

withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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 In a letter dated September 6, 2002, Allergan clarified that it was not requesting that approval be withdrawn for NDA 20-613, nor was Alphagan 0.2% being recalled from the market.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Inc. (IVAX), requested that the agency determine whether brimonidine tartrate ophthalmic solution 0.2% was withdrawn from sale for reasons of safety or effectiveness.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contained in the citizen petitions, comments, and agency records and has determined that Alphagan 0.2% was not withdrawn from sale for reasons of safety or effectiveness.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.*

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## **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