

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 SAMSCA (tolvaptan). SAMSCA is indicated for the treatment of clinically significant hypervolemic and euvoletic hyponatremia, including patients with heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for SAMSCA (U.S. Patent Nos. 5,258,510 and 5,753,677) from Otsuka Pharmaceutical Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated March 3, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SAMSCA 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 SAMSCA is 4,722 days. Of this time, 4,147 days occurred during the testing phase of the regulatory review period, while 575 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:* June 16, 1996. The applicant claims October 23, 1997, as the date the investigational new drug application (IND) became effective. However, according to FDA records, this IND was not the first IND received for this active ingredient. In general, FDA has used the first IND of the active ingredient of the drug product as the beginning of the testing phase, if information derived from this first IND was or could have been relied on or was relevant for approval to market the drug product. FDA records indicate that the effective date of the first IND for tolvaptan was June 16, 1996, which was

30 days after FDA receipt of this first IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* October 23, 2007. FDA has verified the applicant's claim that the new drug application (NDA) for SAMSCA (NDA 22-275) was submitted on October 23, 2007.

3. *The date the application was approved:* May 19, 2009. FDA has verified the applicant's claim that NDA 22-275 was approved on May 19, 2009.

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 1,826 days or 1,827 days respectively 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 February 14, 2011. 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 June 13, 2011. 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. It is no longer necessary to send three copies of mailed 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 regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 2010.

Jane A. Axelrad,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; GuLF Worker Study: Gulf Long-Term Follow-Up Study for Oil Spill Clean-Up Workers and Volunteers

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on 7 October 2010 on pages 62132-3 and allowed 60-days for public comment. One public comment was received and addressed regarding the appropriateness and sources for funding the survey. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

5 CFR 1320.5: Reporting and Recordkeeping Requirements: Final Rule: Respondents to this collection of information are not required to respond unless the data collection instruments display a currently valid OMB control number.

Proposed Collection

Title: GuLF Worker Study: Gulf Long-Term Follow-Up Study for Oil Spill Clean-Up Workers and Volunteers. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The purpose of the GuLF Study is to investigate potential short- and long-term health effects associated with oil spill clean-up activities and exposures surrounding the Deepwater Horizon disaster; and to create a resource for additional collaborative research on focused hypotheses or subgroups. Over 55,000 persons participating in oil-spill clean-up activities have been exposed to a range of known and suspected toxins in crude oil, burning oil, and dispersants, to excessive heat, and possibly to stress due to widespread economic and lifestyle disruption. Exposures range from negligible to potentially significant, however, potential long-term human health

consequences are largely unknown due to insufficient research in this area. Participants will be recruited from across job/exposure groups of primarily English, Spanish, or Vietnamese speaking adults (accommodations for other languages developed as appropriate) who performed oil-spill clean-up-related work ("exposed") and similar persons who did not ("unexposed" controls), and followed in either an *Active Follow-up Cohort* (N~27,000) or a *Passive Follow-up*

Cohort (N~28,000). Exposures will be estimated using detailed job-exposure matrices developed from data from monitoring performed by different agencies and organizations during the crisis, information obtained by interview, and the available scientific literature. We will investigate acute health effects among all cohort members via self-report from the enrollment interview, and via clinical measures and biological samples from Active Follow-up Cohort members only. All cohort

members will be followed for development of a range of health outcomes through record linkage (e.g., cancer, mortality) and possibly through linkage with routinely collected health surveillance data (collected by health departments and the CDC) or with electronic medical records. Recruitment of subjects should begin in late 2010, with telephone interviews and the baseline home visits conducted within 18 months.

Activity (3-yrs)	Estimated number of respondents	Estimated responses per respondent	Burden hours per response	Total burden hours per respondent	Estimated total burden hours
Ineligible respondents	25,000	1	0.25	0.25	6,250
Enrollment interview (All)	55,000	1	0.50	0.50	27,500
Home Visit (Active)	27,000	1	2.75	2.75	74,250
Annual Contact Info Update (Passive)	28,000	3	0.25	0.75	21,000
Annual Contact Info Update (Active)	27,000	2	0.25	0.50	13,500
Biennial interview (Active)	27,000	1	0.50	0.50	13,500
Passive Cohort Total responses & hrs	4	1.25
Active Cohort Total responses & hrs	5	4.25
TOTAL responses & avg hrs per response	9	0.58	156,000
Average per year	52,000

Frequency of Response: Participation will include one enrollment telephone interview (0.5 hr); collection of biological and environmental samples, basic clinical measurements, and GPS coordinates (2.75 hr) from the Active Follow-up Cohort only; annual contact information update (0.25; Active and Passive) or biennial follow-up telephone or Web interviews (0.5 hr; Active only) for 10 years or more. We also anticipate screening 25,000 ineligible respondents. **Affected Public:** Individuals or households. **Type of Respondents:** Workers involved in Deepwater Horizon disaster clean-up, and similar individuals not involved in clean-up effort. The annual reporting burden is as follows: **Estimated Number of Respondents:** Active Follow-up Cohort (N~27,000) and Passive Follow-up Cohort (N~28,000).

Estimated Number of Responses per Respondent: See table.

Average Burden Hours Per Response: 0.58 hour; and **Estimated Total Burden Hours Requested:** 156,000 (over 3 years). The average annual burden hours requested is 52,000. The annualized cost to respondents is estimated at \$11.60 (assuming \$20 hourly wage \times 0.58 hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper

performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the project or to obtain a copy of the data collection plans and instruments, contact: Dr. Dale P. Sandler, Chief, Epidemiology Branch, NIEHS, Rall Building A3-05, PO Box 12233, Research Triangle Park, NC 27709; non-toll-free number 919-541-4668 or e-mail sandler@niehs.nih.gov. Include your address.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if

received within 30 days of the date of this publication.

Dated: December 9, 2010.

W. Christopher Long,
NIEHS, Acting Associate Director for Management, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Recruitment and Screening for the Insight Into Determination of Exceptional Aging and Longevity (IDEAL) Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Aging (NIA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 17, 2010, page 57038 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30-days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an