Standard Pharmaceutical Product Information (Rx Product Only)

**PRODUCT INFORMATION**

**Company Name:** Zydus Pharmaceuticals USA Inc.  
**Application for NDA/ANDA/BLA, Med Device:** 91352  
**Rx Product/Proprietary Name:** Omeprazole Delayed-Release Capsules, USP 20mg, 30 ct  
**NDC:** 68382-412-06  
**UPC:** 365362412065  
**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

**SPECIAL HANDLING AND STORAGE REQUIREMENTS**

**a. Temperature – Indicate the USP temperature range for this product.**

- **I. Freezer –** between -25 and -10 C (-13° – 14° F)
- **II. Cold –** between 2 and 8 C (36° – 46° F)
- **III. Cool –** between 8 and 15 C (46° – 59° F)
- **IV. Controlled Room –** between 20 and 25 C (68° – 77° F)
- **V. Avoid Excessive Heat –** above 40 C (>104° F)
- **VI. Other Temperature Range Requirement** (write in)

**b. Contact for temperature excursion questions:**

- **Name:**  
- **Number:** (609) 730 1991  
- **Fax:** (609) 730 1991

**c. Special regulations for product in certain states?**

- **No**

**d. Special returns requirements for this product?**

- **No**

**e. Shelf life:** 24 Months  
**Initial shelf life at launch (if different):**

**ADDITIONAL PRODUCT INFORMATION**

**Is the Product...**

- **Legend Device?** No
- **State Control?** No
- **ARGOS reportable?** No
- **Co-Licensed?** No
- **Controlled Substance?** No
- **Schedule No.**  
- **(incl. N for non-narcotic)**
- **Controlled Substance Code:**  
- **Hazardous Material/Cytotoxic Agent?** No
- **Is Item...**
- **If Unit Dose, is item bar coded to unit dose for hospital scanning?**  
- **Is it reverse numbered?**  
- **Vendor #:**  
- **Whsl. Code #:**  
- **Fineline Code:**

**ORDER INFORMATION**

- **Unit of Sale:**  
- **What is the NDC selling unit?** Each  
- **Weight Lbs.:** 32.0  
- **Dimensions (US msmts.):** 2.375 x 1.531  
- **Volume (Cube):** 3.63613  
- **# Pieces:** 24

**ITEM AND PACKAGING INFORMATION**

- **Item:**  
- **UPC:**  
- **Regular Cost Per Unit of Sale ($)** $11.01  
- **Invoice Cost (WAC) ($)**  
- **Federal Excise Tax Per Unit of Sale**

**WHOLSEALER USE ONLY:**

- **Rx billing unit to pharmacy:**
  - **Each**  
  - **Gram**  
  - **Milliliter**

*Please provide any additional information on page 2.*

See new p. 3 for Designated Drop Ship Only.
**Is this product (check all that apply):**
- Cytotoxic? **No**
- CA Prop. 65 Carcinogen or Reproductive Toxicant? **No**
  - Carcinogen
  - Reproductive Toxicant
  - Both
  - Warning appears on label
- Contact Hazard? **No**
- Does this product require special clean-up instructions? **No**
- Does the product contain DEHP? **No**

**Is this product regulated for shipment by the DOT?** **No**
- DOT Hazard Class
- 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? **No**
  - 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#
- Is the product restricted for air shipment? **No**
  - 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: **Yes**
- Restricted to retail pharmacy only: **No**
- Restricted to hospital, clinics, and physician offices only: **No**
- Restricted from US territories? (explain in comments) **No**

**RETURN INSTRUCTIONS**
Contact tel. # if product received damaged: 877-993-8779
Is product returnable for credit: 
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:**

**Release DATE**
## Standard Pharmaceutical Product Information (Page 3)

### Order Method for Designated Drop Ship Product

<table>
<thead>
<tr>
<th>Purchase orders may be accepted by:</th>
<th>Standard Order Receipt and Processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. EDI</td>
<td>Purchase order daily receipt cut off time by supplier</td>
</tr>
<tr>
<td>b. Autofax</td>
<td>Cut off time:</td>
</tr>
<tr>
<td>c. Fax</td>
<td>Shipping lead time of PO:</td>
</tr>
<tr>
<td>d. Phone only</td>
<td>Hours</td>
</tr>
<tr>
<td>e. Supplier Web Site only</td>
<td>Ships same day for next day receipt:</td>
</tr>
<tr>
<td>Minimum Order Quantity:</td>
<td>Ships for second day receipt:</td>
</tr>
<tr>
<td>Supplier's Customer Service Number:</td>
<td>Ships regular ground for 3-10 days receipt:</td>
</tr>
<tr>
<td>Contracted 3PL company / contact #:</td>
<td></td>
</tr>
</tbody>
</table>

### Expedited Freight Charges or Other Designated Drop Ship Fees:

<table>
<thead>
<tr>
<th>Expedited freight fees billed with each order:</th>
<th>Overnight and Priority Overnight PO Processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drop Ship service fee billed with each order:</td>
<td>Overnight receipt available:</td>
</tr>
<tr>
<td>Drop Ship miscellaneous fees billed:</td>
<td>PO Receipt cut off time:</td>
</tr>
<tr>
<td>Comments:</td>
<td>Days of week overnight is available:</td>
</tr>
</tbody>
</table>

### Expedited Freight Charges or Other Designated Drop Ship Fees:

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<thead>
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<th>Expedited freight fees billed with each order:</th>
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<tr>
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<td>PO Receipt cut off time:</td>
</tr>
<tr>
<td>Comments:</td>
<td>Days of week overnight is available:</td>
</tr>
</tbody>
</table>

### 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:                                     | |

### REMS or Registry Restrictions

<table>
<thead>
<tr>
<th>REMS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>REMS Program Manager Name:</td>
</tr>
<tr>
<td>Supplier Manages REMS registry exclusively:</td>
</tr>
<tr>
<td>Wholesale distributor support:</td>
</tr>
<tr>
<td>Provider Name:</td>
</tr>
<tr>
<td>Site Enrollment Number assigned by Supplier:</td>
</tr>
<tr>
<td>DEA #:</td>
</tr>
<tr>
<td>PCPDP #:</td>
</tr>
<tr>
<td>NPI #:</td>
</tr>
<tr>
<td>Comments:</td>
</tr>
<tr>
<td>Registry:</td>
</tr>
<tr>
<td>Registry Program Contact Name:</td>
</tr>
<tr>
<td>Phone:</td>
</tr>
</tbody>
</table>

### Return Instructions

| Contact # if product is received damaged: |
| Is product returnable for credit: |
| URL/Link to returns policy: |
| Special regulations or returns requirements for this product in certain states? |
| If so, which states? Other requirements? Comments? |

### ADDITIONAL INFORMATION

| Is product order for scheduled patient procedure? |
| Is product order for restocking purposes? |

### Other Data Information Required to Process PO:

| Patient Procedure Date: |
| Physician Name: |
| Physician/Clinic Phone #: |
| Physician State License #: |
| Physician/Clinic DEA #: |
| Physician/Clinic Specialty: |

### Miscellaneous Notes:
Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Company Name: Zydus Pharmaceuticals USA Inc.
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
CVX Code: MVX Code: 366382412010
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

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? Yes
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? No
Are any waivers granted for product ID/barcode? No
If yes, attach documentation from FDA

ADDITIONAL PRODUCT INFORMATION

Order Information

<table>
<thead>
<tr>
<th>Unit of Sale</th>
<th>What is the NDC selling unit?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bottle</td>
<td>Each</td>
</tr>
<tr>
<td>Box/Carton</td>
<td>(Write-in, e.g. 1 Box of 10 Vials)</td>
</tr>
<tr>
<td>Ampule</td>
<td></td>
</tr>
<tr>
<td>Tube</td>
<td></td>
</tr>
<tr>
<td>Vial Liquid Sgl</td>
<td></td>
</tr>
<tr>
<td>Vial Liquid Multi</td>
<td></td>
</tr>
<tr>
<td>Vial Powder Sgl</td>
<td></td>
</tr>
<tr>
<td>Vial Powder Multi</td>
<td></td>
</tr>
<tr>
<td>Other: Write In</td>
<td></td>
</tr>
</tbody>
</table>

Minimum order quantity? Yes
If Yes, how many of which package type? Each Inner/Carton/Pack Case

ADDITIONAL INFORMATION

ORDER INFORMATION

<table>
<thead>
<tr>
<th>Item</th>
<th>Weight Lbs.</th>
<th>Dimensions (US msmts.)</th>
<th>Volume (Cube)</th>
<th># Pieces</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>55.0 G</td>
<td>3.127</td>
<td>1.922</td>
<td>6.01009</td>
</tr>
<tr>
<td>Case</td>
<td>4.80LBS</td>
<td>7.76</td>
<td>4.61</td>
<td>11.57</td>
</tr>
<tr>
<td>Pallet</td>
<td>47.24</td>
<td>47</td>
<td>39.37</td>
<td>87412.4236</td>
</tr>
</tbody>
</table>

Additional Product Information

Pharmacy Order / Bill Unit

<table>
<thead>
<tr>
<th>Rec. sell unit to customer?</th>
<th>Size/Strength/Form:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Write-in, e.g. 1 Vial)</td>
<td>100mg/20mg/Capsule</td>
</tr>
</tbody>
</table>

Other Product Information

<table>
<thead>
<tr>
<th>Product Shape</th>
<th>Product Color</th>
<th>Product Imprint</th>
<th>Regular Cost Per Unit of Sale ($)</th>
<th>Invoice Cost (WAC) ($)</th>
<th>Federal Excise Tax Per Unit of Sale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsule</td>
<td>Tan/White</td>
<td>ZA 10 20mg</td>
<td>$36.71</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

As of date: 4/28/2015

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

<table>
<thead>
<tr>
<th>Is this product (check all that apply):</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Cytotoxic?</td>
</tr>
<tr>
<td>b. CA Prop., 65 Carcinogen or Reproductive Toxicant?</td>
</tr>
<tr>
<td>c. Contact Hazard?</td>
</tr>
<tr>
<td>d. Does this product require special clean-up instructions?</td>
</tr>
<tr>
<td>e. Does the product contain DEHP?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is this product regulated for shipment by the DOT?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is this a reportable quantity?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RQ Threshold:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Is this a marine pollutant?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is this product shipped utilizing an authorized DOT exception or Special Permit?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited Quantity</td>
</tr>
</tbody>
</table>

### ADDITIONAL PRODUCT INFORMATION - Serialization

<table>
<thead>
<tr>
<th>Level</th>
<th>How?</th>
<th>GTIN-14</th>
</tr>
</thead>
<tbody>
<tr>
<td>x Item</td>
<td>x 2D</td>
<td>Linear</td>
</tr>
<tr>
<td>x Box/Carton</td>
<td>x 2D</td>
<td>Linear</td>
</tr>
<tr>
<td>x Case</td>
<td>x 2D</td>
<td>Linear</td>
</tr>
<tr>
<td>x pallet</td>
<td>x 2D</td>
<td>Linear</td>
</tr>
</tbody>
</table>

### ADDITIONAL INFORMATION - Serialization

<table>
<thead>
<tr>
<th>Item</th>
<th>2D Linear RFID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case</td>
<td>1036832412017</td>
</tr>
</tbody>
</table>

### ADDITIONAL INFORMATION - GTIN-14

<table>
<thead>
<tr>
<th>SPN</th>
<th>1036832412017</th>
</tr>
</thead>
</table>

### REMS or REGISTRY RESTRICTIONS

<table>
<thead>
<tr>
<th>Is there a REMS on this product?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If Yes, is it managed with a pharmacy registry?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Website URL: <a href="http://www.zydususa.com">www.zydususa.com</a></td>
</tr>
</tbody>
</table>

### ADDITIONAL INFORMATION - RETURN INSTRUCTIONS

<table>
<thead>
<tr>
<th>Contact tel. # if product received damaged:</th>
</tr>
</thead>
<tbody>
<tr>
<td>877-993-8779</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is product returnable for credit?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Special regulations or returns requirements for this product in certain states?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If so, which states? Other requirements? Comments?</th>
</tr>
</thead>
</table>

### ADDITIONAL INFORMATION - MISCELLANEOUS NOTES and/or Image of Product Barcode

<table>
<thead>
<tr>
<th>Listed Chemical (List I or II)</th>
<th>(Indicate or Write-in below):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ephedrine</td>
<td>Pseudoephedrine</td>
</tr>
<tr>
<td>Phenylpropanolamine</td>
<td>Iodine (≥2.2%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>CLASS OF TRADE RESTRICTION:</th>
</tr>
</thead>
<tbody>
<tr>
<td>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices</td>
</tr>
<tr>
<td>Restricted to retail pharmacy only:</td>
</tr>
<tr>
<td>Restricted to hospital, clinics, and physician offices only:</td>
</tr>
<tr>
<td>Restricted from US territories? (explain in comments)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COMMENTS:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Release DATE</th>
</tr>
</thead>
</table>
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<td>Cut off time:</td>
</tr>
<tr>
<td>c. Fax</td>
<td>Shipping lead time of PO:</td>
</tr>
<tr>
<td>d. Phone only</td>
<td>Hours   Days</td>
</tr>
<tr>
<td>e. Supplier Web Site only</td>
<td>Ships same day for next day receipt:</td>
</tr>
<tr>
<td>Site Address:</td>
<td>Ships for second day receipt:</td>
</tr>
<tr>
<td></td>
<td>Ships regular ground for 3-10 days receipt:</td>
</tr>
</tbody>
</table>

### Expedited Freight Charges or Other Designated Drop Ship Fees:

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<th>Expedited freight fees billed with each order:</th>
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</table>

### Overnight and Priority Overnight PO Processing:

<table>
<thead>
<tr>
<th>Overnight receipt available:</th>
<th>PO Receipt cut off time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days of week overnight is available:</td>
<td>Monday Wednesday Friday</td>
</tr>
</tbody>
</table>

### Additional Information

**Rems or Registry Restrictions**

<table>
<thead>
<tr>
<th>REMS Program Manager Name:</th>
<th>Phone:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Supplier Manages REMS registry exclusively:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Wholesale distributor support:</td>
<td></td>
</tr>
<tr>
<td>Provider Name:</td>
<td></td>
</tr>
<tr>
<td>Site Enrollment Number assigned by Supplier:</td>
<td></td>
</tr>
<tr>
<td>DEA #:</td>
<td></td>
</tr>
<tr>
<td>PCPDP #:</td>
<td></td>
</tr>
<tr>
<td>NPI #:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comments:</th>
</tr>
</thead>
</table>

### Return Instructions

<table>
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<tr>
<td>URL/Link to returns policy:</td>
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<td>If so, which states? Other requirements? Comments?</td>
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</table>

**Registry**

<table>
<thead>
<tr>
<th>Registry Program Contact Name:</th>
<th>Phone:</th>
</tr>
</thead>
</table>

### Additional Information

<table>
<thead>
<tr>
<th>Is product order for scheduled patient procedure?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is product order for restocking purposes?</td>
</tr>
</tbody>
</table>

### Miscellaneous Notes:

<table>
<thead>
<tr>
<th>Other Data Information Required to Process PO:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Patient Procedure Date:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Physician Name:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Physician/Clinic Phone #</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Physician State License #</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Physician/Clinic DEA #:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Physician/Clinic Specialty:</th>
</tr>
</thead>
</table>
**Standard Pharmaceutical Product Information (Rx Product Only)**

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- **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:** 36538241205
- **Active ingredients:** Omeprazole
- **URL for Additional Product Information:** www.zydususa.com

### FREEZER – BETWEEN -25 AND -10 C (-13° – 14° F)

- **Cold – BETWEEN 2 AND 8 C (36° – 46° F)**
- **Cool – BETWEEN 8 AND 15 C (46° – 59° F)**
- **Controlled Room – BETWEEN 20 AND 25 C (68° – 77° F)**
- **Avoid Excessive Heat – Above 40 C (>104° F)**

### SPECIAL HANDLING AND STORAGE REQUIREMENTS*

- **a. Temperature – Indicate the USP temperature range for this product.**
  - I. Freezer – between -25 and -10 C (-13° – 14° F)
  - II. Cold – between 2 and 8 C (36° – 46° F)
  - III. Cool – between 8 and 15 C (46° – 59° F)
  - IV. Controlled Room – between 20 and 25 C (68° – 77° F)
  - V. Avoid Excessive Heat – above 40 C (>104° F)

### ADDITIONAL PRODUCT INFORMATION

- **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

### COST INFORMATION

<table>
<thead>
<tr>
<th>Item</th>
<th>Regular Cost Per Unit of Sale ($)</th>
<th>Invoice Cost (WAC) ($)</th>
<th>Federal Excise Tax Per Unit of Sale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case</td>
<td>833.16728 12</td>
<td>87412.4236</td>
<td></td>
</tr>
</tbody>
</table>

- **UPC:** 68382-412-05

### ORDER INFORMATION

- **Unit of Sale:** Each
- **What is the NDC selling unit?** Each
- **Minimum order quantity?** Yes
- **If Yes, how many of which package type?**
  - Inner/Carton/Pack: 1

### ITEM AND PACKING INFORMATION

- **Pharmacy Order / Bill Unit:** Rec. sell unit to customer?
  - Yes

### PHARMACY ORDER / BILL UNIT

- **Product Color:** Tan/White
- **Product Imprint:** ZA 10 20mg

### WHolesaler Use Only:

- **Rx Billing unit to pharmacy:** Each
- **Rx Billing Unit to Pharmacy:** Each
- **Whs Code #:**
- **Fineline Code:**

---

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: [Signature]

**Note:** Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.
### Standard Pharmaceutical Product Information (Page 2)

**For Designated Drop Ship Only Products, Please Use Page 3**

<table>
<thead>
<tr>
<th>MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this product (check all that apply):</td>
</tr>
<tr>
<td>a. Cytotoxic? No</td>
</tr>
<tr>
<td>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No</td>
</tr>
<tr>
<td>- Carcinogen</td>
</tr>
<tr>
<td>- Reproductive Toxicant</td>
</tr>
<tr>
<td>- Both Warning appears on label</td>
</tr>
<tr>
<td>c. Contact Hazard? No</td>
</tr>
<tr>
<td>d. Does this product require special clean-up instructions? No</td>
</tr>
<tr>
<td>(If yes, attach SDS with special instructions.)</td>
</tr>
<tr>
<td>e. Does the product contain DEHP? No</td>
</tr>
<tr>
<td>Is this product regulated for shipment by the DOT? No</td>
</tr>
<tr>
<td>Is this a reportable quantity? No</td>
</tr>
<tr>
<td>RQ Threshold:</td>
</tr>
<tr>
<td>Is this a marine pollutant? No</td>
</tr>
<tr>
<td>Is this product shipped utilizing an authorized DOT exception or Special Permit?</td>
</tr>
<tr>
<td>(if yes, identify method below)</td>
</tr>
<tr>
<td>Limited Quantity</td>
</tr>
<tr>
<td>Consumer Commodity, ORM-D</td>
</tr>
<tr>
<td>Small Quantity (49 CFR 173.4)</td>
</tr>
<tr>
<td>Special Permit; DOT-SP</td>
</tr>
<tr>
<td>Special Provision (listed in Column 7 of 49 CFR 172.101); SP#</td>
</tr>
<tr>
<td>Is the product restricted for air shipment? If so, indicate restriction:</td>
</tr>
<tr>
<td>Passenger</td>
</tr>
<tr>
<td>Cargo</td>
</tr>
<tr>
<td>Passenger &amp; Cargo</td>
</tr>
</tbody>
</table>

### ADDITIONAL PRODUCT INFORMATION - Serialization

**Additional Information**

**Class of Trade Restriction:**

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

**Release DATE**

**Hazardous Waste Identification**

<table>
<thead>
<tr>
<th>EPA Hazardous Waste Code:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**ADDITIONAL INFORMATION**

**MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION**

<table>
<thead>
<tr>
<th>Is this product regulated for shipment by the DOT? No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this a reportable quantity? No</td>
</tr>
<tr>
<td>RQ Threshold:</td>
</tr>
<tr>
<td>Is this a marine pollutant? No</td>
</tr>
<tr>
<td>Is this product shipped utilizing an authorized DOT exception or Special Permit?</td>
</tr>
<tr>
<td>(if yes, identify method below)</td>
</tr>
<tr>
<td>Limited Quantity</td>
</tr>
<tr>
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<td>Passenger</td>
</tr>
<tr>
<td>Cargo</td>
</tr>
<tr>
<td>Passenger &amp; Cargo</td>
</tr>
</tbody>
</table>

### ADDITIONAL PRODUCT INFORMATION - Serialization

**Level**

- Item
- Box/Carton
- Case
- Pallet

**How?**

- Linear
- RFID

**GTIN-14**

10368382412055

**REMS or REGISTRY RESTRICTIONS**

<table>
<thead>
<tr>
<th>Is there a REMS on this product? No</th>
</tr>
</thead>
<tbody>
<tr>
<td>If Yes, is it managed with a pharmacy registry?</td>
</tr>
<tr>
<td>Website URL:</td>
</tr>
</tbody>
</table>

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

**RETURN INSTRUCTIONS**

- Contact tel. # if product received damaged: 877-993-8779
- Is product returnable for credit: www.zydususa.com
- URL/Link to returns policy: No
- Special regulations or returns requirements for this product in certain states? No
- If so, which states? Other requirements? Comments?

**ADDITIONAL INFORMATION**

**LISTED CHEMICAL (List I or II) (Indicate or Write-in below):**

- Ephedrine
- Pseudoephedrine
- Phenylephrine
- Iodine (≥2.2%)
- Other:

**CLASS OF TRADE RESTRICTION:**

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

<table>
<thead>
<tr>
<th>Misclassified notes or Image of Product Barcode:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

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

**If so, which states? Other requirements? Comments?**

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

**Is product returnable for credit: www.zydususa.com**

**URL/Link to returns policy:**

<table>
<thead>
<tr>
<th>No</th>
</tr>
</thead>
</table>

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

**If so, which states? Other requirements? Comments?**

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

**Is product returnable for credit: www.zydususa.com**

**URL/Link to returns policy:**

<table>
<thead>
<tr>
<th>No</th>
</tr>
</thead>
</table>
### Standard Pharmaceutical Product Information (Page 3)

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

<table>
<thead>
<tr>
<th>Purchase orders may be accepted by:</th>
<th>Standard Order Receipt and Processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. EDI</td>
<td>Purchase order daily receipt cut off time by supplier</td>
</tr>
<tr>
<td>b. Autofax</td>
<td>Cut off time:</td>
</tr>
<tr>
<td>c. Fax</td>
<td>Shipping lead time of PO:</td>
</tr>
<tr>
<td>d. Phone only</td>
<td>Hours</td>
</tr>
<tr>
<td>e. Supplier Web Site only</td>
<td>Ships same day for next day receipt:</td>
</tr>
<tr>
<td>Minimum Order Quantity:</td>
<td>Ships for second day receipt:</td>
</tr>
<tr>
<td>Supplier's Customer Service Number:</td>
<td>Ships regular ground for 3-10 days receipt:</td>
</tr>
<tr>
<td>Contracted 3PL company / contact #:</td>
<td></td>
</tr>
<tr>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td></td>
</tr>
</tbody>
</table>

### Expedited Freight Charges or Other Designated Drop Ship Fees:

<table>
<thead>
<tr>
<th>Expedited freight fees billed with each order:</th>
<th>Overnight and Priority Overnight PO Processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drop Ship service fee billed with each order:</td>
<td>PO Receipt cut off time:</td>
</tr>
<tr>
<td>Drop Ship miscellaneous fees billed:</td>
<td>Days of week overnight is available:</td>
</tr>
<tr>
<td>Comments:</td>
<td>Monday</td>
</tr>
<tr>
<td></td>
<td>Tuesday</td>
</tr>
<tr>
<td></td>
<td>Wednesday</td>
</tr>
<tr>
<td></td>
<td>Thursday</td>
</tr>
<tr>
<td></td>
<td>Friday</td>
</tr>
</tbody>
</table>

### Class of Trade Restriction:

<table>
<thead>
<tr>
<th>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restricted to retail pharmacy only:</td>
</tr>
<tr>
<td>Restricted to hospital, clinics, and physician offices only:</td>
</tr>
<tr>
<td>Restricted from US territories? (explain in comments)</td>
</tr>
<tr>
<td>Comments:</td>
</tr>
</tbody>
</table>

### REMS or Registry Restrictions

<table>
<thead>
<tr>
<th>REMS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>REMS Program Manager Name:</td>
</tr>
<tr>
<td>Phone:</td>
</tr>
<tr>
<td>Supplier Manages REMS registry exclusively:</td>
</tr>
<tr>
<td>Wholesale distributor support:</td>
</tr>
<tr>
<td>Provider Name:</td>
</tr>
<tr>
<td>Site Enrollment Number assigned by Supplier:</td>
</tr>
<tr>
<td>DEA #:</td>
</tr>
<tr>
<td>PCPDP #:</td>
</tr>
<tr>
<td>NPI #:</td>
</tr>
<tr>
<td>Comments:</td>
</tr>
</tbody>
</table>

### Return Instructions

<table>
<thead>
<tr>
<th>Contact # if product is received damaged:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is product returnable for credit:</td>
</tr>
<tr>
<td>URL/Link to returns policy:</td>
</tr>
<tr>
<td>Special regulations or returns requirements for this product in certain states?</td>
</tr>
<tr>
<td>If so, which states? Other requirements? Comments?</td>
</tr>
<tr>
<td>Comments:</td>
</tr>
</tbody>
</table>

### ADDITIONAL INFORMATION

<table>
<thead>
<tr>
<th>Is product order for scheduled patient procedure?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is product order for restocking purposes?</td>
</tr>
</tbody>
</table>

### Other Data Information Required to Process PD:

<table>
<thead>
<tr>
<th>Patient Procedure Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Name:</td>
</tr>
<tr>
<td>Physician/Clinic Phone #:</td>
</tr>
<tr>
<td>Physician State License #:</td>
</tr>
<tr>
<td>Physician/Clinic DEA #:</td>
</tr>
<tr>
<td>Physician/Clinic Specialty:</td>
</tr>
<tr>
<td>Comments:</td>
</tr>
</tbody>
</table>
**Standard Pharmaceutical Product Information (Rx Product Only)**

**PRODUCT INFORMATION**

<table>
<thead>
<tr>
<th>Company Name:</th>
<th>Zydus Pharmaceuticals USA Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Number for NDA/ANDA/BLA, Med Device:</td>
<td>91352</td>
</tr>
<tr>
<td>Rx Product/Proprietary Name:</td>
<td>Omeprazole Delayed-Release Capsules, USP 20mg, 1000 ct</td>
</tr>
<tr>
<td>NDC:</td>
<td>68382-412-10</td>
</tr>
<tr>
<td>CVX Code:</td>
<td>68382412102</td>
</tr>
<tr>
<td>Description:</td>
<td>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 &amp; white body printed with “20 mg” in black ink.</td>
</tr>
<tr>
<td>Active ingredients:</td>
<td>Omeprazole</td>
</tr>
<tr>
<td>URL for Additional Product Information:</td>
<td><a href="http://www.zydususa.com">www.zydususa.com</a></td>
</tr>
</tbody>
</table>

**ADDITIONAL PRODUCT INFORMATION**

| Address: | 73 Route 31 North |
| City: | Pennington |
| Key Contact: | (609) 730 1900 |
| Phone Number: | (609) 730 1991 |

**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 |

**SPECIAL HANDLING AND STORAGE REQUIREMENTS**

- **a. Temperature – indicate the USP temperature range for this product.**
  - I. Freezer – between -25 and -10 C (-13° – 14° F)
  - II. Cold – between 2 and 8 C (36° – 46° F)
  - III. Cool – between 8 and 15 C (46° – 59° F)
  - IV. Controlled Room – between 20 and 25 C (68° – 77° F)
  - V. Avoid Excessive Heat – above 40 C (>104° F)
  - VI. Other Temperature Range Requirement (write in)

- **b. Contact for temperature excursion questions:**
  - Name: Prilosec |
  - Number: (609) 730 1901

- **c. Special regulations for product in certain states?**
  - No

- **d.  Store product (unit of sale) upright?**
  - Yes

- **e. Shelf life:**
  - 24 Months

**ITEM AND PACKING INFORMATION**

<table>
<thead>
<tr>
<th>Is the Product...</th>
<th>Direct Ship Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legend Device?</td>
<td>No</td>
</tr>
<tr>
<td>State Control?</td>
<td>No</td>
</tr>
<tr>
<td>ARGOS reportable?</td>
<td>No</td>
</tr>
<tr>
<td>Co-Licensed?</td>
<td>No</td>
</tr>
<tr>
<td>Controlled Substance?</td>
<td>No</td>
</tr>
<tr>
<td>Schedule No.? (incl. N for non-narcotic)</td>
<td>No</td>
</tr>
<tr>
<td>Controlled Substance Code:</td>
<td>No</td>
</tr>
<tr>
<td>Hazardous Material/Cytotoxic Agent?</td>
<td>No</td>
</tr>
<tr>
<td>Is Item...</td>
<td></td>
</tr>
<tr>
<td>If Unit Dose, is item bar coded to unit dose for hospital scanning?</td>
<td>No</td>
</tr>
<tr>
<td>Is it reverse numbered?</td>
<td>No</td>
</tr>
</tbody>
</table>

**ORDER INFORMATION**

<table>
<thead>
<tr>
<th>What is the NDC selling unit?</th>
<th>(Write-in, e.g. 1 Box of 10 Vials)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum order quantity?</td>
<td>Yes</td>
</tr>
<tr>
<td>If Yes, how many of which package type?</td>
<td>Each, Inner/Carton/Pack</td>
</tr>
</tbody>
</table>

**PHARMACY ORDER / BILL UNIT**

<table>
<thead>
<tr>
<th>Rec. sell unit to customer?</th>
<th>(Write-in, e.g. 1 Vial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Capsule</td>
</tr>
<tr>
<td>Product Shape</td>
<td>Capsule</td>
</tr>
<tr>
<td>Product Color</td>
<td>Tan/White</td>
</tr>
<tr>
<td>Product Imprint</td>
<td>ZA 10 20mg</td>
</tr>
</tbody>
</table>

**WHALESLER USE ONLY:**

<table>
<thead>
<tr>
<th>Rx billing unit to pharmacy:</th>
<th>Each</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vendor #:</td>
<td></td>
</tr>
<tr>
<td>Whsl. Code #:</td>
<td></td>
</tr>
<tr>
<td>Fineline Code:</td>
<td></td>
</tr>
</tbody>
</table>

**COST INFORMATION**

- **Regular Cost Per Unit of Sale ($)**: $367.02
- **Invoice Cost (WAC) ($)**: 1428.5376
- **Federal Excise Tax Per Unit of Sale**: 11.79LBS

*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature: [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

Is this product regulated for shipment by the DOT?  No (if yes, answer a-d below and provide SDS)

   a. DOT Hazard Class
   b. UN/ID Number
   c. Packing Group
   d. Inhalation Hazard?

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?  No

   a. Limited Quantity
   b. Small Quantity (49 CFR 173.4)
   c. Special Permit; DOT-SP
   d. Special Provision (listed in Column 7 of 49 CFR 172.101); SP#

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

   a. Passenger
   b. Cargo
   c. 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):
   a. Ephedrine
   b. Pseudoephedrine
   c. Phenylpropanolamine
   d. Iodine (≥2.2%)
   e. Other:

CLASS OF TRADE RESTRICTION:

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

MISCELLANEOUS NOTES and/or Image of Product Barcode:

ADDITIONAL INFORMATION - Serialization

   ADDITIONAL PRODUCT INFORMATION - Serialization

   Level  How?  GTIN-14
   x Item  x 2D  Linear  RFID  10368382412109

   x Box/Carton  x 2D  Linear  RFID
   x Case  x 2D  Linear  RFID
   x Pallet  x 2D  Linear  RFID

REMS or REGISTRY RESTRICTIONS

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

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

RETURN INSTRUCTIONS

   Contact tel. # if product received damaged:  877-993-8779
   Is product returnable for credit:  No
   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:

Release DATE
# Standard Pharmaceutical Product Information (Page 3)

## Order Method for Designated Drop Ship Product

<table>
<thead>
<tr>
<th>Purchase orders may be accepted by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. EDI</td>
</tr>
<tr>
<td>b. Autofax</td>
</tr>
<tr>
<td>c. Fax</td>
</tr>
<tr>
<td>d. Phone only</td>
</tr>
<tr>
<td>e. Supplier Web Site only</td>
</tr>
<tr>
<td>Minimum Order Quantity:</td>
</tr>
<tr>
<td>Supplier's Customer Service Number:</td>
</tr>
<tr>
<td>Contracted 3PL company / contact #:</td>
</tr>
</tbody>
</table>

## Standard Order Receipt and Processing

<table>
<thead>
<tr>
<th>Purchase order daily receipt cut off time by supplier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cut off time:</td>
</tr>
<tr>
<td>Shipping lead time of PO:</td>
</tr>
<tr>
<td>Hours                         Days</td>
</tr>
<tr>
<td>Ships same day for next day receipt:</td>
</tr>
<tr>
<td>Ships for second day receipt:</td>
</tr>
<tr>
<td>Ships regular ground for 3-10 days receipt:</td>
</tr>
</tbody>
</table>

## Expedited Freight Charges or Other Designated Drop Ship Fees:

| Expedited freight fees billed with each order:       |
| Drop Ship service fee billed with each order:        |
| Drop Ship miscellaneous fees billed:                |

## Overnight and Priority Overnight PO Processing

| Overnight receipt available:                         |
| PO Receipt cut off time:                             |
| Days of week overnight is available:                 |
| Priority Overnight receipt available:                |
| PO Receipt cut off time:                             |
| Order receipt method:                                |
| Phone:                                               |
| Fax:                                                 |
| EDI:                                                 |
| Overnight Fees apply:                                |
| Other fees apply:                                    |

## 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)                                           |

## REMS or Registry Restrictions

<table>
<thead>
<tr>
<th>REMS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>REMS Program Manager Name:</td>
</tr>
<tr>
<td>Phone:</td>
</tr>
<tr>
<td>Supplier Manages REMS registry exclusively:</td>
</tr>
<tr>
<td>Wholesale distributor support:</td>
</tr>
<tr>
<td>Provider Name:</td>
</tr>
<tr>
<td>Site Enrollment Number assigned by Supplier:</td>
</tr>
<tr>
<td>DEA #:</td>
</tr>
<tr>
<td>PCPDP #:</td>
</tr>
<tr>
<td>NPI #:</td>
</tr>
<tr>
<td>Comments:</td>
</tr>
<tr>
<td>Registry:</td>
</tr>
<tr>
<td>Registry Program Contact Name:</td>
</tr>
<tr>
<td>Phone:</td>
</tr>
<tr>
<td>Comments:</td>
</tr>
</tbody>
</table>

## Return Instructions

| Contact # if product is received damaged:         |
| Is product returnable for credit:                |
| URL/Link to returns policy:                      |
| Special regulations or returns requirements for this product in certain states? |
| If so, which states? Other requirements? Comments? |

## ADDITIONAL INFORMATION

| Is product order for scheduled patient procedure? |
| Is product order for restocking purposes?        |

## Other Data Information Required to Process PO:

| Patient Procedure Date:                          |
| Physician Name:                                  |
| Physician/Clinic Phone #:                        |
| Physician State License #:                       |
| Physician/Clinic DEA #:                          |
| Physician/Clinic Specialty:                      |

## Miscellaneous Notes: