Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item | [ ] Final Version | **Date:** 8/30/2016

PRODUCT INFORMATION

Company Name: Amneal Pharmaceuticals | **Application:** ANDA
Application Number for NDA/ANDA/BLA, Med Device:
Rx Product/Proprietary Name: Yuvafem (estradiol vaginal tablets, USP) 10mcg
NDC: 65162-226-21 | **UPC:** 3-6516222621-8
CVX Code: | **MVX Code:**
Description: White to off-white, round biconvex, film-coated unscored tablets debossed with "276" on obverse and "AN" on the reverse. Each Yuvafem, estradiol vaginal tablet,10 mcg is contained in a disposable, single-use applicator, packaged in a blister pack.
Active ingredients: Estradiol
URL for Additional Product Information:

Address: 118 Beaver Trail | **Address 2:**
City: Glagow | **State:** KY | **Zip:** 42141
Key Contact: | **Email:**
Phone Number: 866-525-7270 | **Fax:** 866-525-7271

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB | **II. Brand Name:** Vagifem
III. Generic Equivalent for Brand: Yuvafem (estradiol vaginal tablets, USP) 10mcg

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes | **DUNS:** 831227777
Is product exempt from DSCSA? No
If yes, select exemption:
Other exemption - Write in:
Is product repackaged? No | **If Yes, was original product purchased direct from mfr?**
Is product sold by manufacturer's exclusive distributor? No
Are any waivers granted for product ID/barcode? No | **If yes, attach documentation from FDA**

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)
- [x] IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
- [ ] V. Avoid Excessive Heat – above 40 C (>104° F)
- [ ] VI. Other Temperature Range Requirement (write in)
- [ ] VII. No Requirement

b. Contact for temperature excursion questions:
Name:
Number: 866-525-7270
Is this product to be shipped to customers on ice? No
Is this product to be shipped to customers on dry ice? No

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

d. Store product (unit of sale) upright? Yes
Protect product (unit of sale) from light? No

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

ADDITIONAL PRODUCT INFORMATION

Is the Product… Direct Ship Item
Legend Device? No
State Control? No
ARCOS reportable? No
Co-Licensed? No
Controlled Substance? No
Schedule No.?
(incl. N for non-narcotic)
Controlled Substance Code:
Hazardous Material/Cytotoxic Agent?

Is Item...
If Unit Dose, is item bar coded to unit dose for hospital scanning?
Is it reverse numbered?

ORDER INFORMATION

	Unit of Sale
[ ]	Bottle
[x]	Box/Carton
[ ]	Ampule
[ ]	Glass
[ ]	Tube
[ ]	Vial Liquid Sgl
[ ]	Vial Liquid Multi
[ ]	Vial Powder Sgl
[ ]	Vial Power Multi
[ ]	Other: Write In

What is the NDC selling unit? 8 disposable, single-use applicator, packaged in a blister pack
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

60	Each
	Inner/Carton/Pack
	Case

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width:	Volume (Cube)	# Pieces:
Item:	45.36gm	6"	1"	3.25"		
Box/ Carton:						
Case:	8.05 lbs	15.5"	7.25"	12.5"		60
Pallet:						
UPC:	**Case:**					
	Carton:					

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

- [ ] Each
- [ ] Gram
- [ ] Milliliter

Other Product Information

Size/Strength/Form: 8 single-use applicator; 10mcg; Tablet
Product Shape: round, biconvex
Product Color: White to off-white
Product Imprint: "276" on obverse & "AN" on reverse

COST INFORMATION

Regular Cost Per Unit of Sale ($)	Invoice Cost (WAC) ($)	Federal Excise Tax Per Unit of Sale

As of date:

WHOLESALER USE ONLY:

Vendor #:
Whsl. Code #:
Fineline Code:

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?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
  - [ ] Carcinogen
  - [ ] Reproductive Toxicant
  - [ ] Both
  - [ ] Warning appears on label
- c. Contact Hazard?
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?

Hazardous Waste Identification

EPA Hazardous Waste Code:

Is this product regulated for shipment by the DOT? (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?
RQ Threshold:
Is this a marine pollutant?
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#

Is the product restricted for air shipment? If so, indicate restriction:
- [ ] Passenger
- [ ] Cargo
- [ ] Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization

		Level		How?		GTIN-14
Serialized?	Yes	[ ] Item	[ ] 2D	[ ] Linear	[ ] RFID	
If not, when?		[ ] Box/Carton	[ ] 2D	[ ] Linear	[ ] RFID	
Items aggregated to case?		[x] Case	[x] 2D	[ ] Linear	[ ] RFID	50365162226237
		[ ] Pallet	[ ] 2D	[ ] Linear	[ ] 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:

- [ ] Listed Chemical (List I or II) (Indicate or Write-in below):
  - [ ] Ephedrine
  - [ ] Pseudoephedrine
  - [ ] Phenylpropanolamine
  - [ ] Iodine (≥2.2%)
  - [ ] Other:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 866-525-7270
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?

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:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

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

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

Standard Order Receipt and Processing

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:
Ships for second day receipt:
Ships regular ground for 3-10 days receipt:

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:
Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:
PO Receipt cut off time:
Days of week overnight is available:
Monday
Tuesday
Wednesday
Thursday
Friday

Priority Overnight receipt available:
PO Receipt Cut off time:

Saturday Overnight receipt available:
PO Receipt Cut off time:

Order receipt method: Phone: Phone #:
Fax: 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)
Comments:

REMS or Registry Restrictions

REMS:
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively:
Wholesale distributor support:
Provider Name:
Site Enrollment Number assigned by Supplier:
DEA #:
PCPDP #:
NPI #:
Comments:

Registry:
Registry Program Contact Name: Phone:
Comments

Return Instructions

Contact # 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: