PRODUCT INFORMATION  Company Name: AvKARE, INC Application: ANDA  Application Number for NDA/ANDA/BLA, Med Device: [201504
Application Number for NDA/ANDA/BLA, Med Device:   201504
Application Number for NDA/ANDA/BLA, Med Device: 201504  Rr. Product/Proprietary Name: Quetiapine Fumarate 25mg Tablet UD50  NDC: 50268-0630-15  CVX Code: Quetiapine Fumarate 25mg Tablet UD50  Description: Quetiapine Fumarate 25mg Tablet UD50  Active ingredients: VI. Controlled Room – between 20 and 25 C (68° – 77° F)  allows for excuse between 15 and 30 C (59° – 86° F)  V. Avoid Excessive Heat – above 40 C (100° + 8° F)  V. Avoid
NDC: 50268-0630-15 UPC: WX Code: MVX
NDC: 50268-0630-15 UPC: WX Code: MVX
Description:    Quetiapine Fumarate 25mg Tablet UD50
Active ingredients:  URL for Additional Product Information:  URL for Additional Product Information:  Address:  (S15 North First Street  City:  Pulaski  Key Contact:  Kim Bracey  Phone Number:  931-908-028  Fax:  931-928-029  I. Orange Book Rating:  III. Generic Equivalent for Brand:  Quetiapine Fumarite  DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  V. Avoid Excessive Heat – above 40 C (>104° F)  VI. Other Temperature Range Requirement  (write in)  VII. No Requirement  VII. No Requirement  b. Contact for temperature excursion questions:  Name:  Number:  St ibs product to be shipped to customers on ice?  Is this product to be shipped to customers on dry ice?  C. Special regulations for product in certain states?  Special returns requirements for this product?
Active ingredients:  URL for Additional Product Information:  URL for Additional Product Information:  Address:  615 North First Street  City:  Pulaski  State:  IN Zip:   38478  Key Contact:  Kim Bracey  Fox:   931-908-0028   Fax:   931-292-6229    I. Orange Book Rating:   AB
Contact:
URL for Additional Product Information:  Address:  615 North First Street  City:  Pulaski  Key Contact:  Kim Bracey  Phone Number:  931-908-0028  Fax:  931-928-6229  I. Orange Book Rating:  III. Generic Equivalent for Brand:  DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  VII. No Requirement  b. Contact for temperature excursion questions:  Name:  Number:  Number:  Is this product to be shipped to customers on ice?  Is this product to be shipped to customers on dry ice?  C. Special regulations for product in certain states?  Special returns requirements for this product?
Address: 615 North First Street  City: Pulaski State: IN Zip: 38478  Key Contact: Kim Bracey Email: kbracey@avkare.com 931-908-0028 Fax: 931-292-6229  I. Orange Book Rating: AB II. Brand Name: Seroquel  III. Generic Equivalent for Brand: Quetiapine Fumarate  DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  b. Contact for temperature excursion questions: Name: Name: Name: Share: Name: Name: Share: Sh
City: Pulaski State: IN Zip: 38478 Name: Number: S31-98-0028 Email: kbracey@avkare.com   S11-98-0028   Fax: 931-98-0229   Is this product to be shipped to customers on ice? Is this product to be shipped to customers on dry ice?  I. Orange Book Rating: AB II. Brand Name: Seroquel   II. Guetiapine Fumarie   Quetiapine Fumarie   Cuetiapine Fumari
Key Contact: Kim Bracey Email: kbracey@avkare.com   Number:   St his product to be shipped to customers on ice?
Phone Number: 931-908-0028 Fax: 931-292-6229 Is this product to be shipped to customers on ice?  I. Orange Book Rating: AB II. Brand Name: Seroquel  III. Generic Equivalent for Brand: Quetiapine Fumarate  DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  Special regulations for this product?  Special regulations for this product?
FOR GENERIC DRUG PRODUCTS  I. Orange Book Rating: AB II. Brand Name: Seroquel  III. Generic Equivalent for Brand: Quetiapine Fumarate  DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  Special returns requirements for this product?
I. Orange Book Rating: AB II. Brand Name: Seroquel III. Generic Equivalent for Brand: Quetiapine Fumarate  DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  C. Special regulations for product in certain states?  Special returns requirements for this product?
III. Generic Equivalent for Brand:  Quetiapline Fumarate  DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  C. Special regulations for product in certain states?  Special returns requirements for this product?
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Special returns requirements for this product?
Is product exempt from DSCSA?  No  d. Store product (unit of sale) upright?
If yes, select exemption:  Protect product (unit of sale) from light?
Tyes, select semption.  Other exemption - Write in:
Is product repackaged? Yes If Yes, was original product purchased direct from mfr? Yes e. Shelf life: Months
is product repackageur in the state of the s
Are any waivers granted for product ID/barcode? No If yes, attach documentation from FDA
ADDITIONAL PRODUCT INFORMATION ITEM AND PACKING INFORMATION
le the Product Direct Ship Item ORDER INFORMATION Dimensions (IIS memts.) Volume
Is the Product Direct Ship Trem    Ship Trem   Ship Trem   Weight Lbs.   Direct Ship Trem   Weight Lbs.   Depth Height Width: (Cube)
State Control?         No         Bottle         50 pills per box         Item:         0.5         2.00"         4.25"         3.25"
ARCOS reportable? No X Box/Carton 10 boxes per case
Co-Licensed?         No         Ampule         (Write-in, e.g. 1 Box of 10 Vials)         Box/
Controlled Substance? No Glass Carton:
Schedule No.? Tube Tube Minimum order quantity? Yes Case: 5 9.50" 4.50" 6.50"
Controlled Substance Code:
Hazardous Material/Cytotoxic Agent? No Vial Powder Sql Each
Vial Pours Multi
Vial Power Multi
Is Item Unit Dose Vial Power Multi Other: Write In It Unit Dose, is item bar coded to unit dose for
Vial Power Multi   Other Write In   Inner/Carton/Pack   UPC: Case:   UPC: Case:   Carton:   UPC: Case:   UP
Vial Power Multi
Is Item Unit Dose If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered?  Yes No PHARMACY ORDER / BILL UNIT Rec. sell unit to customer?  Size/Strength/Form:  Regular Cost Per Unit of Sale (\$) Invoice Cost (WAC) (\$) Federal Excise T. Unit of Sale
Is Item Unit Dose If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered?  WHOLESALER USE ONLY:  Vial Power Multi Other: Write In 1 Case: UPC: Case: Carton:  UPC: Case: Carton:  UPC: Case: Carton:  Ves Case: Carton:  Ves Case: Carton:  Ves Case: Carton:  Other Product Information Size/Strength/Form: Size/S
Is item Unit Dose If Unit Dose, is item bar coded to unit dose for hospital scanning?  Yes Is it reverse numbered?  WHOLESALER USE ONLY:  Vendor #:  Vial Power Multi Other: Write In  Inner/Carton/Pack Case  UPC: Case:  UPC: Case:  UPC: Case:  UPC: Case:  Other Product Information  Size/Strength/Form:  Size/Strength/Form:  Froduct Shape:  Froduct Shape:  Product Color:  S185.70  \$185.70  \$185.70
Is item Unit Dose If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered?  WHOLESALER USE ONLY:  Whole #:  Whole Sale (S)  Wile in, e.g. 1 Vial)  Rec. sell unit to customer?  Whole Sale (S)  Wile in, e.g. 1 Vial)  Rec. sell unit to customer?  Whole Sale (S)  Whole Sale (S)  Sale (S)  Sale (S)  Sale (S)  Sale (S)  Sale (S)  Federal Excise To Unit of Sale (S)  UPC: Case:  UPC: Case:  Carton:  COST INFORMATION  Invoice Cost (WAC) (S)  Federal Excise To Unit of Sale (S)  Unit of Sale (S)  Sale (S
Sitem   Unit Dose   If Unit Dose, is item bar coded to unit dose for hospital scanning?   Yes   PHARMACY ORDER / BILL UNIT   Size/Strength/Form:   Size/Strength/Form:   Size/Strength/Form:   Sol/Size/Strength/Form:   Sol/Size/Strength/Form:   Sol/Size/Strength/Form:   Sol/Size/Strength/Form:   Sol/Size/Strength/Form:   Sol/Size/Strength/Form:   Sol/Size/Strength/Form:   Sol/Strength/Form:   Sol/Size/Strength/Form:   Sol/Size/
Is item Unit Dose If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered?  WHOLESALER USE ONLY:  Whole Sale Whole S
Sitem