



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:	91352
Rx Product/Proprietary Name:	Omeprazole Delayed-Release Capsules, USP 20mg, 30 ct
NDC:	68382-412-06
UPC:	368382412065
CVX Code:	
MX Code:	
Description:	White to off-white free flowing pellets filled in size '2' hard gelatin capsules with tan-colored cap printed with "ZA-10" in black ink & white body printed with "20 mg" in black ink.
Active ingredients:	Omeprazole
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="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:	AB
II. Brand Name:	Prilosec
III. Generic Equivalent for Brand:	Omeprazole Delayed-Release Capsules, USP 20mg, 30 ct

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

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="checkbox"/>
Legend Device?	<input type="checkbox"/> No
State Control?	<input type="checkbox"/> No
ARCOS reportable?	<input type="checkbox"/> No
Co-Licensed?	<input type="checkbox"/> No
Controlled Substance?	<input type="checkbox"/> No
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="checkbox"/> No
Is Item...	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
Is it reverse numbered?	<input type="checkbox"/>

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 Powder Multi
	<input type="checkbox"/> Other: Write In <input type="text"/>
What is the NDC selling unit?	Each
(Write-in, e.g. 1 Box of 10 Vials)	<input type="text"/>
Minimum order quantity?	<input type="checkbox"/> 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:	32.0 G		2.375	1.531	3.63613	
Box/ Carton:					0	
Case:	2.97LBS	6.22	3.43	9.33	199.051818	24
Pallet:		47.24	47	39.37	87412.4236	
UPC:	Case:					
	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"/>	30ct/20mg/Capsule
(Write-in, e.g. 1 Vial)	
Rx billing unit to pharmacy:	Product Shape:
<input checked="" type="checkbox"/> Each	Capsule
<input type="checkbox"/> Gram	Product Color:
<input type="checkbox"/> Milliliter	Tan/White
	Product Imprint:
	ZA 10 20mg

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$11.01	
As of date: <input type="text" value="4/28/2015"/>		

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:



Standard Pharmaceutical Product Information (Page 2)

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

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No
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# _____

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class _____

b. UN/ID Number _____

c. Packing Group _____

d. Inhalation Hazard? _____

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

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	Yes	Level	How?	RFID	GTIN-14	
Serialized?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	10368382412062
If not, when?	_____	<input checked="" type="checkbox"/> Box/ Carton	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	_____
Items aggregated to case?	<input type="checkbox"/>	<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	_____
		<input checked="" type="checkbox"/> Pallet	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	_____

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product?	<u>No</u>
If Yes, is it managed with a pharmacy registry?	_____
Website URL:	_____
Comments / Details: (For example, iPledge program?)	

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level: _____

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	<u>877-993-8779</u>
Is product returnable for credit:	<input type="checkbox"/>
URL/Link to returns policy:	<u>www.zydususa.com</u>
Special regulations or returns requirements for this product in certain states?	<u>No</u>
If so, which states? Other requirements? Comments?	_____

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other: _____

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments: _____

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here: _____

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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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:	91352
Rx Product/Proprietary Name:	Omeprazole Delayed-Release Capsules, USP 20mg, 100 ct
NDC:	68382-412-01
UPC:	368382412010
CVX Code:	
MX Code:	
Description:	White to off-white free flowing pellets filled in size '2' hard gelatin capsules with tan-colored cap printed with "ZA-10" in black ink & white body printed with "20 mg" in black ink.
Active ingredients:	Omeprazole
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
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?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="checkbox"/> 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:	Prilosec
III. Generic Equivalent for Brand:	Omeprazole Delayed-Release Capsules, USP 20mg, 100 ct

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

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="checkbox"/>
Legend Device?	<input type="checkbox"/> No
State Control?	<input type="checkbox"/> No
ARCOS reportable?	<input type="checkbox"/> No
Co-Licensed?	<input type="checkbox"/> No
Controlled Substance?	<input type="checkbox"/> No
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="checkbox"/> No
Is Item... _____	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
Is it reverse numbered?	<input type="checkbox"/>

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 _____
What is the NDC selling unit?	Each
(Write-in, e.g. 1 Box of 10 Vials)	_____
Minimum order quantity?	<input type="checkbox"/> 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:	55.0 G		3.127	1.922	6.01009	
Box/ Carton:					0	
Case:	4.80LBS	7.76	4.61	11.57	413.900552	24
Pallet:		47.24	47	39.37	87412.4236	
UPC:	Case:					
	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? <input type="checkbox"/>	Size/Strength/Form:
<input type="text"/>	100ct/20mg/Capsule
(Write-in, e.g. 1 Vial)	Product Shape: Capsule
Rx billing unit to pharmacy:	Product Color: Tan/White
<input checked="" type="checkbox"/> Each	Product Imprint: ZA 10 20mg
<input type="checkbox"/> Gram	
<input type="checkbox"/> Milliliter	

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$36.71	
As of date: <input type="text" value="4/28/2015"/>		

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: _____



Standard Pharmaceutical Product Information (Page 2)

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

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No
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#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	Yes	Level	How?	RFID	GTIN-14	
Serialized?	<input checked="" type="checkbox"/>	Item	2D	Linear	<input type="checkbox"/>	10368382412017
If not, when?	<input type="text"/>	Box/ Carton	2D	Linear	<input type="checkbox"/>	
Items aggregated to case?	<input type="text"/>	Case	2D	Linear	<input type="checkbox"/>	
		Pallet	2D	Linear	<input type="checkbox"/>	

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?)

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 877-993-8779

Is product returnable for credit:

URL/Link to returns policy: www.zydususa.com

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

If so, which states? Other requirements? Comments?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Rx Product Only)

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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:	91352
Rx Product/Proprietary Name:	Omeprazole Delayed-Release Capsules, USP 20mg, 500 ct
NDC:	68382-412-05
UPC:	368382412058
CVX Code:	
MVX Code:	
Description:	White to off-white free flowing pellets filled in size '2' hard gelatin capsules with tan-colored cap printed with "ZA-10" in black ink & white body printed with "20 mg" in black ink.
Active ingredients:	Omeprazole
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="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:	AB
II. Brand Name:	Prilosec
III. Generic Equivalent for Brand:	Omeprazole Delayed-Release Capsules, USP 20mg, 500 ct

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

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Legend Device?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
State Control?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
ARCOS reportable?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Co-Licensed?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Controlled Substance?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is Item...	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is it reverse numbered?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	165.00 G		5.734	3.047	17.471498	
Box/ Carton:					0	
Case:	7.3 LBS	9.13	7.48	12.2	833.16728	12
Pallet:		47.24	47	39.37	87412.4236	
UPC:	Case:					
	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? <input type="checkbox"/>	Size/Strength/Form:
<input type="text"/>	500ct/20mg/Capsule
(Write-in, e.g. 1 Vial)	Product Shape:
Rx billing unit to pharmacy:	Capsule
<input checked="" type="checkbox"/> Each	Product Color:
<input type="checkbox"/> Gram	Tan/White
<input type="checkbox"/> Milliliter	Product Imprint:
	ZA 10 20mg

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$183.51	
As of date: <input type="text" value="3/2/2015"/>		

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:



Standard Pharmaceutical Product Information (Page 2)

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

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No
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#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	Yes	Level	How?	RFID	GTIN-14	
Serialized?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	10368382412055
If not, when?	<input type="text"/>	<input checked="" type="checkbox"/> Box/ Carton	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	
Items aggregated to case?	<input type="text"/>	<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	
		<input checked="" type="checkbox"/> Pallet	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	

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?)

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 877-993-8779

Is product returnable for credit:

URL/Link to returns policy: www.zydususa.com

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

If so, which states? Other requirements? Comments?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/></p>	<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>
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 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> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <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: <input type="checkbox"/> Phone: <input type="text"/> Phone #: <input type="text"/></p> <p><input type="checkbox"/> Fax: <input type="text"/> Fax #: <input type="text"/></p> <p><input type="checkbox"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
REMS or Registry Restrictions	Return Instructions
<p>REMS: <input type="checkbox"/></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/></p> <p>Wholesale distributor support: <input type="checkbox"/></p> <p>Provider Name: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>DEA #: <input type="text"/></p> <p>PCPDP #: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments: <input type="text"/></p> <p>Registry: <input type="checkbox"/></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
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:	
<input type="text"/>	



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:	91352
Rx Product/Proprietary Name:	Omeprazole Delayed-Release Capsules, USP 20mg, 1000 ct
NDC:	68382-412-10
UPC:	368382412102
CVX Code:	
MX Code:	
Description:	White to off-white free flowing pellets filled in size '2' hard gelatin capsules with tan-colored cap printed with "ZA-10" in black ink & white body printed with "20 mg" in black ink.
Active ingredients:	Omeprazole
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Phone Number:	(609) 730 1900
Email:	
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="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:	AB
II. Brand Name:	Prilosec
III. Generic Equivalent for Brand:	Omeprazole Delayed-Release Capsules, USP 20mg, 1000 ct

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

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="checkbox"/>
Legend Device?	<input type="checkbox"/> No
State Control?	<input type="checkbox"/> No
ARCOS reportable?	<input type="checkbox"/> No
Co-Licensed?	<input type="checkbox"/> No
Controlled Substance?	<input type="checkbox"/> No
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	<input type="checkbox"/> No
Is Item...	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
Is it reverse numbered?	<input type="checkbox"/>

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?	Each
(Write-in, e.g. 1 Box of 10 Vials)	<input type="text"/>
Minimum order quantity?	<input type="text" value="1"/> Yes
If Yes, how many of which package type?	<input type="text"/>
	Each
	Inner/Carton/Pack
	Case

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	265.00 G		5.827	3.927	22.8826	
Box/ Carton:					0	
Case:	11.79LBS	11.81	7.68	15.75	1428.5376	12
Pallet:		47.24	47	39.37	87412.4236	
UPC:	Case:					
	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"/>	1000ct/20mg/Capsule
(Write-in, e.g. 1 Vial)	Product Shape:
Rx billing unit to pharmacy:	Capsule
<input checked="" type="checkbox"/> Each	Product Color:
<input type="checkbox"/> Gram	Tan/White
<input type="checkbox"/> Milliliter	Product Imprint:
	ZA 10 20mg

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$367.02	
As of date: <input type="text" value="4/28/2015"/>		

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:



Standard Pharmaceutical Product Information (Page 2)

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

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity? No
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#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	Yes	Level	How?	RFID	GTIN-14	
Serialized?	<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID	10368382412109	
If not, when?	<input type="text"/>	Box/ Carton	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID		
Items aggregated to case?	<input type="text"/>	Case	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID		
		Pallet	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID		

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?)

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 877-993-8779

Is product returnable for credit:

URL/Link to returns policy: www.zydususa.com

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

If so, which states? Other requirements? Comments?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> _____ b. Autofax <input type="checkbox"/> _____ Fax Number: _____ c. Fax <input type="checkbox"/> _____ Fax Number: _____ d. Phone only <input type="checkbox"/> _____ Phone No.: _____ e. Supplier Web Site only <input type="checkbox"/> _____ Site Address: _____ Minimum Order Quantity: _____ Supplier's Customer Service Number: _____ Contracted 3PL company / contact #: _____ Name: _____ Phone: _____	Purchase order daily receipt cut off time by supplier Cut off time: _____ Shipping lead time of PO: _____ Hours _____ Days Ships same day for next day receipt: <input type="checkbox"/> _____ Ships for second day receipt: <input type="checkbox"/> _____ Ships regular ground for 3-10 days receipt: <input type="checkbox"/> _____
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: _____ Drop Ship service fee billed with each order: _____ Drop Ship miscellaneous fees billed: _____ Comments: _____	Overnight receipt available: <input type="checkbox"/> _____ PO Receipt cut off time: _____ Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> _____ PO Receipt Cut off time: _____ Saturday Overnight receipt available: <input type="checkbox"/> _____ PO Receipt Cut off time: _____ Order receipt method: Phone: _____ Phone #: _____ Fax: _____ Fax #: _____ EDI: _____ Overnight Fees apply: <input type="checkbox"/> _____ Other fees apply: <input type="checkbox"/> _____
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> _____ Restricted to retail pharmacy only: <input type="checkbox"/> _____ Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> _____ Restricted from US territories? (explain in comments) <input type="checkbox"/> _____ Comments: _____	
REMS or Registry Restrictions	Return Instructions
REMS: _____ REMS Program Manager Name: _____ Phone: _____ Supplier Manages REMS registry exclusively: <input type="checkbox"/> _____ Wholesale distributor support: <input type="checkbox"/> _____ Provider Name: _____ Site Enrollment Number assigned by Supplier: _____ DEA #: _____ PCPDP #: _____ NPI #: _____ Comments: _____ Registry: _____ Registry Program Contact Name: _____ Phone: _____ Comments: _____	Contact # if product is received damaged: _____ Is product returnable for credit: <input type="checkbox"/> _____ URL/Link to returns policy: _____ Special regulations or returns requirements for this product in certain states? _____ If so, which states? Other requirements? Comments? _____
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
Patient Procedure Date: _____ Physician Name: _____ Physician/Clinic Phone #: _____ Physician State License #: _____ Physician/Clinic DEA #: _____ Physician/Clinic Specialty: _____	Miscellaneous Notes: _____