

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<sup>1</sup>

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

<sup>1</sup> 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.*

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**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.*

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**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