withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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.

Alphagan 0.2% (brimonidine tartrate ophthalmic solution) is the subject of NDA 20–613, held by Allergan, Inc. (Allergan). Alphagan 0.2% is administered as an eye drop to lower intraocular pressure in patients with open-angle glaucoma or ocular hypertension. FDA approved NDA 20–613 on September 6, 1996. In a letter dated August 20, 2002, Allergan informed FDA that it was withdrawing Alphagan 0.2% from the market. In a letter dated September 6, 2002, Allergan clarified that it was not requesting that approval be withdrawn for NDA 20–613, nor was Alphagan 0.2% being recalled from the market. Instead, Allergan explained that it was in the process of discontinuing distribution of Alphagan 0.2%. Following receipt of Allergan's letters, the agency moved Alphagan 0.2% from the ''Prescription Drug Product List'' section to the ''Discontinued Drug Product List'' section of the Orange Book.

In citizen petitions submitted under 21 CFR 10.30 and dated August 27, 2002 (Docket No. 02P–0404/CP1), and August 30, 2002 (Docket No. 02P–0391/CP1), respectively, Alcon, Inc. (Alcon), and IVAX Pharmaceuticals, Inc. (IVAX), requested that the agency determine whether brimonidine tartrate ophthalmic solution 0.2% was withdrawn from sale for reasons of safety or effectiveness. On October 28, 2002, Allergan submitted a citizen petition (Docket No. 02P–0469/CP1) opposing the granting of Alcon's and IVAX's petitions. Comments were submitted in response to Allergan's petition on November 13, 2002, and December 5, 2002, by Alcon and Bausch & Lomb, Inc. (Bausch & Lomb), respectively. Allergan responded to the comments on January 23, 2003. Bausch & Lomb submitted additional comments on February 10, 2003, and Allergan responded on March 18, 2003.

FDA has considered the information contained in the citizen petitions, comments, and agency records and has determined that Alphagan 0.2% was not withdrawn from sale for reasons of safety or effectiveness. There are several grounds for FDA's finding. First, Alphagan 0.2% has a safety and effectiveness profile that is comparable to that of Alphagan P (brimonidine tartrate ophthalmic solution 0.15%), the subject of NDA 21–262 approved March 16, 2001, for the same indication as Alphagan 0.2%. Approval of Alphagan P was based, in part, on references to the safety and efficacy of Alphagan 0.2% and the products' comparability as demonstrated in head-to-head studies. Second, FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports regarding brimonidine tartrate ophthalmic solutions, but has found no information that would indicate that Alphagan 0.2% was withdrawn for reasons of safety or effectiveness.

After considering the information contained in the citizen petitions, comments, and agency records, FDA determines that, for the reasons outlined above, brimonidine tartrate ophthalmic solution 0.2% approved under NDA 20–613 was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Alphagan 0.2% (brimonidine tartrate ophthalmic solution) 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 Alphagan 0.2% (brimonidine tartrate ophthalmic solution) may be approved by the agency.

Dated: June 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14680 Filed 6–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Chiropractor and Pharmacist Loan Repayment Demonstration Project

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: General notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications from qualified chiropractors and pharmacists who agree to serve underserved populations in Primary Care Health Professional Shortage Areas (HPSAs) throughout the Nation will be accepted by the National Health Service Corps (NHSC) for loan repayment awards. A two-year service commitment is required. There is no guarantee that participants in this demonstration project will have an opportunity to continue their service and loan repayments beyond the initial two-year service period. Chiropractors and pharmacists, with qualifying educational loans, must serve at organized primary health care sites in Primary Care HPSAs that have another NHSC clinician on staff who will be concurrently fulfilling an NHSC service commitment through the scholarship or loan repayment program and who is licensed to prescribe medications.

This demonstration project will include an evaluation component to determine whether adding chiropractors and pharmacists as permanent NHSC members would enhance the effectiveness of the NHSC. A maximum of 36 individuals will be awarded loan repayment contracts under this demonstration project.

Purpose: Eligible chiropractors and pharmacists will participate in the Loan Repayment Demonstration Project to determine whether their services will enhance the effectiveness of the NHSC.

Legislative Authority: These applications are solicited under section 338L of the Public Health Service (PHS) Act, as amended by Pub. L. 107–251.

Eligible Applicants: Eligible applicants must (1) be citizens or nationals of the United States, (2) possess a current unrestricted license to practice as a chiropractor or pharmacist in the State in which they intend to practice, (3) be negotiating or have secured employment at an eligible community site, and (4) meet the additional eligibility requirements outlined in the application materials. Chiropractors must also have a doctor of chiropractic degree from a four-year chiropractic college that is currently fully accredited by the Commission on Accreditation of the Council on Chiropractic Education, and successfully passed the entire examination by the National Board of Chiropractic Examiners. Pharmacists must also have a baccalaureate or doctor of pharmacy degree from a school that is currently fully accredited by the American Council on Pharmaceutical Education.

Funding Priorities or Preferences: Priority will be given to (A) applicants who have characteristics that increase the probability of their continuing to practice in HPSAs after they have completed service, and (B) subject to paragraph (A), applicants from disadvantaged backgrounds. A funding preference will also be given to applicants serving Primary Care HPSAs

of greatest shortage (based on the HPSA scores).

Statutory Matching or Cost Sharing Requirement: None.

Review Criteria: Loan repayment applications will be evaluated to determine: (1) The eligibility of the applicant, and (2) the applicant's priority for funding.

Estimated Amount of this Competition: $3,000,000.

Estimated Number of Awards: 36.

Estimated or Average Size of Each Award: $75,000.

Estimated Project Period: 2 years.

Application Requests, Availability, Dates and Addresses: Application materials are available for downloading via the web at *http://nhsc.bhpr.hrsa.gov.* Applicants may also request a hard copy of the application materials by contacting the National Health Service Corps at 1–800–221–9393. All applications must be submitted in hard copy format. Only the original signed copy of the application is required for submission. In order to be considered for an award, applications from chiropractors and pharmacists must be postmarked, or delivered to the HRSA National Health Service Corps, by no later than July 11, 2003. Completed applications must be mailed or delivered to: Division of National Health Service Corps, NHSC Loan Repayment Program, c/o I.Q. Solutions, 11300 Rockville Pike, Suite 801, Rockville, MD, 20852. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications postmarked or submitted after the deadline date, or sent to any other address other than that above, will be returned to the applicant and not processed. NHSC will acknowledge receipt of the application if the applicant chooses to complete the notification postcard that is included in the application materials.

Application Availability Date: June 11, 2003.

Application Deadline: July 11, 2003.

Projected Award Date: September 30, 2003.

FOR FURTHER INFORMATION CONTACT: NHSC Loan Repayment Program, 12312–A Wilkins Avenue, Rockville, Maryland, 20852. Telephone: 1–800–221–9393. E-mail: *NHSC@hrsa.gov.*

Paperwork Reduction Act: The application for the Chiropractor and Pharmacist Loan Repayment Demonstration Project has been approved by the Office of Management and Budget under the Paperwork Reduction Act. The OMB clearance number is 0915–0127. Should the evaluation component involve data collection activities that fall under the purview of the Paperwork Reduction Act, OMB clearance will be sought.

The program is not subject to the provision of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

Dated: May 22, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–14681 Filed 6–10–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Porcupine Clinic

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: The Indian Health Service (IHS) announces the Grant Award to the Porcupine Clinic for start up cost in reopening the Porcupine Dialysis Center for the dialysis patients who had utilized this center. Those dialysis patients have had to travel a long distance to make their appointments two to three times a week. The award is issued under the authority of the Indian Health Care Improvement Act, Section 1621(c), and is included under the Catalog of Federal Domestic Assistance number 93.933. The specific objectives of the project are:

1. To be used to prolong the lives of dialysis patients.

2. To provide culturally-based care for the Lakota people; and,

3. To ameliorate conditions resulting from lack of transportation, insufficient funding, and extreme social problems on the Pine Ridge Indian Reservation.

DATES: The Non-Competitive Emergency Grant is from 06/01/2003 to 5/31/2004 with a one time funding of $75,000.

FOR FURTHER INFORMATION CONTACT: For further information for program information, contact Paul Iron Cloud, Porcupine Clinic Executive Director, PO Box 275, Porcupine, South Dakota 57772, telephone (605) 867–5665 or Bruce Williams, Directors, Porcupine Clinic Dialysis Center, telephone (605) 867–6111. For grants information, contact Sylvia Ryan, Grants Management Specialist, Division of Acquisitions and Grants Management Branch, 801 Thompson Avenue, Rockville, Maryland 20852, telephone (301) 443–5204.

SUPPLEMENTARY INFORMATION: This project has been awarded on a non-competitive single source basis. Porcupine Dialysis Center is the only organization that represents approximately 23 dialysis patients who are treated two to three times a week. This dialysis center provides care to Native American people who live on the Pine Ridge and Rosebud reservations or who live in non-reservation areas with significant Native American populations. The population served by these programs is the same as IHS's user population.

The Grant Award has been awarded because of the need for dialysis and to present the need for dialysis renal failure. This grant is for one time funding of $75,000.

Dated: May 30, 2003.

Michel E. Lincoln,

Deputy Director.

[FR Doc. 03–14688 Filed 6–10–03; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: May 2003

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of May 2003, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.