Supporting Statement for
An Information Collection Request (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a). Title and Number of the Information Collection

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

OMB Control No. 2070-0169; EPA ICR No. 2195.04

1(b). Short Characterization

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 and 2013, 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.[1] 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.

This renewal ICR estimates the third party response burden from complying with the requirements in 40 CFR Part 26, as amended in 2006 and 2013. Information is typically submitted by registrants of pesticide products to support the registration of their products.

2. NEED FOR AND USE OF THE COLLECTION

2(a). Need/Authority for the Collection

The 2006 Appropriations Act, Public Law No. 109-54, required EPA to issue a final rule addressing third-party intentional dosing human toxicity studies for pesticides, and EPA conduct of intentional dosing human toxicity studies for pesticides (Attachment B). This ICR applies to all of the information collection activities identified in the 2006 rule that EPA promulgated in

1 Information about the 2013 revisions go to: http://www.epa.gov/oppfead1/guidance/human-test.htm. To access the revised regulation go to: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=194208b684696d8da2f9b00e7abdf8b0&tpl=/ecfrbrowse/Title40/40cfr26_main_02.tpl.

response to the Congressional mandate and which amended 40 CFR Part 26. The 2013 revisions do not change information provided in this ICR because the revisions did not result in changes to the information collection activities and related burden estimates. EPA's statutory authority to require and collect the information identified already existed under FIFRA and FFDCA.

Sections 3(c)(5), 3(g) and 4(g)(2)(D) of FIFRA generally require EPA to determine that a pesticide would not present any "unreasonable adverse effects on the environment"[2] when deciding to grant a new or amended pesticide registration or to continue an existing registration. Section 4(g)(2)(E) of FIFRA and section 408(b)(2)(A)(ii) of FFDCA generally require EPA to determine that there is a reasonable certainty that no harm will result from aggregate exposure to the residue of a pesticide chemical, including all anticipated dietary exposures and all other exposures for which there is reliable information when making pesticide tolerance decisions. FIFRA Section 12(a)(2)(P) forbids any person "to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable from, and (ii) freely volunteer to participate in the test." EPA established this collection of information as part of the 2006 final rule as authorized under section 25 of FIFRA and section 408(e)(1)(C) of FFDCA to:

(1) ensure that sound and appropriate scientific data are available to EPA when making regulatory decisions about pesticides as described in the previous paragraph; and,

(2) protect the interests, rights and safety of human research subjects, as required under FIFRA section 12(a)(2)(P).

Sections 3(c)(5), 3(g), 4(g)(2), and 25 of FIFRA and sections 408(b)(2)(A)(ii) and 408(e)(1)(C) of FFDCA are included as Supporting Statement attachments C and D, respectively.

2(b). Practical Utility/Users of the Data

In order to ensure the availability of sound and appropriate scientific data in its decisions, and to protect of the interests, rights and safety of human research subjects, in 2006 EPA extended the requirements of the Agency's Common Rule, 40 CFR Part 26, prospectively to third-party research intended for submission to EPA under the pesticide laws and involving intentional exposure of non-pregnant, non-nursing adult human subjects. The information provided allows EPA to review protocols and related information before covered research involving human subjects is initiated, but after it has been reviewed and approved by a local IRB. In addition, anyone who submits to EPA a report of research with human subjects must submit concurrently documentation of the ethical conduct of the research. This information collection activity allows EPA to ensure all human subjects in research conducted by EPA (first party), conducted by entities with support from EPA (second parties), or conducted by third parties with the intention to submit it to EPA, are treated ethically.

2 Defined in FIFRA section 2(bb) as ". . . (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) . . . ."

3. NON DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a). Non duplication

The information requirements identified in the regulations at 40 CFR part 26 do not duplicate other federal agency information collections. Other federal agencies have adopted the Common Rule and FDA has established requirements similar to those in the Common Rule for third-party researchers who perform human testing intended for submission to FDA. None of those requirements, however, apply to third-party research that is intended for submission to EPA.

3(b). Public Notice Required Prior to ICR submission to OMB

Pursuant to 5 CFR 1320.8(d), EPA published a Federal Register (FR) Notice on December 7, 2011, soliciting comment on this information collection activity and the Agency's intent to renew the OMB approval of this ICR (76 FR 76399). The docket for this ICR renewal can be accessed at *http://www.regulations.gov* using the docket ID number EPA-HQ-OPP-2011-0704. The Agency did not receive any public comments on this renewal ICR.

3(c). Consultations

During preparation of this ICR renewal, EPA staff contacted the following respondent representatives to seek feedback on the burden estimates in the ICR and the clarity of guidance provided.

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The responses are summarized here. Full copies of the respondents' responses to EPA's consultation efforts are contained in Attachment E.

Two of the three parties consulted indicated that the respondent burden and cost estimates included in the proposed ICR renewal were considerably lower than the actual paperwork burden and costs associated with complying with the rule. This renewal ICR contains revised burden and cost estimates that are drawn from the three consultation responses.

For an explanation of the methodology, data, and assumptions used to calculate the revised estimated respondent burdens and costs, see Attachment F. Additionally, the parties consulted stated that the data collected is not available from another source and the frequency of collection could not be reduced and still produce the same outcome. The consultation participants explained that the instructions to respondents on what to submit and how to submit it are not entirely clear.

3(d). Effects of Less Frequent Collection

Not applicable. This is an event-driven information collection activity and is conducted only as information is submitted to EPA for consideration. As such there is no set collection frequency for the collection of this information.

3(e). General Guidelines

The only guideline established under the Paperwork Reduction Act (PRA) that may be exceeded in this collection is the time period for retaining records. EPA's requirement at 40 CFR 169.2(k) states that records containing research data relating to registered pesticides be retained for as long as the registration is valid and the producer remains in business. Registrations are valid until they are either voluntarily canceled or withdrawn by the registrant or until EPA has cause to suspend or cancel the registration. Since the average period of marketability of a pesticide ranges from 15 to 30 years, the PRA guidelines specifying that data other than health, medical or tax records not be required to be retained for more than three years will be exceeded in this collection activity. This is an existing requirement that was not changed by the 2006 final rule. In any case, the recordkeeping requirement merely codifies the usual and customary business practices of IRBs and third-party researchers; therefore no burden is attributed to the activity.

OMB regulations require agencies to provide a statement indicating whether the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and an explanation of the decision (5 CFR 1320.5(a)(iii)(E)). EPA is not offering a fully electronic submission option at this time. While the Agency is developing an internet portal that would adequately secure any confidential and/or sensitive information submitted electronically, this portal is not yet ready to accept such information.

Respondents who submit study protocols and/or reports to EPA may elect to submit certain information "electronically" via compact disc. Ordinarily, registrants would be required to submit 3 paper copies of study data to EPA. Under this hybrid option, registrants need only submit 2 paper copies if they submit the required study data in Adobe Acrobat Portable Document Format (PDF) on a compact disc. EPA believes that the promotion and facilitation of the hybrid electronic submission option will make its pesticide regulation operations more efficient. Once EPA staff have become familiar with the electronic submission process and the technology, this option can increase the efficiency of operations such as the delivery, review, data interchange capability, and archiving of data supporting national pesticide registration. The Agency expects that registrants will spend less time and money preparing copies and sending

their submissions using the hybrid paper-electronic submission option, and stand to benefit from the efficiencies that EPA expects to experience during data reviews.

3(f). Confidentiality

EPA has implemented procedures to protect any confidential, trade secret or proprietary information from disclosure that provide strict instructions regarding access to and contact with documents confidential business information (CBI). These procedures comply with EPA's CBI regulations at 40 CFR Part 2, Subpart B.

3(g). Sensitive Questions

This information collection activity complies with the provisions of the Privacy Act of 1974 and OMB Circular A-108. No information of a sensitive or private nature is requested in conjunction with this information collection activity. The protection of human research subjects' privacy is a basic, long-standing principle within the scientific community. Reports of human research submitted to federal agencies should not identify subjects by name, or include recognizable photographs, or otherwise identify them. On the rare occasion that the Agency receives identifying information, such information will be treated as confidential and not released to third parties unless required by law.

4. THE RESPONDENTS AND THE INFORMATION REQUESTE

4(a). Respondents/NAICS Codes

This collection of information applies to any entity that submits to EPA protocols and study reports for environmental research involving human subjects under FIFRA and/or FFDCA. Although EPA has only received such third-party research in conjunction with FIFRA from pesticide registrants, it is conceivable that other entities could submit such information to EPA under FIFRA and/or FFDCA in the future. The North American Industrial Classification System (NAICS) code for the principal respondents to this ICR is 541710 (Research and Development in the Physical, Engineering, Life Sciences).

4(b). Information Requested

(i) Data items, including record keeping requirements

The regulation sets forth those additional information activities that are necessary to ensure the protection of human subjects of research when such research is submitted to EPA for consideration under FIFRA and/or FFDCA.

(ii) Respondent Activities

The following information activities are required:

- *Rule Familiarization and Training* - read, and understand what data are to be submitted and understand the protocols must be developed to comply with the Common Rule.

- *Submit Protocol to an IRB and EPA* – Prepare and submit a proposal for test protocol to IRB for review. After approval by the IRB, submit the proposal and related documentation, including a record of the IRB approval, to EPA.

- *Prepare and Submit Ethics Information for EPA Review* - once a study is conducted, compile applicable records to document ethical conduct of the research.

- *Store, File and Maintain Information* – ensure that research information is placed in central records as required by FIFRA and consistent with section 3(e) of this ICR.

5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a). Agency Activities

EPA's information-related activities associated with this collection consist of the following:

- *Conduct Prior review on study protocol* – review and comment on study protocol, document comments/review.

- *Review Ethical Aspect of a Protocol and Study Report* – make formal EPA determination on usefulness and ethical aspects of the study.

- *Record and Report Information* – Document any formal decisions made.

- *Store, File and Maintain Information* – compile information into appropriate databases and archive.

5(b). Collection Methodology and Management

EPA's Office of Pesticide Programs (OPP) completed a major review of its information tracking systems to improve their efficiency and accuracy. This review resulted in the development of a new integrated information system, which, when complete, will improve the quality of the Agency's databases and allows the EPA to respond more timely and accurately to queries from registrants and the public, including requests made under the FOIA.

OPP is also investigating the possibility of providing optional electronic data transfer services to the industry as a means of minimizing the burden of registration activities. The Agency's pesticide program, along with the pesticide industry, recognizes the advantages in terms of accuracy, speed, cost and personnel from electronic data transfer technologies. In

addition, OPP is consulting with industry associations and other federal agencies, and participating in an Agency-wide workgroup to develop electronic reporting standards intended to facilitate collection of information from industry.

OPP does not publish the studies submitted. However, it maintains records of each study in the Office of Pesticide Programs Information Network (OPPIN), and provides public access to OPPIN bibliographies through the National Pesticides Information Retrieval System (NPIRS). NPIRS supports searches for technical documents submitted to EPA by registrants. Information is categorized by chemical, subject, submission date, laboratory, guideline number, and document type. The public may request copies of studies that are non-confidential by submitting a Freedom of Information Act (FOIA) request

5(c). Small Entity Flexibility

Although the Agency cannot predict whether or how many small entities might engage in the subject matter research, the burden and related cost for researchers to comply with these information collection activities is estimated to be a comparatively small portion of the overall cost of performing such studies. After reviewing the history of EPA's consideration on human research in its various program offices, EPA estimates that only a limited number of third-party human studies will be impacted by these activities each year. Because both the number of affected studies is relatively small and the estimated current costs of compliance with the Common Rule are low, the potential overall burden and costs from these activities to third parties are also estimated to be small, regardless of their size. As a result, EPA has not provided any special flexibility for small entities.

5(d). Collection Schedule

A periodic collection schedule is not appropriate for the information collection activity. The information collection activity is initiated by the respondents and therefore EPA expects that respondents will engage in the activities described in this ICR only once, whenever developing and performing a given research study that involves human subjects as governed by EPA's regulations.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

The activities imposed by the rule consist of reporting and record-keeping requirements. Respondents' activities are detailed in Section 4(b)(ii) of this ICR. The burden and cost estimates for this renewal ICR were calculated using estimates provided by 3 respondents during the consultation period. Attachment F explains how the Agency derived the weighed average of the burden estimates for each activity based on these responses. Section 6(a) of this ICR explains the methodology used to calculate the respondent burden, and updated burden and cost estimates are listed in Tables 1, 2 and 5. EPA's burden estimates and methodology are detailed in Section 6(c).

6(a). Estimating Respondent Burden

EPA is estimating only the incremental burden imposed upon respondents for compliance with the paperwork requirements established in the 2006 final rule. EPA is neither estimating, *de novo*, the estimated paperwork burden for compliance with the 1991 Common Rule in this ICR nor the paperwork burden associated with the generation of certain study data that is already covered by other ICRs, such as those requested by EPA in a Data Call-In under FIFRA section 3(c)(2)(B). EPA does assume that IRBs are already in compliance with the 1991 Common Rule requirements and therefore believes that there is no additional burden imposed upon IRBs for compliance with the paperwork requirements established in the 2006 final rule and discussed in this document.

Based upon responses received to the Agency's consultation questions, as well as historical data, EPA anticipates that respondents will submit to OPP an average of 7 pesticide protocols and 7 completed studies per year under FIFRA and/or FFDCA that will involve intentional exposure of human subjects. EPA also expects to receive other types of pesticide research involving human subjects; an average of 10 of these types of studies submitted annually. While EPA assumes that researchers conducting these studies would already be required to comply with the 1991 Common Rule requirements, they will be subject to some additional paperwork requirements under EPA's amendments. Therefore, EPA is estimating only the burden and costs associated with the paperwork activities that are described in the 2006 final rule.

Respondent activities that are within the scope of this ICR include: preparing and submitting protocols, supporting documents, and completed study reports for IRB, EPA, and HSRB review; communicating with IRB and EPA staff regarding required changes to a protocol; communicating with EPA about HSRB recommendations; and documenting protocol changes made at the recommendation of an IRB, EPA, or the HSRB. Activities which are unrelated to the paperwork and recordkeeping requirements of the 2006 final rule, such as the costs of conducting the research, are not incremental paperwork or recordkeeping costs and therefore are not within the scope of this ICR.

The consultation responses indicated that EPA's previous estimates underestimated the burden and costs per response, but overestimated the number of responses per year. Thus, to calculate new burden and cost estimates for this renewal ICR, EPA relied upon the figures provided in the three consultation responses. To account for the fact that some study types are more complex than others, EPA calculated a weighted average of the burden estimates for each activity using the estimates that were provided in each of the consultations responses (see Attachment F).

As shown in Tables 1 and 2, the total annual estimated burden associated with all submitted pesticide research that involves intentional exposure of human subjects is 14,833 hours, and the annual estimated burden for all other pesticide research that involves human subjects is 120 hours. Therefore the total annual burden for this information collection activity is estimated to be 14,953 hours.

Table 1. Weighted average burden and cost estimates for respondents for research involving intentional exposure of human subjects

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $153/hr	Technical $79/hr	Clerical $45/hr	Hours	Cost ($)
Rule familiarization and training	4	4	4	12	1,108
Prepare and submit protocol for IRB review	17	175	30	222	17,776
Prepare and submit protocol for EPA and HSRB review	82	501	36	619	53,745
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol; prepare and submit completed study for IRB, EPA, and HSRB Review	35	1,170	32	1,237	99,225
Store, file, and maintain records	6	15	8	29	2,463
Total per response	144	1,865	110	**2,119**	**174,317**

Annual Burden: 2,119 hours per response * 7 responses per year = **14,833 hours**
Annual Costs: $174,317 per response * 7 responses per year = **$1,220,219**

Table 2. Respondent burden and cost estimates for all other submitted research with human subjects

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $153/hr	Technical $79/hr	Clerical $45/hr	Hours	Cost ($)
Rule familiarization and training	1	1	0	2	232
Prepare and Submit Ethics Information of Completed Human Studies to EPA	0	8	1	9	677
Store, file, and maintain records	0	0	1	1	45
Total per response	1	9	2	**12**	**954**

Annual Burden: 12 hours per study * 10 studies submitted per year = **120 hours**
Annual Costs: $954 per study * 10 studies submitted per year = **$9,540**

6(b). Estimating Respondent Costs

The estimated annual cost for all respondents is $1,229,759. Respondent labor rates are estimated to be $153, $79, and $45 per hour, respectively, for managerial, technical and clerical labor. The labor rates were derived from the Bureau of Labor Statistics' May 2010 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 541710 (Research and Development in the Physical, Engineering, and Life Sciences).[3] These labor rates are fully loaded and include benefits and overhead costs (see Attachment G).

6(c). Estimating Agency Burden and Cost

The estimated Agency annual cost is $259,682. EPA activities include: communicating with respondents, reviewing the ethical aspects of submitted study protocols and completed study reports, making presentations to the HSRB, documenting decisions, and information management activities to record, file, and track the submissions. Agency labor rates are $120, $71, and $45 per hour for management, technical, and clerical staff, respectively. The labor rates were derived from the Bureau of Labor Statistics' May 2010 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 999100 (Federal Executive Branch).[4] These labor rates are fully loaded and include benefits and overhead costs (see Attachment H). The details of the calculations are identified in Tables 3 and 4 in this section.

Table 3. Weighted average burden and cost estimates for agency for research involving intentional exposure

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $120/hr	Technical $71/hr	Clerical $45/hr	Hours	Cost ($)
Rule familiarization and training	1	2	0	3	262
Primary Review of Scientific and Ethical Aspects of a Protocol	3	143	0	143	10,775

3 Bureau of Labor Statistics. "May 2010 National Industry-Specific Occupational Employment and Wage Estimates: 541710 – Research and Development in the Physical, Engineering, and Life Sciences." Accessed at http://www.bls.gov/oes/current/naics5_541710.htm.

4 Bureau of Labor Statistics. "May 2010 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 999100 – Federal Executive Branch." Accessed at http://www.bls.gov/oes/current/naics4_999100.htm.

Primary Review of Scientific and Ethical Aspects of a Completed Study Report	3	229	0	232	16,619
Secondary Review of Scientific and Ethical Aspects of a Protocol	197				4,270*
Secondary Review of Scientific and Ethical Aspects of a Completed Report	197				4,270*
Store, file, and maintain records	0	0	2	2	90
Total per response	7	317	2	**774**	**36,286**

***** Cost of HSRB members working on the HSRB report (collectively spending 197 hours per HSRB report in FY 2011, compensated at the rate of $53/hour), plus the cost of EPA Office of the Science Advisor technical staff working on the HSRB report (30 hours per report, at the technical staff rate of $79/hour). Each HSRB report covers an average of 3 protocols and/or completed studies per report topics, so each topic costs an average of $4,270.

Annual Burden: 774 hours per response x 7 per year = **5,418 hours**
Annual Costs: 36,286 x 7 responses/year = **$254,002**

Table 4. Weighted Average Burden and Cost Estimates for Agency – Research Involving Intentional Exposure – All Other Submitted Research with Human Subjects

Activities	**Average Burden Hours Per Response**			**Total Per Response**	
	Management $120/hr	**Technical $71/hr**	**Clerical $45/hr**	**Hours**	**Cost ($)**
Rule familiarization and training	0	0	0	0	0
Primary Review of Ethical Aspects of a Completed Study Report	0	4	0	4	284
Store, file, and maintain records	0	0	0	0	0
Total per response	0	4	0	**4**	**284**

Annual Burden: 4 hours per study x 20 per year = **80 hours**
Annual Costs: 284 x 20 responses/year = **$5,680**

6(d). Bottom Line Burden Hours and Cost Tables

The total estimate represents the information collection activities expected to occur annually over the next three years. Table 5 provides the total estimated annual burden and costs

for respondents, as well as the total estimated annual burden and costs for the Agency:

Table 5. Total Annual Bottom Line Burden and Costs / Master Table

Collection Activity	Annual Burden Hours	Annual Costs
Annual Respondent Burden and Costs		
Research Involving Intentional Exposure of Human Subjects (Table 1)	14,833	$1,220,219
All Other Submitted Research with Human Subjects (Table 2)	120	$9,540
Respondent Total	**14,953**	**$1,229,759**
Annual Agency Burden		
Research Involving Intentional Exposure of Human Subjects (Table 3)	5,418	$254,002
All Other Submitted Research with Human Subjects (Table 4)	80	$5,680
Agency Total	**5,498**	**$259,682**

6(e). Reasons for Change in Burden

The total annual estimated respondent burden has decreased from 20,572 hours for the currently approved ICR to 14,953 hours for this renewal ICR by 5,619 hours. This change is due to a decrease in the anticipated number of responses per year. The anticipated number of responses per year is based submissions to the Agency in the past, and from estimates obtained during the consultation process from entities that have submitted human subjects research since the implementation of the rule. However, based on the information provided in the consultation responses, it appears that the actual amount of time necessary to comply with the paperwork and recordkeeping requirements for each response is higher than originally estimated. The estimated annual Agency burden has also decreased due to fewer anticipated responses per year.

6(f) . Burden Statement

The total estimated annual paperwork burden to comply with this information collection activity is 14,953 hours. The average burden per activity is estimated to be 2,119 hours per response for research involving intentional exposure of human subjects, and 12 hours per response for all other submitted research with human subjects.

In the context of the PRA, "burden" is defined at 5 CFR 1320.3(b). The 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 number for this information collection appears at the beginning and end of this document. In addition, OMB control numbers for EPA's regulations, after initial display in the Federal Register, are listed in 40 CFR Part 9 (see Attachment I).

The Agency has established a docket for this ICR under Docket ID No. 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. This docket facility is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the reading room is 202-566-1744, and the docket telephone number is 703-305-5805.

You may submit comments regarding the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden, including the use of automated collection techniques. Submit your comments, referencing Docket ID No. EPA-HQ-OPP-2011-0704 and OMB Control No. 2070-0169, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), 1200 Pennsylvania Ave., NW, Washington, DC 20460, 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.

ATTACHMENTS TO THE SUPPORTING STATEMENT:

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number EPA-HQ-OPP-2011-0704. These attachments are available for online viewing at *http://www.regulations.gov* or otherwise accessed as described in section 6(f) of the supporting statement, and as noted below.

Attachment A: Final Rule - 2006 Amendment of 40 Part 26; Protections for Test Subjects in Human Research

Attachment B: Appropriations Act, 2006, Pub. L. No. 109-54

Attachment C: FIFRA Sections 3(c)(5), 3(g), 4(g)(2), and 25

Attachment D: FFDCA Sections 408(b)(2)(A)(ii) and 408(e)(1)(C)

Attachment E: Record of EPA Consultations with Respondents Regarding the ICR Renewal

Attachment F: Assumptions and Methodology to Calculate Respondent and Agency Burden

Attachment G: Wage Rates for Pesticide Registrants

Attachment H: Standard Wages for the Federal Government

Attachment I: Display Related to OMB Control #2070-0169 -Listings of Related Regulations in 40 CFR 9.1