

This designation will become effective on July 22, 2007, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

**FOR FURTHER INFORMATION CONTACT:**

Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 513-533-6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to [OCAS@CDC.GOV](mailto:OCAS@CDC.GOV).

Dated: July 6, 2007.

**John Howard,**

*Director, National Institute for Occupational Safety and Health.*

[FR Doc. 07-3363 Filed 7-10-07; 8:45 am]

**BILLING CODE 4160-17-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Healthcare Research and Quality**

**Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Section 1013: Request for Nominations—The Effective Health Care Stakeholder Group**

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Notice of invitation to submit nominations for the Effective Health Care Stakeholder Group.

**SUMMARY:** The DHHS Agency for Healthcare Research and Quality (AHRQ) invites nominations from interested organizations and knowledgeable individuals for a Stakeholder Group to support the work of the Effective Health Care Program, funded under Section 1013 of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003. The goals of this program are to develop evidence on the effectiveness and comparative effectiveness of different treatments and health care interventions of importance to the Medicare, Medicaid, and State Child Health Insurance. To achieve these goals, AHRQ is supporting projects to review, synthesize, generate and translate published and unpublished scientific evidence, as well as identify important issues for which

existing scientific evidence is insufficient to inform decisions about health care. This evidence will be made readily available to all health care decision-makers. The Stakeholder Group is critical to the success of this project, providing input to the program in collaboration with the Effective Health Care Scientific Resource Center (currently based at the Oregon Evidence-based Practice Center).

The role of the Stakeholder Group will be to:

- Provide input on critical research information gaps for practice and policy and on identifying and developing the key research questions to address these gaps.
- Provide input on implementation issues for Effective Health Care program reports and findings.
- Define information needs and identify types of projects that will be most useful.
- Provide feedback from report users.
- Provide guidance on the program as a whole for quality improvement.
- Provide guidance on how the program can have more of an impact with users.

Members will serve as volunteers for a two-year period from October 2007 through September 2009. Stakeholder Group members will attend 3-4 meetings per year as part of this process. Meetings will be held in Rockville, MD and Portland, Oregon. Meetings will be 1-2 days in length. The Scientific Resource Center (SRC) will make the travel arrangements. The first meeting will be held on October 26, 2007, in Rockville, MD.

Members are expected to actively participate in meetings and to engage in related activities by phone and e-mail between meetings. Between-meeting work may include assisting with agenda planning and session preparation for Stakeholder meetings, consulting with SRC or AHRQ staff on constituency issues, and serving as a resource to the Effective Health Care Program. It is anticipated that the Stakeholder Group member time commitment between meetings will not exceed 10 hours.

The Stakeholder Group will be composed of up to 15 members. The group will represent several broad constituencies of stakeholders and decision-makers at the policy, system, and clinical levels, which will include:

- Third party healthcare payers (including, but not limited to public State or Federal Medicare or Medicaid programs, and private insurance health plans and Health maintenance Organizations).
- Employers and health-related business groups.

- Pharmacy and therapeutic committees.
- Healthcare providers.
- Patient/consumer organizations.
- Consumers of Federal and State beneficiary programs.
- Healthcare industry professional organizations.
- Academic researchers (including, but not limited to those with expertise in evidence-based methods and effectiveness and translational research).

Self-nominations are encouraged. Materials to be submitted are a cover letter and curriculum vitae or similar supportive documentation. The cover letter will provide information on how the nominee's experience, skills and roles fit with the composition and goals of the Stakeholder Group as described above. Specific information on nominee experience in the constituency groups described above is required. Nominees chosen for the Stakeholder Group will be required to declare and submit conflict of interest documentation. This will not necessarily preclude service. Nominees may indicate their willingness to be considered in subsequent calls for nominations if not selected for this Stakeholder Group in their supporting documentation.

All nominations received by submission deadline will be reviewed by a committee composed of representatives from AHRQ and the SRC. Nominees who best represent the broad constituencies described as the goal for composition of the Stakeholder Group will be selected and notified by September 28, 2007. In addition, AHRQ is interested in fostering diversity and including representatives of, or individuals with expertise regarding, populations experiencing health care disparities and in this case individuals with expertise regarding chronic conditions and health care needs of the Medicare, Medicaid, and State Children's Health Insurance Program (CHIP) populations.

**DATES:** Nominations for the Effective Health Care Stakeholder Group must be received by August 31, 2007.

**ADDRESSES:** Nominations for consideration may be e-mailed to [EffectiveHealthCare@ahrq.gov](mailto:EffectiveHealthCare@ahrq.gov).

**FOR FURTHER INFORMATION CONTACT:** Effective Health Care Program at (301) 427-1502 or [EffectiveHealthCare@ahrq.gov](mailto:EffectiveHealthCare@ahrq.gov).

More information about the Effective Health Care Program is available at <http://www.EffectiveHealthCare.ahrq.gov>.

**SUPPLEMENTARY INFORMATION:** Nominees not selected for the Stakeholder Group

are invited to participate in the Effective Healthcare Program by making suggestions for research and providing comment on key questions and draft reviews. In addition, a listserv has been established and those interested may join to be notified when items of interest become available for review or public comment. Opportunities for involvement in the Effective Health Care Program are described at <http://www.EffectiveHealthCare.ahrq.gov>.

Dated: July 3, 2007.

**Carolyn M. Clancy,**  
Director.

[FR Doc. 07-3360 Filed 7-10-07; 8:45 am]

**BILLING CODE 4160-90-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* ANA Consultant and Evaluator Qualifications Form.

*OMB No.:* 0970-0265.

*Description:* The ANA Consultant and Evaluator Qualifications Form is used to collect information from prospective proposal reviewers in compliance with 42 U.S.C. 2291d-1. The form will allow the Commissioner of ANA to select

qualified people to review grant applications for Social and Economic Development Strategies (SEDS), Native Language Preservation and Maintenance, Environmental Regulatory Enhancement, and Environmental Mitigation. The panel review process is a legislative mandate in the ANA grant funding process.

*Respondents:* Native Americans, Native Alaskans, Native Hawaiians and other Pacific Islanders.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ANA Consultant and Evaluator Qualifications Form .....	300	1	1	300

*Estimated Total Annual Burden Hours:* 300.

*Additional Information:*

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:*

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: July 5, 2007.

**Robert Sargis,**

Reports Clearance Officer.

[FR Doc. 07-3351 Filed 7-10-07; 8:45 am]

**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2006P-0218]

**Determination That ARISTOCORT FORTE Injectable Suspension (Triamcinolone Diacetate), 40 Milligrams per Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 milligrams (mg) per milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for triamcinolone diacetate suspension, 40 mg/mL.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Sadove, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved

under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.