



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Sciegen Pharmaceuticals Inc
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	212517
DUNS:	079391286
Proprietary Name (If Applicable) and Established Name:	Naproxen Tablets USP, 500 mg, 100's (BS=1,200,000)
Selling Unit NDC:	50228-436-01
Individual Unit NDC:	1 Bottle
UPC:	350228436014
UDI	
CVX Code:	
MVX Code:	
Description:	Light Yellow Oblong shaped tablets debossed with "SG" along with break-line on one side and "436" on the other side
Active Ingredient(s):	Naproxen
URL for Additional Product Information:	
Address:	89 Arkay Drive
City:	Hauppauge
Key Contact:	Siva Reddy, P.V.
Phone Number:	631-424-2727 XT 107, 631-524-5509
Product Therapeutic Classification:	Non steroidal anti inflammatory
State:	NY
Zip:	11788
Email:	sivareddy@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:	631-424-2727 XT 107, 631-524-5509
Group E-mail:	sivareddy@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?	
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:	0.2835 x 0.6260
Strength:	500 mg
Dosage Form:	Tablet
Product Shape:	Oblong
Product Color:	Light Yellow
Product Imprint:	SG and 436 with breakline

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	50228-436-01
<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 Powder Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	Each
	Inner/Cartron/Pack
	3 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Naprosyn (Naproxen) Tablets
<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="checkbox"/> 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?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	035022800000
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.16	NA	3.3	1.9	#VALUE!	Tablets per B
Box/Cartron/Bundle/Inner Pack:	NA	NA	NA	NA	NA	NA
Case:	4.8	12.1	4.5	8.2	446.49	Bottles per ca
Pallet:	812	48	48	40	92160	Cases per P
UPC:	Case:	350228436014				
	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	00350228436014
If not, when?		Box/Cartron/Bundle/Inner Pack		2D			
Items aggregated?	No	Case	<input checked="" type="checkbox"/>	2D	<input checked="" type="checkbox"/>	24	20350228436018
		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?
 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?
 (if yes, answer a-e below and provide SDS) No

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?
 No (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... No

- 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

Organic
 Inorganic
 Steroid/Androgen

Corrosive
 Oxidizer
 Contact Hazard

Aerosol Class; Identify NFPA Storage Level: []

Is the product a NIOSH hazardous drug?
 If yes, indicate which: No

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: [] Phone: []

Supplier Manages REMS registry exclusively: []

Wholesale distributor support:
 Provider Name: []

Site Enrollment Number assigned
 by Supplier: []

DEA #: []

PCPDP #: []

NPI #: []

Comments: []

Registry: []

Registry Program Contact Name: [] Phone: []

Comments: []

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 631-524-5509

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:

[]

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing																																		
<p>Purchase orders may be accepted by:</p> <table style="width: 100%;"> <tr> <td style="width: 20%;">a. EDI</td> <td style="width: 10%;"><input type="checkbox"/></td> <td style="width: 20%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>b. Autofax</td> <td><input type="checkbox"/></td> <td>Fax Number:</td> <td colspan="3"><input type="text"/></td> </tr> <tr> <td>c. Fax</td> <td><input type="checkbox"/></td> <td>Fax Number:</td> <td colspan="3"><input type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td><input type="checkbox"/></td> <td>Phone No.:</td> <td colspan="3"><input type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="checkbox"/></td> <td>Site Address:</td> <td colspan="3"><input type="text"/></td> </tr> </table> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%;"> <tr> <td style="width: 20%;">Name:</td> <td><input type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input type="text"/></td> </tr> </table>	a. EDI	<input type="checkbox"/>					b. Autofax	<input type="checkbox"/>	Fax Number:	<input type="text"/>			c. Fax	<input type="checkbox"/>	Fax Number:	<input type="text"/>			d. Phone only	<input type="checkbox"/>	Phone No.:	<input type="text"/>			e. Supplier Web Site only	<input type="checkbox"/>	Site Address:	<input type="text"/>			Name:	<input type="text"/>	Phone:	<input type="text"/>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
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e. Supplier Web Site only	<input type="checkbox"/>	Site Address:	<input type="text"/>																																
Name:	<input type="text"/>																																		
Phone:	<input type="text"/>																																		
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																																		
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 20%;">Phone #:</td> <td style="width: 10%;"><input type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input type="text"/></td> <td>Fax #:</td> <td><input type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input type="text"/>	Phone #:	<input type="text"/>	Fax:	<input type="text"/>	Fax #:	<input type="text"/>	EDI:	<input type="text"/>														
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Class of Trade Restriction:	Return Instructions																																		
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Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																																		
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>																																		
Miscellaneous Notes:																																			
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