



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Sciegen Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	211282
DUNS:	079391286
Proprietary Name (If Applicable) and Established Name:	Fluoxetine Tablets USP, 60 mg ,30's per Bottle
Selling Unit NDC:	50228-422-30
Individual Unit NDC:	1 Bottle
UPC:	350228442305
UDI	
CVX Code:	
MVX Code:	
Description:	white to off white, Capsule shape film coated tablet with scored line on both sides debossed with "SG 422" on one side and plain on other side.
Active Ingredient(s):	Fluoxetine Hydrochloride
URL for Additional Product Information:	
Address:	89 arkay drive
City:	Hauppauge
Key Contact:	Siva Reddy.P.V
Phone Number:	631-434-2723 XT 107, 631-524-5509
Product Therapeutic Classification:	Antidepressant
Application:	ANDA
State:	NY
Zip:	11788
Email:	sivareddyp@sciegenpharm.com
Fax:	631-357-3178

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Controlled Room – between 20 and 25 C (68° – 77° F)
Temperature Range	
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	Siva Reddy.P.V
Number:	631-434-2723 XT 107, 631-524-5509
Group E-mail:	sivareddyp@sciegenpharm.com
c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	Yes
Protect product (unit of sale) from light?	No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product... Direct-Ship Only	
Is the Product... Unit of Use	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose NDC, indicate NDC here:	
Country of Origin	USA
Is this product covered under the Trade Agreements Act (TAA)?	Yes

PRODUCT DESCRIPTION INFORMATION	
Size:	0.2400" X 0.5550"
Strength:	60mg
Dosage Form:	Tablets
Product Shape:	Capsule
Product Color:	White to off white
Product Imprint:	"SG 422" on one side and plain on other side.

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Yes Bottle	1 Bottle of 30 Tablets
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<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	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	24 Bottles Each
	per Case Inner/ Carton/Pack
	3 Cases Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Fluoxetine HCl by alvogen
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="Bottle"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	
Has FDA granted waiver/exception/exemption for product?	No
GLN:	350228000000
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.07	NA	2.8	1.6	#VALUE!	30 Tablets per Bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	2.3	11.5	4.1	7.4	348.91	24 Bottles per Case
Pallet:	390	48	48	40	92160	152 Cases per Pallet
UPC:	Case:	350228442305				
	Carton:					

GTIN PRODUCT INFORMATION							
Serialized?	Level	Saleable Unit	Quantity	GTIN-14			
Yes	<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/>	2D	<input checked="" type="checkbox"/>	1	00350228442305
If not, when?		Box/Carton/Bundle/Inner Pack		2D			
Items aggregated?	No	Case	<input checked="" type="checkbox"/>	2D	<input checked="" type="checkbox"/>	24	20350228442309
		Pallet		2D			
				2D			
				2D			
				2D			
				2D			
				2D			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

For Designated Drop Ship Only Products, Please Use Page 3
MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):
a. Cytotoxic? No
b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No
Is the product a CA Prop 65 carcinogen? No
Is the product a CA Prop 65 reproductive toxicant? No
Does the product label bear a CA Prop 65 warning? No
c. Contact Hazard? No
d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.)
e. Does the product contain DEHP? No
Is this product regulated for shipment by DOT or IATA? No

(if yes, answer a-e below and provide SDS)
a. UN/Identification Number
b. Proper Shipping Name
c. DOT Hazard Class
d. Packing Group
e. Inhalation Hazard? No

Is the product restricted for air shipment? If so, indicate restriction:
Passenger
Cargo
Passenger & Cargo

Is this a reportable quantity?
RQ Threshold:
Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?
(if yes, identify method below)
Limited Quantity
Consumer Commodity, ORM-D
Small Quantity (49 CFR 173.4)
Special Permit; DOT-SP
Special Provision (listed in Column 7 of 49 CFR 172.101);
SP#

ADD'L STORAGE INFORMATION

Is the Product...
Controlled Substance? No
Controlled by State(s)? No
ARCOS Reportable?
Schedule No. (inc. N for non-narcotic)
Controlled Substance Code
Listed Chemical (List I or II)
If yes, indicate which:
Is it a scheduled listed chemical product?:

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
Restricted to retail pharmacy only:
Restricted to hospital, clinics, and physician offices only:
Restricted from US territories? (explain in comments)
Comments:

SDS Hazard Classification
[X] Organic
Inorganic
Steroid/Androgen
Corrosive
Oxidizer
Contact Hazard
Aerosol Class; Identify NFPA Storage Level:
Is the product a NIOSH hazardous drug? No
If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No
If Yes, is it managed with a pharmacy registry?
Website URL:

Comments / Details: (For example, iPledge program?)

REMS:
REMS Program Manager Name:
Supplier Manages REMS registry exclusively:
Wholesale distributor support:
Provider Name:
Site Enrollment Number assigned by Supplier:
Phone:
DEA #:
PCPDP #:
NPI #:

Comments

Registry:
Registry Program Contact Name:
Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1877-671-6307

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

