is withdrawn.

**Metabolic Changes:** Atypical antipsychotic drugs have been associated with metabolic changes that include:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics. There have been reports of hyperglycemia in patients treated with oral aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia, including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients require continuation of antidiabetic treatment despite discontinuation of the suspect drug.
- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.
- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

**Pathological Gambling and Other Compulsive Behaviors:**

Compulsive or uncontrollable urges to gamble have been reported with use of aripiprazole. Other compulsive urges less frequently reported include sexual urges, shopping, binge eating and other impulsive or compulsive behaviors which may result in harm for the patient and others if not recognized. Closely monitor patients and consider dose reduction or stopping aripiprazole if a patient develops such urges.

**Orthostatic Hypotension:** Aripiprazole may cause orthostatic hypotension which can be associated with dizziness, lightheadedness, and tachycardia. Monitor heart rate and blood pressure, and warn patients with known cardiovascular or cerebrovascular disease and risk of dehydration and syncope.

**Falls:** Antipsychotics including ARISTADA INITIO and ARISTADA may cause somnolence, postural hypotension or motor and sensory instability which may lead to falls and subsequent injury. Upon initiating treatment and recurrently, complete fall risk assessments as appropriate.

**Leukopenia, Neutropenia, and Agranulocytosis:**

Leukopenia, neutropenia and agranulocytosis have been reported with antipsychotics. Monitor complete blood count in patients with pre-existing low white blood cell count (WBC)/absolute neutrophil count or history of drug-induced leukopenia/neutropenia. Discontinue ARISTADA INITIO and/or ARISTADA at the first sign of a clinically significant decline in WBC and in severely neutropenic patients.

**Seizures:** Use with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

**Potential for Cognitive and Motor Impairment:** ARISTADA INITIO and ARISTADA may impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are certain therapy with ARISTADA INITIO and/or ARISTADA does not affect them adversely.

**Body Temperature Regulation:** Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

**Dysphagia:** Esophageal dysmotility and aspiration have been associated with antipsychotic drug use; use caution in patients at risk for aspiration pneumonia.

**Concomitant Medication:** ARISTADA INITIO is only available at a single strength as a single-dose pre-filled syringe, so dosage adjustments are not possible. Avoid use in patients who are known CYP2D6 poor metabolizers or taking strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or strong CYP3A4 inducers, antihypertensive drugs or benzodiazepines.

Depending on the ARISTADA dose, adjustments may be recommended if patients are 1) known as CYP2D6 poor metabolizers and/or 2) taking strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or strong CYP3A4 inducers for greater than 2 weeks. Avoid use of ARISTADA 662 mg, 882 mg, or 1064 mg for patients taking both strong CYP3A4 inhibitors and strong CYP2D6 inhibitors. (See Table 4 in the ARISTADA full Prescribing Information.)

**Commonly Observed Adverse Reactions:** In pharmacokinetic studies the safety profile of ARISTADA INITIO was generally consistent with that observed for ARISTADA. The most common adverse reaction ( $\geq 5\%$  incidence and at least twice the rate of placebo reported by patients treated with ARISTADA 441 mg and 882 mg monthly) was akathisia.

**Injection-Site Reactions:** In pharmacokinetic studies evaluating ARISTADA INITIO, the incidences of injection-site reactions with ARISTADA INITIO were similar to the incidence observed with ARISTADA. Injection-site reactions were reported by 4%, 5%, and 2% of patients treated with 441 mg ARISTADA (monthly), 882 mg ARISTADA (monthly), and placebo, respectively. Most of these were injection-site pain and associated with the first injection and decreased with each subsequent injection. Other injection-site reactions (induration, swelling, and redness) occurred at less than 1%.

**Dystonia:** Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first days of treatment and at low doses.

**Pregnancy/Nursing:** May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Advise patients to notify their healthcare provider of a known or suspected pregnancy. Inform patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ARISTADA INITIO and/or ARISTADA during pregnancy. Aripiprazole is present in human breast milk. The benefits of breastfeeding should be considered along with the mother's clinical need for ARISTADA INITIO and/or ARISTADA and any potential adverse effects on the infant from ARISTADA INITIO and/or ARISTADA or from the underlying maternal condition.

**Please see full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.**

**References:** 1. Centers for Medicare & Medicaid Services. HCPCS Quarterly Update. Revised Other New Codes Published 7-26-2019 Effective 10-1-2019 and 1-1-2020. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/Other-Codes-2019-July-Revised.zip>. Accessed August 15, 2019.



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aripiprazole lauroxil  
extended-release injectable suspension

675 mg

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441 mg 662 mg 882 mg 1064 mg

**BUSINESS APPLICATION (PAGE 1 OF 2)**

05.09.2019

**1. CUSTOMER INFORMATION**

LEGAL ENTITY NAME (name registered with Secretary of State) \_\_\_\_\_  
 DOING BUSINESS AS (IF APPLICABLE) \_\_\_\_\_  
 IS YOUR BUSINESS A:  Proprietorship\*  Partnership†  Corporation  Subsidiary  LLC DATE OFFICE ESTABLISHED \_\_\_/\_\_\_/\_\_\_  
 \* attach Driver's License † attach partnership paperwork, ie. Articles of Incorporation \_\_\_\_\_  
 STATE OF INCORPORATION/REGISTRATION \_\_\_\_\_ ORGANIZATION ID# ISSUED BY STATE \_\_\_\_\_ STATE OF CHIEF EXECUTIVE OFFICER \_\_\_\_\_

**2. BILLING INFORMATION**

BILL-TO NAME \_\_\_\_\_  
 ADDRESS \_\_\_\_\_ CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP \_\_\_\_\_  
 SUITE/BLDG # \_\_\_\_\_ PHONE \_\_\_\_\_ FAX \_\_\_\_\_  
 ACCTS PAYABLE CONTACT \_\_\_\_\_ TAX ID # \_\_\_\_\_ TAX EXEMPT?  YES\*  NO  
 ↳ EMAIL \_\_\_\_\_ \* If yes, please include your tax exemption certificate.  
 DO YOU USE PURCHASE ORDERS?  YES  NO IF HEALTH SYSTEM, DO PHYSICIAN LOCATIONS REQUIRE PO?  YES  NO

**3. SHIPPING INFORMATION** [Note:  "X" here if you have multiple shipping addresses; please attach a list.]

SHIP-TO NAME \_\_\_\_\_  
 ADDRESS \_\_\_\_\_ CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP \_\_\_\_\_  
 SUITE/BLDG # \_\_\_\_\_ PHONE \_\_\_\_\_ FAX \_\_\_\_\_  
 PURCHASING CONTACT \_\_\_\_\_ OFFICE HOURS (for delivery) \_\_\_\_\_  
 ↳ EMAIL \_\_\_\_\_  
 STATE MEDICAL LICENSE # \_\_\_\_\_ PHYSICIAN NAME \_\_\_\_\_ EXP. \_\_\_/\_\_\_/\_\_\_  
 DEA LICENSE # \_\_\_\_\_ PHYSICIAN NAME \_\_\_\_\_ EXP. \_\_\_/\_\_\_/\_\_\_  
 If ship-to name is an individual physician, SML & DEA information must be for the same physician.

**4. REFERENCE INFORMATION** (Please supply a non-distributor vendor reference; supplying a statement at the time of the application will help expedite process)

GPO (GROUP PURCHASING ORG.) MEMBER?  YES  NO IF YES, GPO NAME \_\_\_\_\_ MEMBER ID # \_\_\_\_\_  
 PRACTICE SPECIALTY \_\_\_\_\_ PRODUCT INTEREST \_\_\_\_\_  
 HOW MANY LOCATIONS DO YOU HAVE \_\_\_\_\_ HOW MANY PHYSICIANS \_\_\_\_\_  
 ESTIMATED MONTHLY PURCHASES \_\_\_\_\_ HOW DID YOU HEAR ABOUT BESSE \_\_\_\_\_  
 PROVIDE CREDIT REFERENCE LIST (companies you pay for supplies/services) INCLUDE: BUSINESS NAME, CONTACT, PHONE #, FAX #, ACCOUNT #  
 \_\_\_\_\_  
 \_\_\_\_\_

- If you wish to be pre-pay at the time of setup.
- If you will be ordering **controlled substances** from Besse, please "X" here. We will fax you a questionnaire to complete before you can order.
- Besse Medical sends important product announcements, industry updates, recall notices, promotions, price changes, and other pertinent product and/or industry related news by FAX. By "X"ing the box at the left, Customer gives permission to Besse and its affiliates to send these documents, order and shipment details, advertising and promotional material and other product and sales information, to the fax number(s) provided in this Application. Customer may opt-out of receiving fax communications at any given time by contacting Besse at 800.543.2111 or emailing customerCARE@besse.com.

**5. SIGN. CUSTOMER MUST COMPLETE THE SECTION BELOW FOR THE APPLICATION TO BE PROCESSED**

I represent and warrant that (i) the foregoing information is true and correct, (ii) I have the authority to bind Customer to the terms and conditions, including those on page 2, and (iii) Customer is liable for and will pay all invoice amounts, regardless of whether Customer is reimbursed by any insurer or other third party for the invoice(s) amount.

**X** \_\_\_\_\_ Date \_\_\_\_\_  
 Signature of Customer (if individual) or Authorized Agent/Officer (if legal entity)  
 \_\_\_\_\_  
 Print Name and Title

**YOU MUST SEND IN BOTH PAGES OF THIS APPLICATION. PLEASE REMEMBER TO INITIAL PAGE 2.**

**Please complete this page and read all terms and conditions on page 2. Sign and date this page, initial page 2, and fax both pages to 888.375.0030, or scan and email to accountsetup@besse.com**

**Please read all information carefully.**

As required by state and federal law, BESSE requires copies of (i) a valid DEA registration and (ii) a valid physician or pharmacy license and/or permit. If BESSE cannot obtain a license through federal, state or other third party sources, BESSE may request copies of a valid DEA, physician or pharmacy license from you. In addition:

- If you are a legal entity and provide a physician license, we require a letter of affiliation certifying that the physician is affiliated with the entity. Please include full list of officers, partners, proprietors with application.
  - If you provide a physician license and the address on the license does not match the above shipping address, we require a letter of affiliation certifying that the physician is affiliated with the shipping address.
- If your account requires a Letter of Affiliation, simply call 1.800.543.2111 to request a copy or fax this application and, if required, we will send you the Letter of Affiliation.

**REQUIRED**

**Practice Name** \_\_\_\_\_

**Initials of Customer** \_\_\_\_\_

*You must fax this page (page 2) back with page 1 of the Besse Business Application.  
Fax back to 1.888.375.0030*

**BUSINESS APPLICATION - TERMS AND CONDITIONS**

**TERMS:** This business application (Application) is submitted to Besse Medical (BESSE) for the purpose of obtaining credit. Customer represents and warrants that all information contained herein is current, correct, and complete and that BESSE may rely on such information in deciding to extend or discontinue credit. Customer agrees to notify BESSE immediately, in writing, of any change in the foregoing information including, without limitation, any change in the nature of the business, ownership, licensure, registration name, location of the business, or financial condition. Customer authorizes BESSE to obtain written and oral credit reports from any credit reporting agency. Customer further authorizes any bank or commercial business with whom Customer is doing or has done any business with to give any and all necessary information to BESSE that will assist BESSE in the credit investigation. Customer further authorizes BESSE to reinvestigate Customer's credit status from time to time as BESSE deems necessary and should BESSE upon such reinvestigation deem it necessary to limit or terminate the credit arrangement with Customer, Customer shall be notified of any adverse action.

**PAYMENT:** Except as provided in writing by BESSE, terms of payment for all orders are: Net - 30 days from date of invoice. Please verify invoice terms with a BESSE customer service representative at the time of sale. Prices billed are the prices in effect at the time Customer is invoiced by BESSE. Prices are subject to change without notice. Prices on invoices reflect a discount for payment by cash, check, EFT or similar means other than the use of a credit card, unless otherwise noted. Customer agrees to pay all debts, accounts, and invoices owing to BESSE in full in accordance with the terms of the sale as set forth on the invoice. In the event any such debts, accounts, or invoices owing are not paid when due, BESSE may, in addition to BESSE's right to exercise other remedies, withhold any credits or payments to Customer and assess a per-day late payment fee at a rate equal to the lower of eighteen percent (18%) per annum or the maximum rate allowed by law on the amount due until paid in full, beginning on the first business day after such due date. BESSE may charge a processing fee of \$50 for any dishonored payment. Customer hereby agrees to pay all fees and collection costs including attorneys' fees and expenses, in the event BESSE pursues a legal or collection action.

**SECURITY INTEREST:** To secure all of Customer's existing and future liabilities to BESSE, including the repayment of any amount that BESSE may advance or spend for the maintenance or preservation of the Collateral (as defined below) or otherwise (collectively, the "Obligations"), Customer grants to BESSE a purchase money security interest in Inventory and a lien upon and security interest in all its personal property and any and all additions, substitutions, Accessions and Proceeds thereto or thereof, wherever located, and now owned or hereafter acquired or arising, including the following (collectively, the "Collateral"): All of Customer's (a) Accounts; (b) Inventory; (c) Chattel Paper; (d) Commercial Tort Claims as disclosed on Customer's Financial Statements; (e) Deposit Accounts; (f) Documents; (g) Equipment; (h) General Intangibles; (i) Goods; (j) Instruments; (k) Investment Property; (l) Letter of Credit Rights; (m) insurance on all of the foregoing and the proceeds of that insurance; (n) Customer's money and other property of every kind and nature now or at any time or times hereafter in the possession of or under the control of BESSE; and (o) the Cash proceeds, Noncash proceeds and products of all of the foregoing and the Proceeds of other Proceeds. All capitalized terms used but not defined herein have the meanings given to them in the Uniform Commercial Code as in effect in any jurisdiction in which any of the Collateral may at the time be located (the "UCC"). Customer authorizes BESSE to file a UCC financing statement describing the Collateral as set forth in this Application. Customer will cooperate with BESSE or any successor secured party in obtaining control with respect to the Collateral, including Deposit Accounts, Investment Property, Letter-of-Credit rights, electronic chattel paper and the like. Customer hereby grants to BESSE an irrevocable power of attorney coupled with an interest for the purpose of exercising and perfecting any and all rights and remedies available to BESSE pursuant to this Application and applicable law, including enforcing Customer's rights against account debtors and obligors. Customer has the risk of loss of the Collateral. Customer will not make any sales, leases or other disposition of any of the Collateral except in the ordinary course of business. Customer will not grant any other security interest in any of the Collateral. Customer represents and warrants to BESSE that, as of the date hereof, this Application accurately sets forth (i) the state in which Customer's chief executive office is located, (ii) the state in which Customer's registration or certification documents are filed, and (iii) the organization ID or file number issued

by such state. Customer will not change the state of its certification or registration, or change its name, without first providing BESSE with thirty (30) days' prior written notice to give BESSE the opportunity to file whatever financing statements or other documents may be necessary or advisable to maintain the perfection and priority of its security interests in the Collateral.

**CREDITS AND RETURNS:** Credit for returned merchandise will be assessed upon receipt of the merchandise and only for items that are authorized for return by BESSE. Issuance of a return authorization does not guarantee credit will be issued. All credits will be reflected in Customer's account to apply toward future purchases. Customer must report any errors and/or discrepancies in orders within 48 hours of receipt for non-pharmaceutical items, and same day as receipt for pharmaceutical items. BESSE is not obligated to issue credit for errors on discrepancies not reported within such time period. Credits will be issued at the original purchase price shown on the invoice or current program price (whichever is less), less the amount of off-invoice allowances or adjustments, including but not limited to manufacturer restocking fees, restrictions and /or adjustments. Items returned due to Customer error or overstocking are subject to a handling charge. All returns must comply with these terms and conditions and all applicable laws, rules and regulations

**ORDERS AND SHIPPING:** Customer shall pay an additional shipping charge applicable to orders requesting upgraded, emergency and/or same day delivery of Product. BESSE will ship orders only to addresses reflected on a license that is current and valid under applicable law, or as otherwise permitted under applicable law.

**OWN USE:** Except as provided in writing by BESSE, Customer hereby represents and warrants that all products purchased from BESSE are intended for Customer's "Own Use" as that term is defined by the United States Supreme Court in *Abbott Labs. v. Portland Retail Druggists Assoc.*, 425 U.S. 1 (1976).

**GOVERNING LAW:** This Application shall be construed and enforced in accordance with the laws of the State of Ohio, without reference to its principles of conflict of laws. Customer agrees that BESSE may bring any legal or equitable action against Customer, and that Customer shall bring any legal or equitable action against BESSE, in any court of general jurisdiction in Butler County, Ohio. Customer irrevocably consents to personal jurisdiction, and waives any objection it may have to the laying of venue of any such action, in such court. Customer irrevocably agrees to service of process by certified mail, return receipt requested, to the address of Customer set forth on the attached business application or any related agreement.

**WAIVER OF JURY TRIAL:** EXCEPT AS PROHIBITED BY APPLICABLE LAW, THE PARTIES HEREBY WAIVE ANY AND ALL RIGHTS THEY MAY HAVE TO A JURY TRIAL IN CONNECTION WITH LITIGATION COMMENCED BY OR AGAINST BESSE WITH RESPECT TO THEIR RIGHTS AND OBLIGATIONS (1) UNDER THIS APPLICATION OR ANY OTHER AGREEMENT BETWEEN THE PARTIES AND (2) IN ANY MANNER CONNECTED WITH, RELATED TO OR INCIDENTAL TO TRANSACTIONS BETWEEN THE PARTIES, WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE.

**PRESCRIPTION DRUG MARKETING ACT OF 1987:** In accordance with the requirements of the Prescription Drug Marketing Act of 1987, as amended, Customer does hereby, and will, so long as it purchases products from BESSE, continue to certify, represent, warrant, agree and covenant to BESSE, with respect to all products to be returned to BESSE for credit on and after the date of this Application, that (1) all such products were purchased by Customer from BESSE; (2) the credit amount claimed by Customer and indicated on the credit memorandum and/or transmitted electronically to BESSE is no greater than the actual net acquisition price invoiced to or paid by Customer by BESSE for each product; (3) Customer shall provide any and all data and information, written or otherwise, requested by BESSE, including information requested by the product manufacturer; (4) until products are received by BESSE, such products have been properly stored, handled and shipped in accordance with all applicable laws, rules, regulations and standards; (5) Customer shall maintain documents that evidence each return of product to BESSE and the source from which the product was originally purchased for a period of three [3] years from the date such documents are created; and (6) Customer has established and will maintain sufficient and appropriate business policies and processes, including periodic audits and reviews, to ensure Customer's compliance with the foregoing certifications with respect to each product returned by Customer to BESSE. No modification or termination of this Application, or any part hereof shall be valid or effective unless agreed to and accepted in writing and signed by an authorized officer of BESSE.