



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

| 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="77-751"/> | | |
| Rx Product/Proprietary Name: | <input type="text" value="Pravastatin Sodium Tablets, 20 mg 90's"/> | | |
| NDC: | <input type="text" value="68382-071-16"/> | UPC: | <input type="text" value="368382071163"/> |
| CVX Code: | <input type="text"/> | MVX Code: | <input type="text"/> |
| Description: | <input type="text" value="White to off-white, oval-shaped, bioconvex uncoated tablets debossed with the logo of 'ZC45' on one side and plain on the other side."/> | | |
| Active ingredients: | <input type="text" value="Pravastatin Sodium"/> | | |
| 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"/> | Email: | <input type="text"/> |
| Phone Number: | <input type="text" value="(609) 730 1900"/> | 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="Pravachol"/> |
| III. Generic Equivalent for Brand: | <input type="text" value="Pravastatin Sodium Tablets, 20 mg 90's"/> |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | |
|--|--|
| Does supplier meet DSCSA definition of manufacturer? | <input type="text" value="Yes"/> |
| DUNS: | <input type="text" value="156861945"/> |
| 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... Direct Ship Item | <input type="text"/> | Unit of Sale | <input checked="" type="checkbox"/> Bottle |
| Legend Device? | <input type="text" value="No"/> | What is the NDC selling unit? | <input type="text" value="Each"/> |
| State Control? | <input type="text" value="No"/> | (Write-in, e.g. 1 Box of 10 Vials) | <input type="text"/> |
| ARCOS reportable? | <input type="text" value="No"/> | Minimum order quantity? | <input type="text" value="Yes"/> |
| Co-Licensed? | <input type="text" value="No"/> | If Yes, how many of which package type? | <input type="text"/> |
| Controlled Substance? | <input type="text" value="No"/> | <input type="text"/> | Each |
| Schedule No.? | <input type="text"/> | <input type="text"/> | Inner/ Carton/Pack |
| (incl. N for non-narcotic) | | <input type="text" value="1"/> | Case |
| Controlled Substance Code: | <input type="text"/> | | |
| Hazardous Material/Cytotoxic Agent? | <input type="text" value="No"/> | | |
| 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: | 37.00 G | | 3.025 | 1.615 | 4.88538 | |
| Box/ Carton: | | | | | 0 | |
| Case: | 3.29LBS | 7.76 | 4.06 | 11.54 | 363.574624 | 24 |
| Pallet: | | 47.24 | 50.39 | 39.37 | 93717.2771 | 144 |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

| WHOLESALE USE ONLY: | | PHARMACY ORDER / BILL UNIT | Other Product Information |
|---------------------|----------------------|-----------------------------|---|
| Vendor #: | <input type="text"/> | Rec. sell unit to customer? | Size/Strength/Form: |
| Whsl. Code #: | <input type="text"/> | <input type="text"/> | <input type="text" value="90ct/20mg/Tablets"/> |
| Fineline Code: | <input type="text"/> | (Write-in, e.g. 1 Vial) | Product Shape: |
| | | | <input type="text" value="Oval"/> |
| | | | Product Color: |
| | | | <input type="text" value="White to off white"/> |
| | | | Product Imprint: |
| | | | <input type="text" value="ZC45"/> |

| COST INFORMATION | | |
|--|-------------------------|-------------------------------------|
| Regular Cost Per Unit of Sale (\$) | Invoice Cost (WAC) (\$) | Federal Excise Tax Per Unit of Sale |
| | \$44.11 | |
| As of date: <input type="text" value="9/10/2014"/> | | |

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

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

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 PRODUCT INFORMATION - Serialization

| Serialized? | Yes | Level | | How? | | GTIN-14 | |
|---------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--------------------------|--------------------------|---------|-----------------------|
| | | Item | 2D | Linear | RFID | | |
| Serialized? | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | RFID | 10368382071160 |
| If not, when? | <input type="text"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | RFID | |
| Items aggregated to case? | <input type="text"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | RFID | |
| | | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <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?)

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?

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Rx Product Only)

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Final Version

Date:

| PRODUCT INFORMATION | |
|--|--|
| Company Name: | Zydus Pharmaceuticals USA Inc. |
| Application: | ANDA |
| Application Number for NDA/ANDA/BLA, Med Device: | 77-751 |
| Rx Product/Proprietary Name: | Pravastatin Sodium Tablets, 20 mg 500's |
| NDC: | 68382-071-05 |
| UPC: | 368382071057 |
| CVX Code: | |
| MVX Code: | |
| Description: | White to off-white, oval-shaped, biconvex uncoated tablets debossed with the logo of 'ZC45' on one side and plain on the other side. |
| Active ingredients: | Pravastatin Sodium |
| 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: | Pravachol |
| III. Generic Equivalent for Brand: | Pravastatin Sodium Tablets, 20 mg 500's |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | |
|--|---|
| Does supplier meet DSCSA definition of manufacturer? | <input checked="" type="text" value="Yes"/> |
| DUNS: | 156861945 |
| 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 | |
|---|---------------------------------|
| Is the Product... Direct Ship Item | <input type="text"/> |
| Legend Device? | <input type="text" value="No"/> |
| State Control? | <input type="text" value="No"/> |
| ARCOS reportable? | <input type="text" value="No"/> |
| Co-Licensed? | <input type="text" value="No"/> |
| Controlled Substance? | <input type="text" value="No"/> |
| 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... | <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"/> |

| 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="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: | 129.00 G | | 3.97 | 2.21 | 8.7737 | |
| Box/ Carton: | | | | | 0 | |
| Case: | 4.71LBS | 7.64 | 5 | 10.12 | 386.584 | 12 |
| Pallet: | | 47.24 | 50.39 | 39.37 | 93717.2771 | 126 |
| 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"/> | 500ct/20mg/Tablets |
| (Write-in, e.g. 1 Vial) | |
| Rx billing unit to pharmacy: | Product Shape: |
| <input checked="" type="checkbox"/> Each | Oval |
| <input type="checkbox"/> Gram | Product Color: |
| <input type="checkbox"/> Milliliter | White to off white |
| | Product Imprint: |
| | ZC45 |

| COST INFORMATION | | |
|--|-------------------------|-------------------------------------|
| Regular Cost Per Unit of Sale (\$) | Invoice Cost (WAC) (\$) | Federal Excise Tax Per Unit of Sale |
| | \$245.03 | |
| As of date: <input type="text" value="9/10/2014"/> | | |

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"/> | 10368382071054 |
| 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:

