authority, FDA participates with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

The NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors. Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038 entitled ''Interstate Shellfish Dealer's Certificate.'' FDA uses this information to publish the ''Interstate Certified Shellfish Shippers List,'' a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, the NSSP would not be able to control the distribution of uncertified, and possibly unsafe, shellfish in interstate commerce, and its effectiveness would be nullified.

In the **Federal Register** of March 6, 2003 (68 FR 10730), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3038	34	62	2,108	.10	211

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on the numbers of certificates received in the past 3 years.

Dated: June 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14622 Filed 6–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0383]

Agency Information Collection Activities; Announcement of OMB Approval; Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 7, 2003 (68 FR 11117), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0012. The approval expires on May 31, 2004.

Dated: June 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14623 Filed 6–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 02P–0391 and 02P–0404]

Determination That Brimonidine Tartrate Ophthalmic Solution 0.2% 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 Alphagan 0.2% (brimonidine tartrate ophthalmic solution) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for brimonidine tartrate ophthalmic solution 0.2%.

FOR FURTHER INFORMATION CONTACT: Aileen H. Ciampa, 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 a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an 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 § 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