

2005 Current Fiscal Year Report: Advisory Committee for Reproductive Health Drugs

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1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2005

3. Committee or Subcommittee

Advisory Committee for Reproductive Health Drugs

3b. GSA

Committee No.

871

4. Is this New During Fiscal Year?

No

5. Current Charter

03/23/2004

6. Expected Renewal Date

03/23/2006

7. Expected Term Date

8a. Was Terminated During Fiscal Year?

No

8b. Specific Termination Authority

8c. Actual Term Date

9. Agency Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

No

10b. Legislation Pending?

11. Establishment Authority

21 U.S.C. 394

12. Specific Establishment Authority

13. Effective Date

11/28/1990

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee: Scientific Technical Program Advisory Board

16a. Total Number of Reports

16b. Report Date Report Title

09/30/2005 Annual Report to the Secretary

Number of Committee Reports Listed: 1

17a. Open

1 17b. Closed 0 17c. Partially Closed 0 Other Activities 0 17d. Total 1

Meetings and Dates

Purpose

Start

End

The committee met to discuss the safety and efficacy of NDA 21-769 - Testosterone Transdermal System, (proposed trade name Intrinsa®), Procter and Gamble, indicated for 12/02/2004 - 12/02/2004 the treatment of hypoactive sexual desire disorder in surgically menopausal women receiving concomitant estrogen therapy

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$5,160.00	\$24,640.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$92,296.00	\$97,217.00
18a(4). Personnel Pmts to Non-Member Consultants	\$3,010.00	\$8,800.00
18b(1). Travel and Per Diem to Non-Federal Members	\$9,822.00	\$46,753.00
18b(2). Travel and Per Diem to Federal Members	\$0.00	\$0.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$5,904.00	\$17,206.00
18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	\$0.00	\$0.00
18d. Other (all other funds not captured by any other cost category)	\$12,547.00	\$38,394.00
18e. Total Costs	\$128,739.00	\$233,010.00

19. Federal Staff 1.08 1.08
Support Years (FTE)

20a. How does the Committee accomplish its purpose?

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in obstetrics, gynecology, endocrinology, pediatrics, epidemiology, urology or statistics, and related specialties. The committee also will include one technically qualified member who is identified with consumer interests and may include one non-voting representative who is identified with industry interests.

20c. How frequent and relevant are the Committee Meetings?

The Advisory committee met one time in FY 2005. On December 2, 2004, the Committee met to evaluate the safety and efficacy of NDA 21-769, Testosterone Transdermal System (TTS), (proposed trade name Intrinsa®), Procter and Gamble, indicated for the treatment of hypoactive sexual desire disorder in surgically menopausal women receiving concomitant estrogen therapy. The Committee felt that the efficacy presented was fairly marginal, but statistically significant, and could represent a clinically meaningful difference from placebo. In the light of the results of the Women's Health Initiative, the Committee expressed concerns about the long-term use of

hormonal treatments, with their widespread biological effects, without greater knowledge of the safety risks. The highest priority would be long-term studies in naturally menopausal women, because the potential for off-label use requires much more data for both safety and efficacy. The studies should include arms with TTS alone, with estrogen, and with both estrogen and progesterone. The Committee emphasized the need for a prospective, long-term, randomized, controlled trial to determine the hazard ratio of this therapy. It is expected that the Advisory Committee for Reproductive Health Drugs will meet 2 to 4 times during FY2006.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the committee are drawn from academia, research, and/or clinical practice. Their advice and input lends credibility to regulatory decisions made and helps those decisions withstand intense public scrutiny. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientists on a full-time basis at maximum rates of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?

There were no closed meetings in FY2005.

21. Remarks

Designated Federal Officer

Teresa A. Watkins Health Science Administrator,
Advisors and Consultants Staff, Center for Drug
Evaluation and Research, FDA, HFD-21

Committee Members	Start	End	Occupation	Member Designation
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Burnett, II, Arthur	12/01/2003	06/30/2007	Professor of Urology, Johns Hopkins University School of Medicine	Special Government Employee (SGE) Member
Dickey, Nancy	12/27/2002	06/30/2005	President & Vice Chancellor for Health Affairs, Texas A & M University System	Special Government Employee (SGE) Member
Emerson, Scott	12/27/2002	06/30/2006	Professor, Department of Biostatistics, University of Washington	Special Government Employee (SGE) Member
Gibbs, Ronald	07/01/2005	06/30/2009	Professor and Chair, Department of Obstetrics and Gynecology, University of Colorado	Special Government Employee (SGE) Member
Giudice, Linda	12/27/2002	06/30/2006	Chief, Division of Reproductive Endocrinology and Infertility, Dept. of ObGyn, Stanford University Medical Center	Special Government Employee (SGE) Member
Hager, William	12/27/2002	06/30/2005	Professor, Dept. of Obstetrics & Gynecology, University of Kentucky	Special Government Employee (SGE) Member
Lewis, Vivian	12/27/2002	06/30/2006	Director, Division of Reproductive Endocrinology, University of Rochester	Special Government Employee (SGE) Member
Lipshultz, Larry	04/11/2003	06/30/2006	Chief, Division of Male Reproductive Medicine & Surgery, Scott Dept. of Urology, Baylor College of Medicine	Special Government Employee (SGE) Member
Lockwood, Charles	12/01/2003	06/30/2007	Anita O'Keefe Young Professor Chairman, Dept. of Obstetrics & Gynecology, Yale University School of Medicine	Special Government Employee (SGE) Member

Macones, George	12/27/2002	06/30/2005	Associate Professor, Department of Obstetrics and Gynecology, University of Penn School of Medicine	Special Government Employee (SGE) Member
Merritt, Diane	11/16/2004	06/30/2008	Professor of Obstetrics and Gynecology, Dept. of Obstetrics and Gynecology, Washington Univ. School of Medicine	Special Government Employee (SGE) Member
Montgomery-Rice, Valerie	12/27/2002	06/30/2006	Chair and Professor, Dept. of Obstetrics & Gynecology, Meharry Medical College	Special Government Employee (SGE) Member
Scott, James	07/01/2005	06/30/2009	Professor, Department of Obstetrics and Gynecology, University of Utah School of Medicine	Special Government Employee (SGE) Member
Stanford, Joseph	12/27/2002	06/30/2005	Associate Professor, Dept. of Family and Preventive Medicine, University of Utah	Special Government Employee (SGE) Member
Steers, William	07/01/2005	06/30/2009	Chairman, Department of Urology, University of Virginia Health System	Special Government Employee (SGE) Member
Tobert, Jonathan	02/02/2004	10/31/2007	Tobert Medical Consulting	Special Government Employee (SGE) Member
Tulman, Lorraine	12/01/2003	06/30/2007	Consumer Representative - Associate Professor, University of Pennsylvania School of Nursing Interim Division	Special Government Employee (SGE) Member
Westney, Ouida	07/01/2005	06/30/2009	Director, Department of Surgery, Division of Urology, Univ. of Texas Medical School at Houston	Special Government Employee (SGE) Member

Number of Committee Members Listed: 18

Narrative Description

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and by helping the public get the accurate, science-based information they need to use medicines and foods to improve their health. The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input checked="" type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input type="checkbox"/>
Increased customer satisfaction	<input checked="" type="checkbox"/>
Implementation of laws or regulatory requirements	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

Outcome Comments

NA

What are the cost savings associated with this committee?

Checked if Applies

- None
- Unable to Determine
- Under \$100,000
- \$100,000 - \$500,000
- \$500,001 - \$1,000,000
- \$1,000,001 - \$5,000,000
- \$5,000,001 - \$10,000,000
- Over \$10,000,000
- Cost Savings Other

Cost Savings Comments

The utilization of the Advisory Committee for Reproductive Health Drugs enabled the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

1

Number of Recommendations Comments

NA

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

80%

% of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

10%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes No Not Applicable

Agency Feedback Comments

It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

Reorganized Priorities	<input checked="" type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input checked="" type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Action Comments

FDA approves or chooses not to approve an investigational new medical or food product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

Checked if Applies

Contact DFO	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>

Online Committee Web Site



Online GSA FACA Web Site



Publications



Other



Access Comments

NA