(3) The suspension decisionmaking process, which shall afford the contractor (and any specifically named affiliates) an opportunity, following the imposition of suspension, to submit, in person, in writing, or through a representative, information and argument in opposition to the suspension;

(4) Recommending to the CG whether or not to solicit offers from, award contracts to, or consent to subcontracts with a contractor who is debarred, suspended, or proposed for debarment; and

(5) Recommending to the CG whether or not to continue current contracts with a contractor or subcontractor who is debarred, suspended, or proposed for debarment.

OGC will review for legal sufficiency:

(1) Referrals by AM to the debarment/suspension official;

(2) Recommendations by AM to the CG that GAO solicit offers from, award contracts to, or consent to subcontracts with a contractor who is debarred, suspended, or proposed for debarment;

(3) Recommendations by AM to the CG to terminate a current contract because a contractor or subcontractor was subsequently debarred, suspended, or proposed for debarment; and

(4) Notices of proposed debarment, notices of suspension, or any other communication to a contractor regarding that contractor's potential or actual suspension or debarment.

Lynn H. Gibson,

General Counsel, U.S. Government Accountability Office.

[FR Doc. 2012–3307 Filed 2–10–12; 8:45 am]

BILLING CODE 1610–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60-days.

Proposed Project: Survey of Primary Care Physicians on Oral Health for the Office on Women's Health (OWH), U.S. Department of Health and Human Services (HHS) (New)—OMB No. 0990–NEW.

Abstract: The Office on Women's Health (OWH) at the Department of Health and Human Services is requesting OMB approval to conduct a new, one time survey of primary care physicians regarding oral health. This survey will provide the agency with information on oral health knowledge, attitudes, and professional experience among practicing physicians throughout the U.S. The study will explore physicians' level of understanding of oral disease and what constitutes health for the oral cavity, oral health training and support needs, current practices and barriers to further involvement. OWH is requesting two years of OMB approval to enable sampling, screening, and survey implementation.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Medical Secretary	Screener	1,300	1	5/60	108
Physician	Survey	600	1	30/60	300
Total					408

Keith A. Tucker,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2012–3210 Filed 2–10–12; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0292]

Determination That KAPVAY (Clonidine Hydrochloride) Extended-Release Tablets, 0.2 Milligram, 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 KAPVAY (clonidine hydrochloride) Extended-Release Tablets, 0.2 milligram (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for clonidine hydrochloride extended-release tablets, 0.2 mg, if all other requirements are met.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6262, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants 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. ANDA applicants 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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

KAPVAY (clonidine hydrochloride) Extended-Release Tablets, 0.2 mg, is the subject of NDA 22–331, held by Shionogi Pharma, Inc., and initially approved on September 28, 2010. KAPVAY is indicated for the treatment of attention deficit hyperactivity disorder as monotherapy or as adjunctive therapy to stimulant medications. Shionogi Pharma has never marketed KAPVAY (clonidine hydrochloride) Extended-Release Tablets, 0.2 mg. In previous instances (see, *e.g.,* 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Actavis, Inc. submitted a citizen petition dated April 20, 2011 (Docket No. FDA–2011–P–0292), under 21 CFR 10.30, requesting that the Agency determine whether KAPVAY (clonidine hydrochloride) Extended-Release Tablets, 0.2 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that KAPVAY (clonidine hydrochloride) Extended-Release Tablets, 0.2 mg, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that KAPVAY (clonidine hydrochloride) Extended-Release Tablets, 0.2 mg, was withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of KAPVAY (clonidine hydrochloride) Extended-Release Tablets, 0.2 mg from sale. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, FDA will continue to list KAPVAY (clonidine hydrochloride) Extended-Release Tablets, 0.2 mg, 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 KAPVAY (clonidine hydrochloride) Extended-Release Tablets, 0.2 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 7, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–3223 Filed 2–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0291]

Determination That JENLOGA (Clonidine Hydrochloride) Extended-Release Tablets, 0.1 Milligram and 0.2 Milligram, Were 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 JENLOGA (clonidine hydrochloride) Extended-Release Tablets, 0.1 milligram (mg) and 0.2 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for clonidine hydrochloride extended-release tablets, 0.1 mg and 0.2 mg, if all other requirements are met.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6262, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants 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. ANDA applicants 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,''