



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION			
Company Name:	<input type="text" value="Citron Pharma LLC"/>	Application:	<input type="text" value="ANDA"/>
Application Number for NDA/ANDA/BLA, Med Device:	<input type="text" value="202726"/>		
Rx Product/Proprietary Name:	<input type="text" value="Gemfibrozil Tablets 600mg60"/>		
NDC:	<input type="text" value="57237-163-60"/>	UPC:	<input type="text" value="357237163603"/>
CVX Code:	<input type="text"/>	MVX Code:	<input type="text"/>
Description:	<input type="text" value="Gemfibrozil tablets, USP are indicated as adjunctive therapy to diet for treatment of adult patients with very high elevations of serum triglyceride levels (Types IV and V hyperlipidemia) who present a risk of pancreatitis and who do not respond adequately to"/>		
Active ingredients:	<input type="text"/>		
URL for Additional Product Information:	<input type="text"/>		
Address:	<input type="text" value="2 Tower Center Boulevard Suite 1101"/>	Address 2:	<input type="text"/>
City:	<input type="text" value="East Brunswick"/>	State:	<input type="text" value="NJ"/>
Key Contact:	<input type="text" value="Kaitlin Alexander"/>	Email:	<input type="text" value="kalexander@citronpharma.com"/>
Phone Number:	<input type="text" value="732-227-1515"/>	Fax:	<input type="text" value="732-227-1513"/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
<b>b. Contact for temperature excursion questions:</b>	
Name:	<input type="text" value="Vikram Ganesh"/>
Number:	<input type="text" value="732-917-6062"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
<b>c. Special regulations for product in certain states?</b>	
Special returns requirements for this product?	<input type="text" value="No"/>
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
<b>e. Shelf life:</b>	
<input type="text" value="24"/> Months	Initial shelf life at launch (if different): <input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AB"/>
II. Brand Name:	<input type="text" value="Lopid"/>
III. Generic Equivalent for Brand:	<input type="text" value="Gemfibrozil"/>

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
DUNS:	<input type="text" value="078731527"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="text" value="No"/>
If Yes, was original product purchased direct from mfr?	<input type="text"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/>
Are any waivers granted for product ID/barcode?	<input type="text" value="No"/>
If yes, attach documentation from FDA	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Legend Device?	<input type="text" value="No"/>	Unit of Sale	<input checked="" type="checkbox"/> Bottle
State Control?	<input type="text" value="No"/>	What is the NDC selling unit?	<input type="text" value="1 Bottle of 60"/>
ARCOS reportable?	<input type="text" value="No"/>	(Write-in, e.g. 1 Box of 10 Vials)	<input type="text"/>
Co-Licensed?	<input type="text" value="No"/>	Minimum order quantity?	<input type="text" value="Yes"/>
Controlled Substance?	<input type="text" value="No"/>	If Yes, how many of which package type?	<input type="text"/>
Schedule No.?	<input type="text"/>	<input type="text"/>	Each
(incl. N for non-narcotic)		<input type="text"/>	Inner/Cartron/Pack
Controlled Substance Code:	<input type="text"/>	<input type="text" value="1"/>	Case
Hazardous Material/Cytotoxic Agent?	<input type="text" value="No"/>		
Is Item... Unit of Use	<input type="text"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value="No"/>		
Is it reverse numbered?	<input type="text" value="No"/>		

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	0.174	1	3.58	1.875	6.7125	1
Box/ Carton:	2.189	7.953	3.858	6.063	186.029052	12
Case:	9.671	12.6	8.86	8.66	966.76776	48
Pallet:	806.775	48	49.213	40	94488.96	3840
UPC:	Case:	<input type="text" value="50357237163608"/>				
	Carton:	<input type="text"/>				

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION		
Vendor #:	<input type="text"/>	Rec. sell unit to customer?	<input type="text"/>	Size/Strength/Form:	<input type="text" value="60/600mg/Tablets"/>	Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)		Product Shape:	<input type="text" value="OVAL (Elliptical, Biconvex)"/>		\$10.42	
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	<input type="checkbox"/> Each	Product Color:	<input type="text" value="WHITE (White to Off-white)"/>			
		<input type="checkbox"/> Gram		Product Imprint:	<input type="text" value="E;82"/>			
		<input type="checkbox"/> Milliliter						
							As of date:	<input type="text"/>

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:



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NDC:	<input type="text" value="57237-163-05"/>	UPC:	<input type="text" value="357237163054"/>
CVX Code:	<input type="text"/>	MVX Code:	<input type="text"/>
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Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="text" value="No"/>
Is Item... Unit of Use	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value="No"/>
Is it reverse numbered?	<input type="text" value="No"/>

ORDER INFORMATION	
Unit of Sale	<input checked="" type="checkbox"/> Bottle
	<input type="checkbox"/> Box/Carton
	<input type="checkbox"/> Ampule
	<input type="checkbox"/> Glass
	<input type="checkbox"/> Tube
	<input type="checkbox"/> Vial Liquid Sgl
	<input type="checkbox"/> Vial Liquid Multi
	<input type="checkbox"/> Vial Powder Sgl
	<input type="checkbox"/> Vial Power Multi
	<input type="checkbox"/> Other: Write In <input type="text"/>
What is the NDC selling unit?	<input type="text" value="1 Bottle of 500"/>
(Write-in, e.g. 1 Box of 10 Vials)	
Minimum order quantity?	<input type="text" value="Yes"/>
If Yes, how many of which package type?	
	<input type="text"/>
	Each
	Inner/Carton/Pack
	Case
	<input type="text" value="1"/>

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	0.179	1	6.31	3.88	24.4828	1
Box/ Carton:	N/A	N/A	N/A	N/A	N/A	N/A
Case:	4.14	16.54	7.68	12.6	1600.54272	12
Pallet:	231.803	48	50.984	40	97889.28	576
UPC:	Case:	<input type="text" value="50357237163059"/>				
	Carton:					

WHOLESALE USE ONLY:	
Vendor #:	<input type="text"/>
Whsl. Code #:	<input type="text"/>
Fineline Code:	<input type="text"/>

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer?	Size/Strength/Form:
<input type="text" value="500/600mg/Tables"/>	<input type="text" value="500/600mg/Tables"/>
(Write-in, e.g. 1 Vial)	
Rx billing unit to pharmacy:	Product Shape:
<input type="checkbox"/> Each	<input type="text" value="OVAL (Elliptical, Biconvex)"/>
<input type="checkbox"/> Gram	Product Color:
<input type="checkbox"/> Milliliter	<input type="text" value="WHITE (White to Off-white)"/>
	Product Imprint:
	<input type="text" value="E;82"/>

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
<input type="text"/>	<input type="text" value="\$59.80"/>	<input type="text"/>
As of date: <input type="text"/>		

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.

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