



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: ☐ New Item

☐ Final Version

Date: 7/5/16

PRODUCT INFORMATION			
Company Name: AvKARE, INC		Application: ANDA	
Application Number for NDA/ANDA/BLA, Med Device: 90548			
Rx Product/Proprietary Name: Atorvastatin 80mg Tablet UD20			
NDC: 50268-0096-12		UPC: 	
CVX Code: 		MVX Code: 	
Description: Atorvastatin 80mg Tablet UD20			
Active Ingredients: 			
URL for Additional Product Information: 			
Address: 615 North First Street		Address 2: 	
City: Pulaski		State: TN Zip: 38478	
Key Contact: Kim Bracey		Email: kbracey@avkare.com	
Phone Number: 931-908-0028		Fax: 931-292-6229	
FOR GENERIC DRUG PRODUCTS			
I. Orange Book Rating: AB		II. Brand Name: Lipitor	
III. Generic Equivalent for Brand: Atorvastatin Calcium			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION			
Does supplier meet DSCSA definition of manufacturer? Yes		DUNS: 796560394	
Is product exempt from DSCSA? No			
If yes, select exemption: Other exemption - Write in: 			
Is product repackaged? Yes If Yes, was original product purchased direct from mfr? Yes			
Is product sold by manufacturer's exclusive distributor? Yes			
Are any waivers granted for product ID/barcode? No If yes, attach documentation from FDA 			
ADDITIONAL PRODUCT INFORMATION		ITEM AND PACKING INFORMATION	
Is the Product... Direct and Drop Ship		Weight Lbs. 0.2	
Legend Device? No		Dimensions (US msmts.) Depth 2.00" Height 4.25" Width 3.25"	
State Control? No		Volume # Pieces: 1	
ARCOS reportable? No		Item: 0.2	
Co-Licensed? No		Box/ Carton: 	
Controlled Substance? No		Case: 5	
Schedule No.? 		Pallet: 	
(incl. N for non-narcotic)		UPC: 	
Controlled Substance Code: 			
Hazardous Material/Cytotoxic Agent? No			
Is Item... Unit Dose			
If Unit Dose, is item bar coded to unit dose for hospital scanning? Yes			
Is it reverse numbered? No			
WHOLESALE USE ONLY:		COST INFORMATION	
Vendor #: 		Regular Cost Per Unit of Sale (\$) \$38.08	
Whsl. Code #: 		Invoice Cost (WAC) (\$) \$10.46	
Fineline Code: 		Federal Excise Tax Per Unit of Sale 	
Rx billing unit to pharmacy: Each		As of date: 7/5/16	
Unit of Sale: Box/Carton			
What is the NDC selling unit? 20 pills per box			
Minimum order quantity? Yes			
If Yes, how many of which package type? 1			
Product Shape: oval			
Product Color: white			
Product Imprint: APO:ATV80			
Rec. sell unit to customer? UD20/80mg Tablet			
Size/Strength/Form: UD20/80mg Tablet			
Product Shape: oval			
Product Color: white			
Product Imprint: APO:ATV80			

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING AND BARCODE.

*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature: