Supporting Statement for
An Information Collection Request (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

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

OMB No. 2070-0169 EPA No. 2195.03

1(b) Short Characterization/Abstract

The Environmental Protection Agency (EPA or the Agency) 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). In January 2006, EPA issued a final rule to amend the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) at 40 CFR part 26. EPA's January 2006 final rule significantly strengthens and expands the protections for subjects of "third-party" human research (i.e., research that is not conducted or supported by EPA). In addition to other protections, the final rule requires 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 imposed by this final rule 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 January 2006 final rule requirements. Information is typically submitted by registrants of pesticide products to support the registration of their products. It is estimated that the annual response burden is approximately 20,572 hours valued at about $1,579,098.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

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

response to the Congressional mandate. EPA's statutory authority to require and collect information identified in the final rule 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"[1] 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 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 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 A and B, 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 the interests, rights and safety of human research subjects, 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 research involving human subjects is initiated, 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.

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1 Defined at 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 final rule 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), in preparing to renew this ICR, EPA published a notice in the Federal Register which provided a 60-day public notice and comment period on the draft ICR (see 73 FR 33811; June 13, 2008). The FR notice and the proposed renewal ICR as well as the public comments received are located in the docket for this action, which can be accessed at http://www.regulations.gov using the docket identifier EPA-HQ-OPP-2008-0414.

The Agency received two public comments on this renewal ICR, from the Agricultural Handler Exposure Task Force (AHETF) and Antimicrobial Exposure Assessment Task Force II (AEATF). These task forces also responded to questions from the Agency, as two of five participants in the consultation process with respondents to this ICR (see section 3(c), below). Both task forces' comments and consultation responses focused primarily on the burdens and costs associated with the human subjects research requirements at 40 CFR part 26 and the input they provided in their public comments was essentially the same as that included in the consultation responses. In particular, both task forces commented that the actual burden and costs associated with complying with the rule substantially exceed the estimates contained in the proposed ICR. Copies of the comments may be accessed at http://www.regulations.gov using the docket identifier EPA-HQ-OPP-2008-0414.

Based on the comments received, as well as the consultation responses and EPA's experience since the enactment of 40 CFR part 26, the Agency acknowledges that the burden and cost estimates in the original ICR are lower than actual costs. Therefore, this renewal ICR contains revised burden and cost estimates that are drawn from the five consultation responses and the public comments. For an explanation of the methodology, data, and assumptions used to calculate the revised estimated respondent burdens and costs (see Attachment G).

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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Full copies of the respondents' responses to EPA's consultation efforts are contained in Attachment D, which may be accessed at http://www.regulations.gov using the docket identifier EPA-HQ-OPP-2008-0414.

All five of the parties consulted agreed 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. As stated above, in section 3(b), this renewal ICR contains revised burden and cost estimates that are drawn from the five consultation responses and the public comments. For an explanation of the methodology, data, and assumptions used to calculate the revised estimated respondent burdens and costs (see Attachment G). 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. Some consulted said that the Agency's draft guidance has helped, but that once the procedure is fully refined EPA should provide final guidance. The Agency is considering the need to issue further guidance.

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 final rule. In any case, EPA asserts that 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. EPA is developing an internet portal that would adequately secure any confidential and/or sensitive information submitted electronically; however, EPA is not yet ready to accept such information in this way.

Respondents that 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. Once EPA staff have become familiar with the electronic submission process and the technology, OPP believes that this option will allow the Agency to achieve operating efficiencies in the regulation of pesticides through the promotion and facilitation of the electronic submission process, including the delivery, review, data interchange capability and archiving of data supporting national pesticide registration. OPP 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 REQUESTED

4(a) Respondents/NAICS Codes

This collection of information applies to any entity that submits 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 final rule 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

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 of the PDMS database by chemical, subject, submission date, laboratory, guideline number, and document type, and the public may request copies of studies that are non-confidential by submitting a 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

6(a) Estimating Respondent Burden

EPA is estimating only the incremental burden imposed upon respondents for compliance with the paperwork requirements established in the 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 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 34 pesticide research 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 20 studies 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 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 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 significantly underestimated the actual burden and costs. Thus, to calculate new burden and cost estimates for this renewal ICR, EPA relied upon the figures provided in the five consultation responses. Two of the five participants in the consultation process were also the two parties that submitted comments during the public comment period; the input they provided in their public comments was essentially the same as that included in the consultation responses. EPA calculated a weighted average of the estimates contained in each of the responses, to account for the fact that some study types are more complex than others. See Attachment G for an explanation of the methodology, data, and assumptions used to calculate the revised estimated respondent burdens and costs used in this ICR renewal.

As shown in Tables 1 and 2, the total annual estimated burden associated with this information collection activity is 20,332 hours for all submitted pesticide research that involves intentional exposure of human subjects, and 240 hours for all other pesticide research that involves human subjects. Therefore the total annual burden for this information collection activity is estimated to be 20,572 hours.

Table 1. Respondent Burden and Cost Estimates – Research Involving Intentional Exposure of Human Subjects

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $138	Technical $73	Clerical $42	Hours	Cost ($)
Rule familiarization and training	2	4	2	8	652
Prepare and submit protocol for IRB review	31	83	33	147	11,723
Prepare and submit protocol for EPA and HSRB review	25	181	37	243	18,217
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol	19	113	21	153	11,753
Document ethical conduct of a pre-rule study for which EPA and the HSRB have not reviewed the protocol	5	16	8	29	2,194
Store, file, and maintain records	4	8	6	18	1,388
Total per response	86	405	107	598	45,927

Annual Burden: 598 hours per protocol or completed study * 34 protocols or completed studies per year = 20,332 hours

Annual Costs: $45,927 per study * 34 protocols or completed studies per year = $1,561,518

Table 2. Respondent Burden and Cost Estimates – All Other Submitted Research with Human Subjects

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $138	Technical $73	Clerical $42	Hours	Cost ($)
Rule familiarization and training	1	1	0	2	211
Prepare and Submit Ethics Information of Completed Human Studies to EPA	0	8	1	9	626
Store, file, and maintain records	0	0	1	1	42
Total per response	1	9	2	12	879

Annual Burden: 12 hours per study * 20 studies submitted per year = 240 hours
Annual Costs: $879 per study * 20 studies submitted per year = $17,580

6(b) Estimating Respondent Costs

The estimated annual cost for all respondents is $1,579,098. Respondent labor rates are estimated to be $138, $73, and $42 per hour, respectively, for managerial, technical and clerical labor. These labor rates were derived from the Bureau of Labor Statistics' May 2007 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 541710 (Research and Development in the Physical, Engineering, and Life Sciences).[2] These labor rates are fully loaded and include benefits and overhead costs, using a methodology developed by OPP's Biological and Economic Analysis Division (see Attachment E).

6(c) Estimating Agency Burden and Cost

The estimated Agency annual cost is $636,060. 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 $103,

2 Bureau of Labor Statistics. "May 2007 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.

$71, and $41 per hour for management, technical, and clerical staff, respectively. These labor rates were derived from the Bureau of Labor Statistics' May 2007 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 999100 (Federal Executive Branch).[3] These labor rates are fully loaded and include benefits and overhead costs, using a methodology developed by OPP's Biological and Economic Analysis Division (see Attachment E).

The details of the calculations are identified in Tables 3 and 4.

Table 3. Agency Burden & Cost Estimates – Review of Research Involving Intentional Exposure of Human Subjects

Activities	Average Burden Hours Per Response			Total Per Response	
	Management $103	Technical $71	Clerical $41	Hours	Cost ($)
Rule familiarization and training	2	2	0	4	348
Primary Review of Scientific and Ethical Aspects of a Protocol	1	113	0	114	8,126
Primary Review of Ethical Aspects of a Completed Study Report	1	57	0	58	4,150
Secondary Review of Scientific and Ethical Aspects of a Protocol or Review of Ethical Aspects of a Completed Study					4,144*
Store, file, and maintain records	0	0	2	2	82
Total per protocol or completed study	4	172	2	178	16,850

- Cost of HSRB members working on the HSRB report (collectively spending 240 hours per HSRB report in FY 2008, compensated at the rate of $53/hour), plus the cost of EPA Office of the Science Advisor technical staff working on the HSRB report (171 hours per report, at the technical staff rate of $71/hour). Each HSRB report covers an average of 6 protocols and/or completed studies per report.
- 240 hours/HSRB Members/report * $53/hour = $12,720/report
- 171 hours/OSA Staff/report*$71/hour = $12,141/report
- Total Cost for HSRB Member and OSA Staff Review Time Per Report = $12,720 + $12,141 = $24,861

3 Bureau of Labor Statistics. "May 2007 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 999100 – Federal Executive Branch." Accessed at http://www.bls.gov/oes/current/naics4_999100.htm.

- If 1 report = 6 protocols
- Total Cost for HSRB Member and OSA Staff Review Time Per Protocol = $24,861/6 = $4,144/protocol

Annual Burden: 178 hours per study or protocol * 34 protocols or completed studies = 6,052 hours
Annual Costs: 16,850 * 34 protocols or completed studies = $572,900

Table 4. Agency Burden & Cost Estimates – Review of All Other Submitted Research with Human Subjects

Activities	Average Burden Hours Per Study			Total Per Study	
	Mgmt. $103/hr	Tech. $71/hr	Cler. $41/hr	Hours	Cost ($)
Rule Familiarization And Training	1	1	0	2	174
Primary Review Ethical Aspects of a Completed Study Report	1	40	0	41	2,943
Store, File and Maintain Information	0	0	1	1	41
Total per study	2	41	1	44	$3,158

Annual Burden: 44 hours/study * 20 studies = 880 hours
Annual Costs: $3,158/study * 20 studies = $63,160

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)	20,332	$1,561,518
All Other Submitted Research with Human Subjects (Table 2)	240	$17,580
Respondent Total	20,572	$1,579,098
Annual Agency Burden		
Research Involving Intentional Exposure of Human Subjects (Table 3)	6,052	$572,900
All Other Submitted Research with Human Subjects (Table 4)	880	$63,160
Agency Total	6,932	$636,060

6(e) Reasons for Change in Burden

The estimated burden to respondents has increased, based on input received during the consultation process from entities that have submitted human subjects research since the implementation of the rule. The burden estimates in the previous ICR were developed before the rule was implemented, and were based on EPA's predictions of how long it would take study sponsors to prepare submissions. 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 is higher than originally estimated.

The estimated Agency burden has decreased due to the fact that the actual cost of operating the HSRB has proven to be lower than the cost that was estimated in the original ICR. The estimates for this renewal ICR are based on actual costs of operating the HSRB during Fiscal Year 2008.

6(f) Burden Statement

The total estimated annual paperwork burden to comply with this information collection activity is 20,572 hours. The average burden is estimated to be 598 hours per response for research involving intentional exposure of human subjects, and 12 hours per response for all other submitted research with human subjects.

According to the Paperwork Reduction Act, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. 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 final rule, are listed in 40 CFR Part 9 (see Attachment F).

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPP-2008-0414, which is available for online viewing at www.regulations.gov, or in person viewing at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. 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-2008-0414 and OMB Control No. 2070-0169, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: Public Information and Records Integrity Branch (PIRIB), Mail Code: 7502P, Office of Pesticide Programs (OPP), Environmental Protection Agency, 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-2008-0414. These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described in section 6(f) of the supporting statement.

Attachment A:	**FIFRA Sections 3(c)(5), 3(g), 4(g)(2), and 25**
Attachment B:	**FFDCA Sections 408(b)(2)(A)(ii) and 408(e)(1)(C)**
Attachment C:	**Final Rule; Protections for Test Subjects in Human Research**
Attachment D:	**Record of EPA Consultations With Respondents Regarding the ICR Renewal**
Attachment E:	**Wage Rate Tables for Pesticide Registrants and EPA**
Attachment F:	**Display Related to OMB Control #2070-0169** -Listings of Related Regulations in 40 CFR 9.1
Attachment G:	**Memorandum on Calculation of Burden and Cost**, from Kelly Sherman to File, September 2, 2008.