the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product JEVTANA (cabazitaxel). JEVTANA, in combination with prednisone, is indicated for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for JEVTANA (U.S. Patent Nos. 5,847,170 and 6,331,635) from Aventis Pharma S.A., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 11, 2011, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of JEVTANA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for JEVTANA is 4,250 days. Of this time, 4,171 days occurred during the testing phase of the regulatory review period, while 79 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* October 30, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 30, 1998.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* March 31, 2010. FDA has verified the applicant's claim that the new drug application (NDA) for JEVTANA (NDA 201023) was submitted on March 31, 2010.

3. *The date the application was approved:* June 17, 2010. FDA has verified the applicant's claim that NDA 201023 was approved on June 17, 2010.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,591 days and 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 3, 2012. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 31, 2012. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 16, 2012.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2012–10828 Filed 5–3–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: 2012 National Mental Health Services Survey (N–MHSS) (OMB No. 0930–0119)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Behavioral Health Statistics and Quality (CBHSQ), is requesting approval for a revision to the National Mental Health Services Survey (N–MHSS) (OMB No. 0930–0119), which expires on February 28, 2013. The N–MHSS provides national and state-level data on the number and characteristics of mental health treatment facilities in the United States.

An immediate need under N–MHSS in 2012 is to update the information about facilities on SAMHSA's online Mental Health Facility Locator (see: *http://store.samhsa.gov/mhlocator*), which was last updated with information from the 2010 N–MHSS. A full N–MHSS is anticipated within about two years, and a separate request for OMB approval will be submitted for that collection. However, until then, an abbreviated version of the N–MHSS will be conducted to collect only the information needed to update the Locator, such as the facility name and address, specific services offered, and special client groups served. The data on the Locator are becoming outdated and need an update method. Other fields in the full N–MHSS not needed for updating the Locator, such as client counts and client demographics, will not be collected in the Locator survey. In addition to the data collection for updating facilities on the Locator, a data collection in conjunction with adding new facilities to the Locator is being requested. Both activities will use the same abbreviated N–MHSS–Locator instrument.

This requested revision seeks to change the content of the currently approved full-scale N–MHSS survey instrument into an abbreviated survey

instrument, henceforth referred to as the N–MHSS–Locator, to accommodate two related N–MHSS activities:

(1) Collection of information from the full N–MHSS universe of mental health treatment facilities during 2012, 2013, and 2014. This abbreviated subset of N–MHSS data will update and expand SAMHSA's existing online Mental Health Facility Locator (see: *http://store.samhsa.gov/mhlocator*), which was last updated with information from the 2010 N–MHSS; and

(2) Collection of information on newly identified facilities throughout the year, as they are identified, so that new facilities can quickly be added to the Locator.

The survey mode for both data collection activities will be Web with telephone follow-up.

The database resulting from the 2012 N–MHSS–Locator will be used to update SAMHSA's online Mental Health Facility Locator and to produce a 2012 compact disk (CD) directory of facilities, both for use by consumers and service providers. In addition, a data file derived from the survey will be used to produce an annual report providing state and national data on the number and types of treatment facilities and services. The annual report and a public-use data file to be released in conjunction with the report will be used by researchers, mental health professionals, State governments, the U.S. Congress, and the general public.

The following table summarizes the estimated response burden for the two survey activities:

ESTIMATED TOTAL RESPONSE BURDEN FOR THE N–MHSS

Type of respondent	Number of respondents	Responses per respondent	Average hours per response	Total hour burden
Facilities in annual N–MHSS–Locator universe	15,000	1	.42	6,300
Newly identified facilities [1]	1,500	1	.42	630
Total Facilities	16,500			6,930

[1] Collection of information on newly identified facilities throughout the year, as they are identified, so that new facilities can quickly be added to the Locator.

Written comments and recommendations concerning the proposed information collection should be sent by June 4, 2012 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2012–10759 Filed 5–3–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: 2012 National Survey on Drug Use and Health (NSDUH) Questionnaire Field Test—NEW

The National Survey on Drug Use and Health (NSDUH) is a survey of the civilian, non-institutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

In order to continue producing current data, SAMHSA's Center for Behavioral Health Statistics and Quality (CBHSQ) must update the NSDUH periodically to reflect changing substance abuse and mental health issues. CBHSQ is planning to redesign the NSDUH for the 2015 survey year. The redesign will seek to achieve two main goals: (1) To revise the questionnaire to address changing policy and research data needs, and (2) to modify the survey methodology to improve the quality of estimates and the efficiency of data collection and processing. SAMHSA is requesting approval to conduct a Questionnaire Field Test (QFT) to test revisions to the questionnaire associated with these goals.

The field test will consist of 2,000 English-speaking respondents in the continental United States. The sample size of the survey will be large enough to detect differences between data collected using the annual NSDUH compared to the redesigned procedures. The total annual burden estimate is shown below:

ESTIMATED BURDEN FOR 2012 NSDUH QFT

Instrument	Number of respondents	Responses per respondent	Hours per response	Total burden hours	Hourly wage rate	Annualized costs
Household Screening	3,338	1	0.083	277	$14.45	$4,003