

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-015/S-010**

**CHEMISTRY REVIEW(S)**

**CHEMIST REVIEW #3  
Supplement**

1. **ORGANIZATION:** HFD-580
2. **NDA Number:** 21-015
3. **SUPPLEMENT NO/DATES:** SCP-010  
**Letter Date:** 9-Apr-2003  
**Stamp Date:** 10-Apr-2003  
**Due Date:** 9-Aug-2003
4. **AMENDMENTS DATES:**  
**Letter Date:** 15-Aug-2003  
**Stamp Date:** 19-Aug-2003  
**Letter Date:** 4-Sept-2003  
**Stamp Date:** 5-Sept-2003  
**Letter Date:** 9-Sept-2003  
**Stamp Date:** 9-Sept-2003
5. **RECEIVED BY CHEMIST:** Apr 2003

6. **SPONSOR NAME AND ADDRESS**

Unimed Pharmaceuticals  
901 Sawyer Road  
Marietta, GA 30062

7. **DRUG PRODUCT NAME:** AndroGel

8. **NONPROPRIETARY NAME:** Testosterone Gel

9. **DRUG SUBSTANCE NAME/STRUCTURE**

Testosterone  
See USP 25 for the chemical structure.

10. **DOSAGE FORM:** Topical Gel

11. **STRENGTH:** 2.5 g gel (25 mg testosterone) 5.0 g gel (50 mg testosterone)

12. **PHARMACOLOGICAL CATEGORY :** testosterone replacement

13. **HOW DISPENSED:** Rx

14. **RECORDS AND REPORTS CURRENT:** Yes

15. **RELATED IND/NDA/DMF:** DMFs \_\_\_\_\_, and \_\_\_\_\_

16. **SUPPLEMENT PROVIDES FOR:** an alternate container/closure system that consists of a multi-use pump and canister delivery system

17. **COMMENTS:** The response to the approvable letter dated August 15, 2003, a revised specification sheet submitted in the amendment of September 4, 2003, and a labeling change in the amendment of September 9, 2003, are reviewed here.

18. **SPECIAL PRODUCTS:** None

19. **CONCLUSIONS AND RECOMMENDATIONS :** This Prior Approval Supplement is recommended for approval. Issue an Approval Letter.

<b>20. REVIEWER NAME</b>	<b>SIGNATURE</b>	<b>DATE COMPLETED</b>
J. Salemme, Ph.D. Review Chemist		5-Sept-2003

APPROVED FOR  
ON ORIGINAL

4 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(4) Draft Labeling

§ 552(b)(5) Deliberative Process

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
Jean Salemmé  
9/11/03 10:06:21 AM  
CHEMIST

Moo-Jhong Rhee  
9/11/03 10:39:11 AM  
CHEMIST  
I concur

APPEARS THIS WAY  
ON ORIGINAL

Addendum to Chemistry Review No. 2  
NDA 21-015/ SCP-010

In the approvable letter to be sent to the sponsor on August 8, 2003, the wording of the request for additional information has been changed from that shown in Chemistry Review 2. The wording has been changed to more clearly specify what data should be submitted. The revised wording is as follows:

The proposal to  
packaged in th

\_\_\_\_\_ is not acceptable. You must provide a better

\_\_\_\_\_ Analytical data should be provided to show that

\_\_\_\_\_ The data should include a summary that \_\_\_\_\_

Signed: J. Salemme, Ph.D., Chemistry Reviewer, HFD-580, August 8, 2003

APPROVED FOR RELEASE  
ON ORIGINAL

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
Jean Saleme  
8/8/03 09:56:43 AM  
CHEMIST

David T. Lin  
8/8/03 10:01:56 AM  
CHEMIST  
I concur.

Received  
the

**CHEMIST REVIEW #2  
Supplement**

1. **ORGANIZATION:** HFD-580
2. **NDA Number:** 21-015
3. **SUPPLEMENT NO/DATES:** SCP-010  
**Letter Date:** 9-Apr-2003  
**Stamp Date:** 10-Apr-2003  
**Due Date:** 9-Aug-2003
4. **AMENDMENTS/REPORTS DATES:**  
**Letter Date:** 6-Jun-2003  
**Stamp Date:** 9-Jun-2003  
**Letter Date:** 23-Jul-2003  
**Stamp Date:** 24-Jul-2003
5. **RECEIVED BY CHEMIST:** Apr 2003

6. **SPONSOR NAME AND ADDRESS**

Unimed Pharmaceuticals  
901 Sawyer Road  
Marietta, GA 30062

7. **DRUG PRODUCT NAME:** AndroGel

8. **NONPROPRIETARY NAME:** Testosterone Gel

9. **DRUG SUBSTANCE NAME/STRUCTURE**

Testosterone  
See USP 25 for the chemical structure.

10. **DOSAGE FORM:** Topical Gel

11. **STRENGTH:** 2.5 g gel (25 mg testosterone) 5.0 g gel (50 mg testosterone)

12. **PHARMACOLOGICAL CATEGORY:** testosterone replacement

13. **HOW DISPENSED:** Rx

14. **RECORDS AND REPORTS CURRENT:** Yes

15. **RELATED IND/NDA/DMF:**

16. **SUPPLEMENT PROVIDES FOR:** an alternate container/closure system that consists of a multi-use pump and canister delivery system

17. **COMMENTS:** Responses to deficiencies provided to the Agency in the 6-Jun-2003 and 23-Jul-2003 submissions are reviewed here.

18. **SPECIAL PRODUCTS:** None

19. **CONCLUSIONS AND RECOMMENDATIONS :** This Prior Approval Supplement is approvable pending additional information. Issue an **Approvable** letter with the following comment.

The proposal to \_\_\_\_\_  
\_\_\_\_\_ is not acceptable. A scientific rationale that  
\_\_\_\_\_ should be provided. In addition, include  
\_\_\_\_\_  
\_\_\_\_\_

20. **REVIEWER NAME**  
J. Salemme, Ph.D.  
Review Chemist

**SIGNATURE**

**DATE COMPLETED**  
01-Aug-2003

APPROVED FOR SIGNATURE  
ON 7/28/03

8 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(4) Draft Labeling

§ 552(b)(5) Deliberative Process

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
Jean Salemmme  
8/6/03 09:48:44 AM  
CHEMIST

David T. Lin  
8/6/03 09:55:47 AM  
CHEMIST  
I concur.

APPEARS THIS WAY  
ON ORIGINAL

**CHEMIST REVIEW #1  
Supplement**

1. **ORGANIZATION:** HFD-580
2. **NDA Number:** 21-015
3. **SUPPLEMENT NO/DATES:** SCP-010  
**Letter Date:** 9-Apr-2003  
**Stamp Date:** 10-Apr-2003  
**Due Date:** 9-Aug-2003
4. **AMENDMENTS/REPORTS DATES:**  
**Letter Date:** N/A  
**Stamp Date:** N/A
5. **RECEIVED BY CHEMIST:** Apr 2003

6. **SPONSOR NAME AND ADDRESS**

Unimed Pharmaceuticals  
901 Sawyer Road  
Marietta, GA 30062

7. **DRUG PRODUCT NAME:** AndroGel

8. **NONPROPRIETARY NAME:** Testosterone Gel

9. **DRUG SUBSTANCE NAME/STRUCTURE**

Testosterone  
See USP 25 for the chemical structure.

10. **DOSAGE FORM:** Topical Gel

11. **STRENGTH:** 2.5 g gel (25 mg testosterone) 5.0 g gel (50 mg testosterone)

12. **PHARMACOLOGICAL CATEGORY :** testosterone replacement

13. **HOW DISPENSED:** Rx

14. **RECORDS AND REPORTS CURRENT:** Yes

15. **RELATED IND/NDA/DMF:**

16. **SUPPLEMENT PROVIDES FOR:** an alternate container/closure system that consists of a multi-use pump and canister delivery system

17. **COMMENTS:** See review on the following pages.

18. **SPECIAL PRODUCTS:** None

19. **CONCLUSIONS AND RECOMMENDATIONS** : This Prior Approval Supplement is recommended for approval pending satisfactory resolution of the deficiencies outlined in the Deficiency Letter.

20.	<b><u>REVIEWER NAME</u></b>	<b><u>SIGNATURE</u></b>	<b><u>DATE COMPLETED</u></b>
	J. Salemme, Ph.D. Review Chemist		

14 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

       § 552(b)(4) Draft Labeling

       § 552(b)(5) Deliberative Process

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/  
-----

Jean Salemmé  
5/20/03 12:31:31 PM  
CHEMIST

David T. Lin  
5/20/03 12:44:33 PM  
CHEMIST  
I concur.

APPEARING THIS WAY  
ON 5/20/03