DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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July 11, 2007

Elizabeth A. Marro
Senior Director, Regulatory Affairs and Quality Assurance
West-ward Pharmaceutical Corp.
465 Industrial Way West
Eatontown, NJ 07724

Re: Docket No. 2006P-0218/CP1

Dear Ms. Marro:

This letter responds to your citizen petition submitted on May 24, 2006, requesting that the Food and Drug Administration (FDA) determine whether Triamcinolone Diacetate Suspension (40 mg/mL) (NDA No. 12-802), held by Sandoz Canada Inc., was voluntarily withdrawn from sale for safety or efficacy reasons.

The FDA has reviewed its records and determined that Triamcinolone Diacetate Suspension (40 mg/mL) was not withdrawn from sale for reasons of safety or effectiveness. Thus, the FDA will maintain Triamcinolone Diacetate Suspension (40 mg/mL) in the *Discontinued Drug Product List* of *Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 443-5534.

Sincerely,

Elizabeth Sadove

Elizabeth Sadove
Division of Regulatory Policy I
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

2006P-0218

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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.*

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.

ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 mg/mL, is the subject of approved NDA 12–802 currently held by Sandoz Canada Inc., a Novartis AG company (Sandoz). Triamcinolone diacetate suspension (40 mg/mL) is a synthetic glucocorticoid for use as an anti-inflammatory or immunosuppressant agent. Sandoz ceased manufacturing ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 mg/mL, in March 2004. West-ward Pharmaceutical Corp. submitted a citizen petition dated May 22, 2006 (Docket No. 2006P–0218/CP1), under 21 CFR 10.30, requesting that the agency determine whether triamcinolone diacetate suspension, 40 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that triamcinolone diacetate suspension, 40 mg/mL, was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that for the reasons outlined previously in this document, ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 mg/mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 mg/mL, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: June 28, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13416 Filed 7–10–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Funding Opportunity Number: HHS–2007–IHS–UIHP–0001

Office of Urban Indian Health Programs; Announcement Type: Competitive Supplemental Grant Announcement

Catalog of Federal Domestic Assistance Number: 93.193

Key Dates: Application Deadline Date: August 13, 2007.

Review Date: August 16, 2007.

Earliest Anticipated Start Date: August 24, 2007.

I. Funding Opportunity Description

The Indian Health Service (IHS), Office of Urban Indian Health Programs (OUIHP) announces competitive 4-in-1 Title V grant supplements responding to an Office of Minority Health, HIV/AIDS Initiative. This program is authorized under the authority of the Snyder Act and 25 U.S.C. 1652, 1653 of the Indian Health Care Improvement Act, Public Law 94–437, as amended. This program is described at 93.193 in the Catalog of Federal Domestic Assistance (CFDA).

This competitive supplement seeks to expand OUIHP's existing Title V grants to increase the number of American Indians/Alaska Natives (AI/AN) with the awareness of his/her HIV status. This will provide routine and/or rapid HIV screening, prevention, pre and post test counseling, case management (if available) and data collection. Enhancement of urban Indian health program HIV/AIDS activities is necessary to reduce the incidence of HIV/AIDS in the urban Indian communities.

The purpose of the announcement is to respond to the fact that communities of color have been disproportionately affected by HIV and the need exists for access to early testing, diagnosis, treatment and prevention services. Over the past decade, the AI/AN community has developed and maintained a higher rate of HIV than Caucasians. It has also been demonstrated that AI/ANs have a decreased longevity once diagnosed compared to other races/ethnicities. These supplements will be used to enhance HIV testing, including rapid testing and/or standard HIV antibody testing and to provide a more focused effort to address HIV/AIDS prevention targeting some of the largest urban Indian populations in the United States.

The nature of these projects will require collaboration with the OUIHP to: (1) Coordinate activities; (2) participate in projects in other operating divisions of the Department such as CDC, SAMHSA, HRSA and the Office of Minority Health; and (3) submit and share data on HIV/AIDS testing, treatment and education.

II. Award Information

Type of Award: Title V Grant Supplements.

Estimated Funds Available: The total amount identified for Fiscal Year (FY) 2007 is seven supplement awards totaling $316,000. The award is for one year in duration and the average award, per program is approximately $45,142. Awards under this announcement are subject to the availability of funds.

Anticipated Number of Awards: Seven grant supplements will be made under the Program.

Project Period: April 1, 2007–March 31, 2008.

Award Amount: $316,000.

A. Requirements of Recipient Activities

In FY 2007 each grantee's attempted goal shall include screening as many individuals as possible; however, increasing screening 10% or to a minimum of 200 American Indians/Alaska Natives (AI/AN) tested per program funded—adjusted due to variations in size of facility and user population may be required. This does not include counts of re-testing individuals in the same year. Each program shall also collect evidence, as part of the testing process, to potentially address utility and barriers of increased routine HIV screening within this population.

III. Eligibility Information

1. *Eligible Applicants:* Urban Indian organizations, as defined by 25 U.S.C. 1603(h), limited to Urban Indian organizations which meet the following criteria:

a. Received State certification to conduct HIV rapid testing;

b. Health professionals and staff have been trained in the HIV/AIDS screening tools, education, prevention, counseling, and other interventions for American Indians/Alaskan Natives;

c. Attuned to the risk factors driving the HIV/AIDS epidemics among urban American Indians/Alaskan Natives;

d. Developed programs to address community and group support to sustain risk-reduction skills;