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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2011-0704; FRL-9520-9]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: *Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects; EPA ICR No. 2195.04, OMB Control No. 2070-0169*. This is a request to renew an existing approved collection. The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before [insert date 30 days after publication in the Federal Register].

ADDRESSES: Submit your comments, referencing Docket ID No. EPA-HQ-OPP-2011-0704, to (1) EPA online using *http://www.regulations.gov* (our preferred method), or by mail to: OPP Docket, EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC., and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Lily G. Negash, Field & External Affairs Division (7605P), Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave., NW, Washington, DC 20460; telephone number: 703-347-8515; fax number: 703-305-5884; email address: *negash.lily@epa.gov*.

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval under the PRA, 44 U.S.C 3501 *et. seq.,* and according to the procedures prescribed in 5 CFR 1320.12. On December 7, 2011 (76 FR 76399), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID number EPA-HQ-OPP-2011-0704, which is available at *http://www.regulations.gov*, or in person viewing at the OPP Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA/DC Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202-566-1744, and the telephone number for the OPP Docket is 703-305-5805.

Use EPA's electronic docket and comment system at *http://www.regulations.gov*, to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select "docket search," then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov*.

Title: Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects

ICR numbers: EPA ICR No. 2195.04, OMB Control No. 2070-0169.

ICR Status: OMB approval of this ICR is currently scheduled to expire on August 31, 2012. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. 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. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register when approved, are listed in 40 CFR part 9, are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable.

Abstract: EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). As revised in 2006, EPA regulations at 40 CFR Part 26 protect subjects of "third-party" human research (i.e., research that is not conducted or supported by EPA). In addition to other protections, the regulations require affected entities to submit information to EPA and an institutional review board (IRB) prior to initiating, and to EPA upon the completion of, certain studies that involve human research participants. The information collection activity consists of activity-driven reporting and recordkeeping requirements for those who intend to conduct research for submission to EPA under the pesticide laws. If such research involves intentional dosing of human subjects, these individuals (respondents) are required to submit study protocols to EPA and a cognizant local Human Subjects IRB before such research is initiated so that the scientific design and ethical standards that will be employed during the proposed study may be reviewed and approved. Also, respondents are required to submit information about the ethical conduct of completed research that involved human subjects when such research is submitted to EPA.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 2119 hours per response for research involving exposure of human subjects, and 12 hours per response for all other submitted research with human subjects. Burden is defined in 5 CFR 1320.3(b).

Respondents/Affected Entities: Any entity that submits protocols and study reports for environmental research involving human subjects under FIFRA and/or FFDCA.

Estimated Number of Respondents: 7 annually for research involving intentional exposure of human subjects, and 10 annually for all other submitted research with human subjects.

Frequency of Response: Occasional.

Estimated Total Annual Burden: 14,833 hours for research involving intentional exposure of human subjects, and 120 hours for all other submitted research with human subjects.

Estimated Total Annual Cost: $1,299,759, which includes $0 annualized capital or O&M costs.

Changes in the Estimates: There is a decrease of 5,619 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease is due to a decrease in the anticipated number of responses per year. This change is an adjustment.

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John Moses, Director, Collection Strategies Division.

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