

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
TOTAL	4	4	6	9,100	13,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 4, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; Comment Request; Obstetrician-Gynecologists' Knowledge and Practice Patterns With Regard to Hormone Therapy

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* Obstetrician-Gynecologists' Knowledge and Practice Patterns with Regard to Hormone Therapy. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This study will evaluate and track the effect of results from the Federally-funded Women's Health Initiative (WHI) trials of estrogen plus progestin and estrogen alone, and of updated guidelines provided by Federal agencies and professional bodies, on the knowledge, attitudes and prescription behavior of members of the American College of Obstetricians and Gynecologists (ACOG) in regard to the use of postmenopausal hormone therapy. The publication of the WHI trial findings for estrogen plus progestin in 2002 generated massive media coverage and revisions to the guidelines for the use of hormones, including revisions of the package insert by the Food and Drug Administration. The revised view of the value of hormone therapy to prevent chronic diseases has had a major impact on obstetrician-gynecologists, who are among the principal health care providers for women and who now account for the majority of prescriptions

for postmenopausal hormones. The investigators propose to survey fellows of ACOG over a four and a half year period. Objectives of the study are to evaluate the extent to which the WHI findings for estrogen plus progestin have been accepted by ACOG members, and what the effect has been on their prescription patterns. The initial two surveys will also form a baseline for two further surveys subsequent to the anticipated publication of the WHI estrogen-only trial results in 2005. The findings will provide valuable information concerning ACOG members' knowledge of current and past research findings regarding hormone therapy, their awareness of ACOG and Federal guidelines for the use of hormone therapy, their own current practice and changes from past practice, their concerns and informational and educational needs. The proposed surveys, performed over a period, will allow the investigators to track changes in knowledge, attitudes, and practice over a period of evolving knowledge among a representative sample of obstetrician-gynecologists. The finding will assist the Government and professional bodies in evaluating the degree of translation of research findings into practice, and with developing educational materials for physicians to assist with translation. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; Businesses or other for-profit. *Type of Respondents:* Physicians. The annual reporting burden is as follows: *Estimated Number of Respondents:* 1825; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 25, and *Estimated Total Annual Burden Hours Requested:* 456. The annualized costs to respondents is estimated at: \$34,200. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's

estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Jacques E. Rossouw, Project Officer, Women's Health Initiative, NHLBI, NIH, Rockledge 1 Building, Suite 300, 6705 Rockledge Drive, Bethesda, MD 20892, or call (301) 435-6669 (not a toll-free number) or E-mail you request, including your address to: [rossouwj@nih.gov](mailto:rossouwj@nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: October 28, 2003.

**Jacques Rossouw,**

*NHLBI, National Institutes of Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, NHLBI.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 52b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Heart, Lung, and Blood Institute, including consideration of personnel