



Standard Pharmaceutical Product Information (Rx Product Only)

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Introduction Type:

Final Version

Date:

PRODUCT INFORMATION			SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																					
Company Name: <input type="text" value="Megalith Pharmaceuticals Inc."/>		Application: <input type="text" value="ANDA"/>		<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)																																		
Application Number for NDA/ANDA/BLA, Med Device: <input type="text"/>		Rx Product/Proprietary Name: <input type="text" value="Metformin tablets 850mg"/>		<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)																																		
NDC: <input type="text" value="71717-105-50"/>		UPC: <input type="text" value="71717-105-50"/>		<input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F)		<input type="checkbox"/> VI. Other Temperature Range Requirement																																		
CVX Code: <input type="text"/>		MXV Code: <input type="text"/>		<input type="checkbox"/> VII. No Requirement		<input type="checkbox"/> (write in) <input type="text"/>																																		
Description: <input 850"="" debossed="" on="" one="" side."="" type="text" value="White, round tablets, debossed with "/>		Active ingredients: <input type="text" value="Metformin"/>		b. Contact for temperature excursion questions:		Name: <input type="text"/> Number: <input type="text"/>																																		
URL for Additional Product Information: <input type="text"/>		Address: <input type="text" value="302 Carnegie Center Blvd, Suite 100 Princeton, NJ, 08540"/>		<input type="checkbox"/> Is this product to be shipped to customers on ice? <input type="text" value="No"/>		<input type="checkbox"/> Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>																																		
Address 2: <input type="text"/>		City: <input type="text" value="Princeton"/>		State: <input type="text" value="NJ"/>		Zip: <input type="text"/>																																		
Key Contact: <input type="text" value="Tina Tian"/>		Email: <input type="text" value="tian.pengjing@megalithpharma.com"/>		c. Special regulations for product in certain states?		<input type="text"/> Special returns requirements for this product?																																		
Phone Number: <input type="text" value="609-356-0210 x110"/>		Fax: <input type="text" value="609-432-2067"/>		d. Store product (unit of sale) upright? <input type="text"/>		Protect product (unit of sale) from light? <input type="text"/>																																		
FOR GENERIC DRUG PRODUCTS																																								
I. Orange Book Rating: <input type="text" value="AB"/>		II. Brand Name: <input type="text" value="GLUCOPHAGE"/>		e. Shelf life: <input type="text" value="24"/> Months		Initial shelf life at launch (if different): <input type="text"/> Months																																		
III. Generic Equivalent for Brand: <input type="text"/>		DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																																						
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>		DUNS: <input type="text" value="421303775"/>		ADDITIONAL PRODUCT INFORMATION																																				
Is product exempt from DSCSA? <input type="text" value="No"/>		If yes, select exemption: <input type="text"/>		IS THE PRODUCT...																																				
Other exemption - Write in: <input type="text"/>		Is product repackaged? <input type="text" value="No"/>		<input type="checkbox"/> Direct Ship Item																																				
Is product sold by manufacturer's exclusive distributor? <input type="text" value="Yes"/>		If Yes, was original product purchased direct from mfr? <input type="text"/>		Legend Device? <input type="text" value="No"/>																																				
Are any waivers granted for product ID/barcode? <input type="text"/>		If yes, attach documentation from FDA <input type="text"/>		State Control? <input type="text" value="No"/>																																				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION				ITEM AND PACKING INFORMATION																																				
UNIT OF SALE <input 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"/> <input type="checkbox"/> Case		ORDER INFORMATION What is the NDC selling unit? <input type="text" value="Bottles of 500"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="text" value="Yes"/>		Weight Lbs. <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Item:</th> <th colspan="3">Dimensions (US msmts.)</th> <th rowspan="2">Volume (Cube)</th> <th rowspan="2"># Pieces:</th> </tr> <tr> <th>Depth</th> <th>Height</th> <th>Width:</th> </tr> </thead> <tbody> <tr> <td>Item:</td> <td>1.36</td> <td>3.74</td> <td>7.09</td> <td>3.74</td> <td>99.17</td> </tr> <tr> <td>Box/ Carton:</td> <td>33</td> <td>16.34</td> <td>15.16</td> <td>13.39</td> <td>3316.9</td> </tr> <tr> <td>Case:</td> <td>8.25</td> <td>11.22</td> <td>7.09</td> <td>7.48</td> <td>595.03</td> </tr> <tr> <td>Pallet:</td> <td>935</td> <td>47.24</td> <td>50.79</td> <td>39.37</td> <td>94461.21</td> </tr> </tbody> </table>		Item:	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	Depth	Height	Width:	Item:	1.36	3.74	7.09	3.74	99.17	Box/ Carton:	33	16.34	15.16	13.39	3316.9	Case:	8.25	11.22	7.09	7.48	595.03	Pallet:	935	47.24	50.79	39.37	94461.21	Volume <input type="text"/>	
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PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? <input type="text" value="Bottles of 500"/> (Write-in, e.g. 1 Vial)		Other Product Information Size/Strength/Form: <input type="text" value="500/850mg/Tablets"/> Product Shape: <input type="text" value="Round"/> Product Color: <input type="text" value="White"/> Product Imprint: <input type="text" value="850"/>		COST INFORMATION <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <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><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> </tbody> </table>		Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale	<input type="text"/>	<input type="text"/>	<input type="text"/>	As of date: <input type="text"/>																												
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<input type="text"/>	<input type="text"/>	<input type="text"/>																																						
WHOLESALE USE ONLY: Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> Fineline Code: <input type="text"/>		Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter		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: <input type="text"/>																																				



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?
 No (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

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

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	<input type="checkbox"/> No	Level	<input type="checkbox"/> 2D	How?	<input type="checkbox"/> Linear	GTIN-14
If not, when?	<input type="text"/>	Item	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>
Items aggregated to case?	<input type="checkbox"/>	Box/Case	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>
		Case	<input checked="" type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>
		Pallet	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	<input type="checkbox"/> RFID	<input type="text"/>

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

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:	866-525-7270
Is product returnable for credit:	<input type="text"/>
URL/Link to returns policy:	<input type="text"/>
Special regulations or returns requirements for this product in certain states?	<input type="text"/>
If so, which states? Other requirements? Comments?	<input type="text"/>

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	<input type="text"/>
Restricted to retail pharmacy only:	<input type="text"/>
Restricted to hospital, clinics, and physician offices only:	<input type="text"/>
Restricted from US territories? (explain in comments)	<input type="text"/>
Comments:	<input type="text"/>

ADDITIONAL INFORMATION	
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
MISCELLANEOUS NOTES and/or Image of Product Barcode:	
<input type="text"/>	



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"/> _____ c. Fax <input type="checkbox"/> _____ d. Phone only <input type="checkbox"/> _____ e. Supplier Web Site only <input type="checkbox"/> _____ Minimum Order Quantity: <input type="text"/> _____ Supplier's Customer Service Number: <input type="text"/> _____ Contracted 3PL company / contact #: _____ Name: _____ Phone: _____		Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> _____ Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> 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: <input type="checkbox"/> _____ Drop Ship service fee billed with each order: <input type="checkbox"/> _____ Drop Ship miscellaneous fees billed: <input type="checkbox"/> _____ Comments: <input type="text"/> _____		Overnight receipt available: <input type="checkbox"/> _____ PO Receipt cut off time: <input type="text"/> _____ Days of week overnight is available: <table border="1"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table>		<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday
<input type="checkbox"/>	Monday												
<input type="checkbox"/>	Tuesday												
<input type="checkbox"/>	Wednesday												
<input type="checkbox"/>	Thursday												
<input type="checkbox"/>	Friday												
Class of Trade Restriction:		Priority Overnight receipt available: <input type="checkbox"/> _____ PO Receipt Cut off time: <input type="text"/> _____											
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: <input type="text"/> _____		Saturday Overnight receipt available: <input type="checkbox"/> _____ PO Receipt Cut off time: <input type="text"/> _____ Order receipt method: _____ Phone: _____ Phone #: _____ Fax: _____ Fax #: _____ EDI: _____ Overnight Fees apply: <input type="checkbox"/> _____ Other fees apply: <input type="checkbox"/> _____											
REMS or Registry Restrictions		Return Instructions											
REMS: <input type="checkbox"/> _____ REMS Program Manager Name: _____ Phone: _____ Supplier Manages REMS registry exclusively: <input type="checkbox"/> _____ Wholesale distributor support: _____ Provider Name: _____ Site Enrollment Number assigned by Supplier: _____ DEA #: _____ PCPDP #: _____ NPI #: _____ Comments: <input type="text"/> _____		Contact # if product is received damaged: <input type="text"/> _____ Is product returnable for credit: <input type="checkbox"/> _____ URL/Link to returns policy: <input type="text"/> _____ Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> _____ If so, which states? Other requirements? Comments? <input type="text"/> _____											
Registry:		ADDITIONAL INFORMATION											
Registry Program Contact Name: _____ Phone: _____ Comments: <input type="text"/> _____		Is product order for scheduled patient procedure? <input type="checkbox"/> _____ Is product order for restocking purposes? <input type="checkbox"/> _____											
Other Data Information Required to Process PO:		Miscellaneous Notes:											
Patient Procedure Date: <input type="text"/> _____ Physician Name: <input type="text"/> _____ Physician/Clinic Phone #: <input type="text"/> _____ Physician State License #: <input type="text"/> _____ Physician/Clinic DEA #: <input type="text"/> _____ Physician/Clinic Specialty: <input type="text"/> _____		<input type="text"/> _____											