

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]

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## 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.