

Hormone Pellet Implants & Injectables





Hormone Pellets & Injectables

Belmar Select Outsourcing (BSO) is Belmar Pharma Solutions' 503B Outsourcing Facility dedicated to the production of hormone pellets and injectable testosterone cypionate. The facility is managed by a team of experts with extensive experience in cGMP Manufacturing and Quality Assurance. Our track record with the FDA speaks volume to our focus on precision and our respect for the guidelines put in place to protect patients and prescribers.

Being a 503B Outsourcing Facility allows you to order in bulk, and get orders shipped directly to your office.

What to Expect from BSO

- Quality medication and fast turn-around!
- After your application is complete and an order is placed, we bill you and ship directly to your DEA-Registered shipping address.
- One-Stop-Shop: Ability to order disposable trocar kits and reusable stainless-steel trocars with your pellet order.
- Once your order is shipped, you will receive an email with your tracking information and a signature will be required upon delivery.
- A receipt, invoice and packing slip will arrive with the order for your records.

Benefits of Buying from BSO

- Inventory management assistance
- Customizable brochures for your medical office
- Quarterly business reviews
- No Contracts
- Access to Belmar Medical Director with over 25 years of hormone experience
- Free monthly educational webinars
- Free Pellet Dosing Calculator for active accounts



We are licensed in 40 states. We cannot ship to, Alabama, Alaska, Maine, New York, North Dakota, South Dakota, Rhode Island, Vermont, West Virginia, and Wyoming.

Working with a 503B Facility

- You can order in bulk, shipped directly to your office.
- All finished products are third-party tested for potency.
- BSO is held to the same standards as those required of major drug manufacturers.

Easy Ordering and Same Day Shipping

Orders placed before 12pm Mountain Time are processed and shipped same day. Orders can be faxed, phoned, or emailed in. **NO CONTRACTS REQUIRED!**

Extensive Formulary

A wide range of strengths in testosterone, testosterone/anastrozole combo pellet estradiol, anastrozole, and progesterone pellets in stock.

Our testosterone pellets are available in pure and cholesterol (2% or 4%)

Testosterone Cypionate available with Anastrozole or DHEA with grapeseed oil.

Pellet Manufacturing Process Steps

Belmar Select Outsouring (BSO) - an FDA Registered 503B Outsourcing Facility - pellets are made under cGMP with equipment that allows for consistency throughout the manufacturing process. During the manufacturing process pellets are 100% weight tested and visually inspected. Our pellets are packaged in glass vials that are designed to maintain the sterility of the unopened product. Each vial has a label with a perforated edge to assist in determining if the vial has been opened. BSO pellets are sterilized using e-beam radiation, widely considered an effective and reliable way to achieve sterilization. The final step in the process is third-party testing. Each lot of pellets is tested for potency and the presence of endotoxins. This ensures each pellets implanted is the intended dose.



Inspection/Sampling of **Incoming Materials**

- External Testing:
- Endotoxin
- Heavy Metals
- Chemical ID
- Microbial

Preparations and Pellet Punching

- In-Process Testing
- 100% Weight
- Hardness (if applicable)

Visualization Inspection and Packaging

Testing:

- 100% Visual Inspection
- Container **Closure/Stability Studies**



Sterilizations -E-beam Radiation

Testing:

- Sterilization Validation
- Biological Indicator (BI) Testing



Finished Product Testing

External Testing:

- Endotoxin
- Potency



The information provided herein is for prescriber information only and nothing herein should be construed as making a claim about the safety or effectiveness of compounded products, including any products compounded by BSO Select Outsourcing. Nothing herein is intended to replace or influence the independent judgment of any licensed professional. Patients interested in any products compounded by BSO Select Outsourcing are encouraged to speak to a medical professional about their medical options and before seeking treatment.

Why Choose Belmar Terminally Sterilized Liquid Injectables over Aseptically Compounded Liquid Injectables

Terminal sterilization is the process of sterilizing a product in its final container, while aseptic processing involves combining separately sterilized components under aseptic conditions. Unintentional mishaps at any point during aseptic processing will render the product non-sterile. Terminal sterilization guarantees product sterility regardless of any mishaps during the manufacturing process.

Manufacturing Process Steps

Belmar Select Outsourcing (BSO) – an FDA Registered 503B Outsourcing Facility – liquid injectable vials are made under cGMP with equipment that allows for consistency throughout the manufacturing process. During the manufacturing process, the active pharmaceutical ingredients and pharmaceutical-grade inactive ingredients are vigorously mixed in an industrial high shear mixer that results in a homogenous solution. The solution is then filtered to remove any particulates that could have entered during the mixing process and filled in glass vials that are designed to maintain the sterility of the unopened product. The flip-off cap on each vial helps maintain closure integrity as well as double as a tamper-evident seal. Each vial is 100% visually inspected for particulates before being labeled. BSO liquid injectable vials are sterilized using e-beam radiation, widely considered an effective and reliable way to achieve sterilization. The final step in the process is third-party testing. Each lot is tested for potency, particulate matter, pH, and the presence of endotoxins. This ensures each product used for injection is the intended dose.



The information provided herein is for prescriber information only and nothing herein should be construed as making a claim about the safety or effectiveness of compounded products, including any products compounded by BSO Select Outsourcing. Nothing herein is intended to replace or influence the independent judgment of any licensed professional. Patients interested in any products compounded by BSO Select Outsourcing are encouraged to speak to a medical professional about their medical options and before seeking treatment.



Account Application

Checklist:

Account Application

Authorized Agents Form

- Government Issued Photo ID Credit Card Authorization Form Additional Licenses (if applicable)
- Copy of Federal DEA License Essential Copies Attestation Form

Please Note: Your state may require additional information.

Practitioner Name & Title	
Practitioner's Facility	
Office Address	
City	State Zip
Phone	Fax
Website	Practice Email
Practice Contact	Contact Email:
How many years at this location?	Days & Hours of Operation
DEA License	DEA Expiration
State License	Expiration
State Controlled Substance License	Expiration

(Please provide copies of DEA & State Licenses. Fax to: 1-877-267-3409

Estimated number of total patients using testosterone pellets? (Even if your practice is just starting out, an estimate is required.)

The DEA requires th	at we track controlled	d substance ordering	trends.				
How many of each strength of testosterone pellet listed below do you plan on ordering in a month? Pellets are sold in sets of 10. Estimates are ok.							
12.5mg	25mg	37.5mg	50mg	62.5mg			
70mg	80mg	87.5mg	100mg	200mg			
Practitioner Signature		cense Holder		Date:			

It is the responsibility of the DEA license holder to notify BSO of ANY changes to his/her license information including: renewal, change of address, abandonment, or authorized personnel.

Internal Use - Scan this document and attach to practitioner record.



Practitioner Name	
Practice Name	State

Please provide the following information regarding ordering of liquid injectables from Belmar Select Outsourcing.

How many of the following products listed below do you plan on ordering in a month?

Medication	Estimated Number
Testosterone Cypionate/Anastrozole (in grapeseed oil) 200mg/1mg/mL 10 mL vials	
Testosterone Cypionate/Anastrozole (in grapeseed oil) 200mg/0.5mg/mL 10 mL vials	
Testosterone Cypionate/DHEA (in grapeseed oil) 200mg/10mg/mL 10 mL vials	

Practitioner Signature_____

Date:



Use of Compounded Testosterone Hormone Pellet & Injection Attestation

Check all that apply:

- A) □ In my professional judgement, I have determined these compounded products (hormone pellets and/ or injectable testosterone cypionate) are clinically necessary to meet the unique needs of individual patients where commercially available drugs do not meet those needs due to allergies, intolerance to excipients, and/or product labeling and directions for use restrict my ability to provide appropriate treatment and/or dosing to my patient(s).
- **B**) In my professional judgment and experience, the use of the above indicated compounded drug preparation is clinically necessary to provide the appropriate dosing based on treatment protocols that cannot be met by the commercially available product.

In signing this document, I hereby attest that I am the practitioner who will administer the compounded preparation(s) listed above, or I have the authority to speak on behalf of practitioners who will administer the compounded preparation(s) listed above. Additionally, in signing this document, I hereby attest that the compounded preparation(s) listed above will only be administered to patients for whom the practitioner determines will produce a clinical difference from the comparable approved drug product, as described more fully above.

Facility Name:	
Practitioner Name:	DEA #:
Facility Contact Name and Title:	
Signature:	Date:

Internal Use: Per BSO's Essential Copies Comparison Study, BSO has determined these compounded products (hormone pellets) are not essential copies of any FDA approved product per Appendix A & B of the Compounded Drug Products that are Essential Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act, Guidance for Industry.



Cardholder Name			
Practitioner's Name			
Practice Name			
Billing Address			Suite
City	State	Zip	
Credit Card Number	Exp. Date		CVV

By providing your credit card information:

- You are stating that you are an authorized user of the credit card and that the associated information provided (account holder name, account number, billing address, etc.) is accurate.
- Vou authorize BSO to charge the amount you have requested to be charged to your credit card.
- Vou also authorize BSO to return to your credit card any funds due to you by BSO resulting from use of this Service.
- If a charge is declined or reversed by the credit card issuer or network, you agree to pay us a service charge and to reimburse us for all resonable costs of collection. Your credit card issuer may also assess its customary charge for such transactions.
- If your credit card issuer or network does not honor a payment transaction, then we have the right to charge the amount of any such transaction to your account or to collect the amount from you using another payment option.
- If your credit card issuer or network does not honor a payment transaction, we may terminate any or all Service, and may cancel your right to order from BSO.
- BSO testosterone pellets are in multiples of 10 per pellet strength. If quantity ordered is not in a multiple of 10 you authorize BSO to round up your order to the next multiple of 10 per pellet strength. BSO packages testosterone cypionate vials in multiples of 5 per concentration. If quantity ordered is not in a multiple of 5 you authorize BSO to round up your order to the next multiple of 5 per concentration.

Cardholder's Signature

Date: _____



Written Authorization of an Agent

Only the DEA license holder and representatives listed as authorized agents below can place orders through Belmar Select Outsourcing.

It is the responsibility of the DEA license holder to notify Belmar Select Outsourcing of any changes to their license information including renewal, change of address, abandonment, or authorized personnel.

If an order is placed by an individual who is not listed as an authorized agent designated by the practitioner, the order will not be processed until we have received written documentation that the individual placing the order is an authorized agent of the DEA license holder. Verbal updates to authorized agents will not be accepted. If the authorized DEA license holder is the only individual placing orders, please document this information below.

Name of DEA registered individual practitioner	
DEA registration number:	
List Authorized Agents of DEA License Holder:	
Name	Title
I,	(Name of DEA registered individual practitioner), the undersigned,
who is authorized to procure controlled substances, hereby author	ize the above individuals to act as my agent for ordering from Relmar

who is authorized to procure controlled substances, hereby authorize the above individuals to act as my agent for ordering from Belmar Select Outsourcing via phone, e-mail, fax, or an electronic ordering system.

Signature of DEA registered individual practitioner:

Signed and dated on the _____ day of _____ (month), _____ (year), at _____



Pellet Order Form

Fax order to: (877)-267-3409 | Email order to: orders@belmarselectoutsourcing.com

Hours of Operation: Mon-Thurs 8am - 5pm | Fri 8am - 3pm MST Orders received before 12pm MST will be processed same business day.

Practitioner Name		Date
Pellet Order Submitted by		Phone
Email for Tracking		Date Needed
Credit Card on File Ending in	Call for Credit Card	For Appt. On

Testosterone pellets must be ordered in multiples of 10 per pellet strength (10, 20, 30).

Estradiol (Pure) No Minimum		Testoste (Cholesterol <			Testoste (Pure)	rone	
Strength	Quantity	Strength	Quantity		Strength	Quantity	
6mg		12.5mg		_	12.5mg		_
10mg _		. 25mg		_	25mg		_
12.5mg		. 37.5mg		_	37.5mg		_
15mg		. 50mg		_	50mg		_
18mg		62.5mg		_	62.5mg		_
20mg _		70mg		_	70mg		_
22mg		. 80mg		_	80mg		_
25mg		. 87.5mg		_	87.5mg		_
37.5mg		100mg		_	100mg		_
50mg _		* 200mg		Round End	200mg		B
		* 200mg		Blunt End			

Testosto (Cholesterol			Anastro No Minimum		Progesterone No Minimum								Testosterone/Anas No Minimum		rozole
Strength	Quantity		Strength	Quantity		Strength	Quantity		Strength	Quantity					
100mg		_	6mg			50mg		_	100mg/4mg		Blunt End				
* 200mg		Round End	10mg			75mg		_	200mg/8mg		Blunt End				
* 200mg		Blunt End	20mg			* Not recommende	ed for protection of the	endo	ometrium.						

Shipping Options* No returns, exchanges, or refunds. Shipping times not guaranteed.

FedEx/UPS 3rd Day / by 4:30pm (\$20)

FedEx/UPS 2nd Day / by 12:00pm (\$27)

FedEx/UPS Priority Overnight / by 12:00pm (\$45)

FedEx/UPS 2nd Day / by 4:30pm **DEFAULT** (\$24)

FedEx/UPS First Overnight / by 8:00am (\$105)

UPS Ground 5 days Continental US Only (\$10)

FedEx/UPS Standard Overnight / by 4:30pm (\$40)

When you place an order of \$1000 or more, FREE 2ND DAY Shipping (DEFAULT) or \$24 off any other shipping option. *Shipping carrier may vary.

Questions? Call: (877) 267-3410 or visit www.BelmarSelectOutsourcing.com



Fax order to: (877)-267-3409 | Email order to: orders@belmarselectoutsourcing.com

Hours of Operation: Mon-Thurs 8am - 5pm | Fri 8am - 3pm MST Orders received before 12pm MST will be processed same business day.

Note: The manufacturer/supplier of trocars may vary

Disposable Trocars	Quantity	
Pellet Insertion Procedure Tray Only (Does not contain instrument)		
Plastic Disposable Trocar Kit Small*		
Plastic Disposable Trocar Kit Large**		
Stainless Steel Tip Disposable Trocar Kit Small*		
Stainless Steel Tip Disposable Trocar Kit Large**		
* "Small" trocars work with pellets that are 100mg or smaller		

** "Large" trocars work with 200mg pellets

Reuseable Trocars (\$175)

6mg - 100mg Pellets (Female)	Quantity
Stainless Steel Long Trocar Kit 3.5mm (3.5FL)	
Stainless Steel Short Trocar Kit 3.5mm (3.5FS)	
200mg Pellets (Male)	Quantity
Stainless Steel Long Trocar Kit 4.6mm (4.6ML)	
Stainless Steel Short Trocar Kit 4.6mm (4.6MS)	

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Orders received before 12pm MST will be processed same business day.

Practitioner Name		Date
Order Submitted by		Phone
Email for Tracking		Date Needed
Credit Card on File Ending in	Call for Credit Card	For Appt. On

* Injectables must be ordered in multiples of 5 vials per concentration. (5, 10, 15)

Medication	Concentration	Price per Vial	Vial Size	Total Qty.
Testosterone Cypionate / Anastrozole (Grapeseed Oil)	200mg/1mg per mL	\$36	10mL	
Testosterone Cypionate / Anastrozole (Grapeseed Oil)	200mg/0.5mg per mL	\$36	10mL	
Testosterone Cypionate / DHEA (Grapeseed Oil)	200mg/10mg per mL	\$34	10mL	

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FedEx/UPS Priority Overnight / by 12:00pm (\$45)

FedEx/UPS First Overnight / by 8:00am (\$105)

- FedEx/UPS 2nd Day / by 12:00pm (\$27)
- UPS Ground 5 days Continental US Only (\$10)

FedEx/UPS Standard Overnight / by 4:30pm (\$40)

FedEx/UPS 2nd Day / by 4:30pm **DEFAULT** (\$24)

When you place an order of \$1000 or more, FREE 2ND DAY Shipping (DEFAULT) or \$24 off any other shipping option. Pre-Sale Orders of \$500 or more will ship via UPS Ground at no charge (\$10 value)

*Shipping carrier may vary.

Questions? Call: (877) 267-3410 or visit www.BelmarSelectOutsourcing.com