Bureau, and the Family and Youth Services Bureau will be represented.

Because of the limited time for this day-long Consultation Session, ACF has partnered with the NCAI to plan and facilitate the session. NCAI will be responsible for coordinating the stakeholders who wish to participate in the Consultation Session. NCAI will work with a tribal planning committee to develop a structured agenda, identifying key issues to be raised and spokespersons to present testimony on the issues.

For further information for the ACF National Native American Conference contact: Stacia Henderson at 703–821–2226 x232 at Native American Management Services, Inc. (NAMS) or toll-free 866–313–2955 or on-line at: *http://www.acfconference@namsinc.org.*

Dated: November 5, 2003.

Quanah Crossland Stamps,

Commissioner, Administration for Native Americans.

[FR Doc. 03–28336 Filed 11–10–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0481]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on food additive petitions.

DATES: Submit written or electronic comments on the collection of information by January 12, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed [extension/reinstatement] of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Additive Petitions—21 CFR Part 571

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation that prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of the act specifies the information that must be submitted by a petition in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provision of section 409 of the act, procedural regulations have been issued under part 571 (21 CFR part 571). These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the law. The regulations add no substantive requirements to those indicated in the law, but attempt to explain the requirements and provide a standard format for submission to speed the processing of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in 21 CFR parts 572, 573, and 580. The labeling regulations are considered by FDA to be cross referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
571.1(c) moderate category	1	1	1	1,800	1,800
571.1(c) complex category	1	1	1	6,000	6,000
571.6	2	2	4	1,300	5,200

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]—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

[1] 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.

[FR Doc. 03–28252 Filed 11–10–03; 8:45 am]

BILLING CODE 4160–01–S

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 Rocklege 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.*

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.

[FR Doc. 03–28281 Filed 11–10–03; 8:45 am]

BILLING CODE 4140–01–M

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