



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc. Application: ANDA
Application Number for NDA/ANDA/BLA, Med Device:	90-403
Rx Product/Proprietary Name:	Indomethacin Capsules, USP 25mg 100 count
NDC:	68382-293-01 UPC: 368382293015
CVX Code:	MXV Code:
Description:	green colored cap imprinted with "293" in black ink and green colored body imprinted with "25 mg" in black ink.
Active ingredients:	Indomethacin
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North Address 2:
City:	Pennington State: NJ Zip: 08534
Key Contact:	Email:
Phone Number:	(609) 730 1900 Fax: (609) 730 1991

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<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="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	_____
Number:	_____
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
c. Special regulations for product in certain states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
<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:	AB II. Brand Name: Indomethacin
III. Generic Equivalent for Brand:	Indomethacin Capsules, USP 25mg 100 count

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes DUNS: 156861945
Is product exempt from DSCSA?	No
If yes, select exemption:	_____
Other exemption - Write in:	_____
Is product repackaged?	No If Yes, was original product purchased direct from mfr? _____
Is product sold by manufacturer's exclusive distributor?	No
Are any waivers granted for product ID/barcode?	No If yes, attach documentation from FDA

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Box/ Carton:	57 g		3.127	1.922	6.010094	
Case:	4.90 lbs	8.07	4.8	11.89	460.57104	24
Pallet:	577 lbs	47	39	47	86151	112
UPC:	Case:					
	Carton:					

PHARMACY ORDER / BILL UNIT		Other Product Information	
Rec. sell unit to customer?	_____ (Write-in, e.g. 1 Vial)	Size/Strength/Form:	100/25mg/Capsule
Rx billing unit to pharmacy:	<input checked="" type="checkbox"/> Each	Product Shape:	Capsule
	<input type="checkbox"/> Gram	Product Color:	Green
	<input type="checkbox"/> Milliliter	Product Imprint:	"293" & "25 mg"

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$19.10	
As of date: <input type="text" value="8/2/2016"/>		

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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PRODUCT INFORMATION			
Company Name:	<input type="text" value="Zydus Pharmaceuticals USA Inc."/>	Application:	<input type="text" value="ANDA"/>
Application Number for NDA/ANDA/BLA, Med Device:	<input type="text" value="90-403"/>		
Rx Product/Proprietary Name:	<input type="text" value="Indomethacin Capsules, USP 25mg 1000 count"/>		
NDC:	<input type="text" value="68382-293-10"/>	UPC:	<input type="text" value="368382293107"/>
CVX Code:	<input type="text"/>	MVX Code:	<input type="text"/>
Description:	<input type="text" value="green colored cap imprinted with '293' in black ink and green colored body imprinted with '25 mg' in black ink."/>		
Active ingredients:	<input type="text" value="Indomethacin"/>		
URL for Additional Product Information:	<input type="text" value="www.zydususa.com"/>		
Address:	<input type="text" value="73 Route 31 North"/>	Address 2:	<input type="text"/>
City:	<input type="text" value="Pennington"/>	State:	<input type="text" value="NJ"/>
Key Contact:	<input type="text"/>	Zip:	<input type="text" value="08534"/>
Phone Number:	<input type="text" value="(609) 730 1900"/>	Email:	<input type="text"/>
		Fax:	<input type="text" value="(609) 730 1991"/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<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. Contact for temperature excursion questions:	
Name:	<input type="text"/>
Number:	<input type="text"/>
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"/>
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	
<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="Indomethacin"/>
III. Generic Equivalent for Brand:	<input type="text" value="Indomethacin Capsules, USP 25mg 1000 count"/>

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/> Yes <input type="text" value="156861945"/> DUNS:
Is product exempt from DSCSA?	<input type="text" value="No"/> No
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="text" value="No"/> No <input type="text" value=""/> If Yes, was original product purchased direct from mfr?
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/> No <input type="text" value=""/> If yes, attach documentation from FDA
Are any waivers granted for product ID/barcode?	<input type="text" value="No"/> No <input type="text" value=""/> If yes, attach documentation from FDA

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	343 g		6.55	3.93	25.7415	
Box/ Carton:					0	
Case:	14.30 lbs	11.81	9.76	15.75	1815.4332	12
Pallet:	473 lbs	47	39	47	86151	32
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information	
Vendor #:	<input type="text"/>	Rec. sell unit to customer?	<input type="text"/>	Size/Strength/Form:	<input type="text" value="1000/25mg/Capsule"/>
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)		Product Shape:	<input type="text" value="Capsule"/>
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	<input checked="" type="checkbox"/> Each	Product Color:	<input type="text" value="Green"/>
		<input type="checkbox"/> Gram		Product Imprint:	<input type="text" value="'293' & '25 mg'"/>
		<input type="checkbox"/> Milliliter			

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$181.45	
As of date: <input type="text" value="8/2/2016"/>		

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: