AMERICAN CHEMISTRY COUNCIL

Antimicrobial Exposure Assessment Task Force II

Consultation for OPP ICR Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects (OMB Control #2070-0169)

March 5, 2012

1. Publicly Available Data

a. Are the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

In some cases publically available data may exist. However, any existing public data are reviewed by AEATF II to determine if they meet the technical needs and the current quality standards prior to generation of new data.

b. If yes, where can you find the data? Is the available data truly duplicative, or are only certain data elements available which may not address our data requirements very well?

Publically available data can be found in the published literature and publically available databases. Typically the available data are not truly duplicative as many critical elements are missing or they are not representative of the scenario being investigated or they are lacking quality control aspects.

2. Frequency of Collection

a. Can the Agency collect the information less frequently and still produce the same outcome?

This is not applicable to the AEATF II.

3. Clarity of Instructions

a. The rule is intended to require respondents to provide certain data for the Agency's use. Is it clear from the regulations and other Agency guidance what you are required to submit and how to submit it? If not, what suggestions do you have to clarify the information?

The rule gives a general explanation of the process, but does not specify what needs to be submitted, how it needs to be submitted, and the steps leading up to the submission. In addition, the required changes to human subject recruitment and consenting processes since 2006 are not clearly documented. It would be helpful if EPA would identify all of these new procedures and requirements in a revision to the OCSPP Series 875 Test Guidelines.

b. Do you understand that you are required to maintain records?

Yes, keeping detailed records is standard practice for the AEATF II as part of the GLP regulations. However, the volume of records that need to be kept has increased significantly. The number of pages in study protocols and final reports has increased 10 to 15 fold as a result of the final rule.

c. Is it difficult to format the information for submission so that it is clear, logical and easy to understand?

The issue with formatting the submission is that it is very time-consuming due to the large number of documents required for each study submission (e.g., protocol, informed consent form, survey reports, detailed sampling plans, SOPs, IRB correspondence, IRB review reports, recruitment flyers, researcher CVs, Spanish translations, etc.). Prior to the final rule, protocol submissions consisted of about 40 pages. After the final rule became effective, that submission has increased to over 500 pages which are arranged in several volumes to make the review of the submission more manageable. Just the specific process of arranging and checking the final documents for a protocol submission involves a minimum of two people, one technical and one clerical, for approximately two to four days.

d. Are there forms associated with this process? If so, do you use them? Are they clear, logical, and easy to complete?

The only form provided by EPA is a short checklist of items from the Rule (40 CFR 26.1125) that must be included in each protocol submission. The form is taken directly from the Rule and is not especially difficult or time-consuming to complete once all of the documents have been formatted into the submission volumes. There is some duplication of information requested on this form. The form could be improved as it does not have sufficient detail to clearly capture all of the key information that a reviewer might need especially if the protocol has been reviewed by the IRB multiple times.

4. Electronic Reporting and Record Keeping

The Government Paperwork Elimination Act requires that agencies make available electronic reporting alternatives to paper-based submissions. Entities that submit study protocols and/or reports in response to EPA's 2006 final rule may elect to submit the information either on paper, or electronically, via email, CD, or DVD.

a. What do you think of electronic alternatives to hard-copy data submissions?

The AEATF II is almost paperless in its documentations, so it definitely prefers electronic submissions.

b. Are you keeping your records electronically? If yes, in what format?

Yes, records are kept in several forms including MS Word, Excel, Adobe Acrobat, JPEG, and e-mail files.

c. Does electronic submission benefit you by reducing your burden or permitting greater efficiency in compiling the information?

Since almost all documents associated with the protocol or a study report are generated and stored electronically, making an electronic submission is easier. The AEATF II submits final reports "electronically", although three hard copies are also required for submission to the EPA Document Processing Office. The burden of making electronic submissions could be reduced significantly by totally eliminating the need for paper hard copies.

5. Burden and Costs

a. The labor rates EPA will use to estimate costs for regulated entities are taken from the May 2010 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 541710 (Research and Development in the Physical, Engineering, and Life Sciences), published by the Bureau of Labor Statistics. The BLS fully-loaded hourly rates for this industry are $153/hour for management, $79/hour for technical staff, and $45/hour for clerical staff. Do you think these labor rates are appropriate? Can you suggest another NAICS code that would be more appropriate?

The labor rates used by EPA are significantly lower than that incurred by the AEATF II, especially for the technical staff. The professional technical and management work of the AEATF II is done by highly specialized research scientists who work for the AEATF II on a consulting basis. The more appropriate rates are $225, $175, and $50 per hour for the management, technical, and clerical classifications respectively.

b. EPA will estimate annual costs by multiplying the estimated average cost of burden hours associated with each of several classes of activities by the estimated number of times each year that class of activity is expected to be performed.

Please enter in Table 1 on the next page your estimates of the incremental paperwork burden in hours by management, technical, and clerical staff associated with each occurrence of each activity listed. Base your estimates on your experience since the rule became effective in 2006, and on your projections for the paperwork and recordkeeping burden of each activity over the period covered by the ICR renewal—i.e., between September 1, 2012 and August 31, 2015.

Please explain how you arrived at your estimates, and please estimate only the incremental burden imposed by the paperwork requirements associated with the rule, not the costs of conducting the research or costs you would have incurred if the rule were not in effect.

Table 1
Respondent Burden Estimates:
Unit Costs of Discrete Activities Required by the New Rule

Activities	Average Burden Hours Per Occurrence			Total Per Response		
	Manage-ment $153[1]	Technical $79	Clerical $45	Total Hours	Cost ($) Based on EPA Nos.	Based on Industry[1] Cost ($)
Rule familiarization and training (per protocol)[2]	*5*	*5*	*5*	*15*	*1,385*	*2,250*
Prepare and submit protocol for IRB review[3]	*20*	*200*	*30*	*225*	*20,210*	*41,000*
Prepare and submit protocol for EPA and HSRB review[4]	*200*	*600*	*40*	*840*	*79,800*	*152,000*
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[5]	*40*	*1000*	*40*	*1,080*	*86,920*	*186,000*
Store, file, and maintain records[6]	*10*	*40*	*10*	*60*	*5,140*	*9,750*
TOTALS	*275*	*1,845*	*125*	*2,245*	*193,455*	*391,000*

Notes for Table 1:

1 Rates are from the May 2010 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 541710 (Research and Development in the Physical, Engineering, and Life Sciences), published by the Bureau of Labor Statistics.

A column was added that reflects more representative estimated costs to the AEATF II based on typical industry labor costs ($225, $175, and $50 per hour for the management, technical, and clerical classifications respectively)

2 Consider this a one-time activity. Enter your estimate of what your total burden will be for rule familiarization and training during 2012-2015. Since you are already familiar with the rule, you may have little additional burden for this activity.

This is not totally a one-time activity due to new people coming on board, normal turn-over of personnel, and training present personnel on changes in the process as they occur.

3 Estimate your average paperwork burden of preparing for a single IRB review which would not have occurred but for the requirements of the human studies rule. Consider IRB reviews both before and after EPA/HSRB review.

4 Estimate your average paperwork burden of preparing a single submission to EPA of a protocol proposing research involving intentional exposure of human subjects. Treat each repellent testing protocol as a single protocol, however many test materials may be involved.

The amount of background research required for designing and documenting the studies as currently required by the Agency and the HSRB, has markedly increased. This is in addition to the extra work now required to prepare the final submission package for EPA/HSRB review. For this task "management" includes not only the task force manager, but other sponsor company members (registrants) who make up the protocol committee and are directly involved with the protocol development and oversight.

5 Estimate your average paperwork burden to document the ethical conduct of a single study for submission to EPA when the protocol has already been reviewed by EPA and the HSRB. Treat all reports reflecting a single execution of one protocol as a single activity, however many test materials may be involved.

6 Estimate your average paperwork burden for managing and archiving records of each submitted protocol or study report.

There is additional work now associated with managing, storing and archiving documents as records containing confidential subject information (ICF, comprehension forms, subject information forms) are to be kept separate from the raw data files.

c. Please estimate in Table 2 below the frequency with which you expect to incur the paperwork burden associated with each class of activity described in Table 1. Your responses will be combined with those from others in EPA's revised burden estimate. Please explain any assumptions underlying your estimates.

Table 2
Respondent Burden Estimates: Estimated Frequency of Activities

Activities	Projected Number of Occurrences by Year		
	Sept 2012-Aug 2013	Sept 2013-Aug 2014	Sept 2014-Aug 2015
Prepare and submit protocol for IRB review[1]	*2*	*3*	*3*
Prepare and submit protocol for EPA and HSRB review[2]	*2*	*3*	*3*
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[3]	*2*	*2*	*2*
Store, file, and maintain records	*2*	*3*	*3*

Notes for Table 2:

[1] Count IRB submissions that would not have occurred but for the requirements of the human studies rule, including those both before and after EPA/HSRB review.

[2] Count each repellent testing protocol as a single occurrence, however many test materials it may involve.

[3] Count each executed repellent protocol only once, however many test materials or physical study volumes it may involve.

d. The Agency assumes there are no capital costs within the scope of this Information Collection Request. Do you agree?

The AEATF II agrees.

e. Are there other activities or incremental costs associated with the paperwork burden imposed by the human studies rule, not listed in the tables but which should be accounted for?

New SOPs and revisions to SOPs have been required to address the changes imposed by the human studies rule. Although a number of new and updated SOPs now exist, continual revisions are still needed based on feedback from EPA and the HSRB. There are management, technical, and clerical costs associated with this activity.

Consultation for OPP ICR Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects (OMB Control #2070-0169)

Carroll-Loye Biological Research

February 15, 2012

1. Publicly Available Data

a. Are the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?
No

b. If yes, where can you find the data? Is the available data truly duplicative, or are only certain data elements available which may not address our data requirements very well?

2. Frequency of Collection

a. Can the Agency collect the information less frequently and still produce the same outcome?
Not in our opinion

3. Clarity of Instructions

a. The rule is intended to require respondents to provide certain data for the Agency's use. Is it clear from the regulations and other Agency guidance what you are required to submit and how to submit it? If not, what suggestions do you have to clarify the information? *Clear*

b. Do you understand that you are required to maintain records?
Yes

c. Is it difficult to format the information for submission so that it is clear, logical and easy to understand?
No

d. Are there forms associated with this process? If so, do you use them? Are they clear, logical, and easy to complete?
None

4. Electronic Reporting and Record Keeping

The Government Paperwork Elimination Act requires that agencies make available electronic reporting alternatives to paper-based submissions. Entities that submit study protocols and/or reports in response to EPA's 2006 final rule may elect to submit the information either on paper, or electronically, via email, CD, or DVD.

a. What do you think of electronic alternatives to hard-copy data submissions?

Preferred

b. Are you keeping your records electronically? If yes, in what format?
PDF

c. Does electronic submission benefit you by reducing your burden or permitting greater efficiency in compiling the information?
To some extent. We are still required to submit paper hardcopy of reports in triplicate to documents processing. This a significant burden for a small company (Staff of 5-9)

5. Burden and Costs

a. The labor rates EPA will use to estimate costs for regulated entities are taken from the May 2010 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 541710 (Research and Development in the Physical, Engineering, and Life Sciences), published by the Bureau of Labor Statistics. The BLS fully-loaded hourly rates for this industry are $153/hour for management, $79/hour for technical staff, and $45/hour for clerical staff. Do you think these labor rates are appropriate? Can you suggest another NAICS code that would be more appropriate? *No objection to use of code 541710*

b. EPA will estimate annual costs by multiplying the estimated average cost of burden hours associated with each of several classes of activities by the estimated number of times each year that class of activity is expected to be performed.

Please enter in Table 1 on the next page your estimates of the incremental paperwork burden in hours by management, technical, and clerical staff associated with each occurrence of each activity listed. Base your estimates on your experience since the rule became effective in 2006, and on your projections for the paperwork and recordkeeping burden of each activity over the period covered by the ICR renewal—i.e., between September 1, 2012 and August 31, 2015.

Please explain how you arrived at your estimates, and please estimate only the incremental burden imposed by the paperwork requirements associated with the rule, not the costs of conducting the research or costs you would have incurred if the rule were not in effect.

Table 1
Respondent Burden Estimates:
Unit Costs of Discrete Activities Required by the New Rule

Activities	Average Burden Hours Per Occurrence			Total Per Response	
	Management $153[1]	**Technical $79**	**Clerical $45**	**Total Hours**	**Cost ($)**
Rule familiarization and training (per protocol)[2]	*1*	*2*	*2*	*5*	*401*
Prepare and submit protocol for IRB review[3]	*7*	*25*	*10*	*42*	*3496*
Prepare and submit protocol for EPA and HSRB review[4]	*5*	*3*	*7*	*15*	*1317*
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[5]	*5*	*10*	*5*	*20*	*1771*
Store, file, and maintain records[6]	*2*	*0*	*10*	*12*	*756*

Notes for Table 1: The bulk of the work of preparing the protocol is completed prior to IRB review so that the IRB reviews essentially the same packet of documents provided for EPA and HSRB review. We find protocol preparation for IRB or EPA/HSRB submission to be a technical task, with the burden of the hours of work completed by staff working at technical grade.

[1] Rates are from the May 2010 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 541710 (Research and Development in the Physical, Engineering, and Life Sciences), published by the Bureau of Labor Statistics.

[2] Consider this a one-time activity. Enter your estimate of what your total burden will be for rule familiarization and training during 2012-2015. Since you are already familiar with the rule, you may have little additional burden for this activity.

[3] Estimate your average paperwork burden of preparing for a single IRB review which would not have occurred but for the requirements of the human studies rule. Consider IRB reviews both before and after EPA/HSRB review.

[4] Estimate your average paperwork burden of preparing a single submission to EPA of a protocol proposing research involving intentional exposure of human subjects. Treat each repellent testing protocol as a single protocol, however many test materials may be involved.

[5] Estimate your average paperwork burden to document the ethical conduct of a single study for submission to EPA when the protocol has already been reviewed by EPA and the HSRB. Treat all reports reflecting a single execution of one protocol as a single activity, however many test materials may be involved.

[5] Estimate your average paperwork burden for managing and archiving records of each submitted protocol or study report.

c. Please estimate in Table 2 below the frequency with which you expect to incur the paperwork burden associated with each class of activity described in Table 1. Your responses will be combined with those from others in EPA's revised burden estimate. Please explain any assumptions underlying your estimates.

Table 2
Respondent Burden Estimates: Estimated Frequency of Activities

Activities	Projected Number of Occurrences by Year		
	Sept 2012-Aug 2013	Sept 2013-Aug 2014	Sept 2014-Aug 2015
Prepare and submit protocol for IRB review[1]	*2*	*2*	*2*
Prepare and submit protocol for EPA and HSRB review[2]	*2*	*2*	*2*
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[3]	*2*	*2*	*2*
Store, file, and maintain records	*2*	*2*	*2*

Answers based on average yearly research activity combined with consideration of anticipated future study activities.

Notes for Table 2:

[1] Count IRB submissions that would not have occurred but for the requirements of the human studies rule, including those both before and after EPA/HSRB review.

[2] Count each repellent testing protocol as a single occurrence, however many test materials it may involve.

[3] Count each executed repellent protocol only once, however many test materials or physical study volumes it may involve.

d. The Agency assumes there are no capital costs within the scope of this Information Collection Request. Do you agree?
Yes

e. Are there other activities or incremental costs associated with the paperwork burden imposed by the human studies rule, not listed in the tables but which should be accounted for?
No

Consultation for OPP ICR Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects (OMB Control #2070-0169)

Response by Agricultural Handlers Exposure Task Force (AHETF)
February 24, 2012

1. Publicly Available Data

a. Are the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

No. Any existing public data are reviewed by AHETF for applicability to its needs prior to generation of new data.

b. If yes, where can you find the data? Is the available data truly duplicative, or are only certain data elements available which may not address our data requirements very well?

This is not applicable to the AHETF.

2. Frequency of Collection

a. Can the Agency collect the information less frequently and still produce the same outcome?

This is not applicable to the AHETF.

3. Clarity of Instructions

a. The rule is intended to require respondents to provide certain data for the Agency's use. Is it clear from the regulations and other Agency guidance what you are required to submit and how to submit it? If not, what suggestions do you have to clarify the information?

The rule gives a general overall explanation of the process but does not cover exactly what needs to be submitted and how it needs to be submitted. However, after considerable interaction with EPA since 2006, the AHETF now has determined how to submit data successfully. EPA should now document the procedures with revised exposure guidelines.

b. Do you understand that you are required to maintain records?

Yes, keeping detailed records is standard practice for the AHETF as part of the GLP regulations. However, the volume of records that need to be kept has increased significantly. The number of pages in protocols and final reports has increased 10 to 15 fold as a result of the final rule.

c. Is it difficult to format the information for submission so that it is clear, logical and easy to understand?

The format is now clear and standardized but it is still time-consuming for the AHETF to format the submission materials due to the large number of documents required for each study (e.g., protocol, informed consent form, input from experts, survey reports, detailed sampling plans, SOPs, IRB correspondence, flyers, letters to qualified study participants, Spanish translations, etc.). Prior to the final rule, submissions contained about 40 pages. After the final rule became effective, that number increased to over 2000 pages. The AHETF and EPA then agreed to some efficiency that lowered the number of pages to 400 to 500 (still more than 10 times what it was before the final rule).

d. Are there forms associated with this process? If so, do you use them? Are they clear, logical, and easy to complete?

The only form provided by EPA is a checklist of items from the rule that must be covered in every protocol. The form is taken directly from the rule and is not especially difficult to complete, but does take a significant amount of time. In order to improve the clarity and efficiency of the protocol and report submissions, AHETF created new formats and tables to convey the information required.

4. Electronic Reporting and Record Keeping

The Government Paperwork Elimination Act requires that agencies make available electronic reporting alternatives to paper-based submissions. Entities that submit study protocols and/or reports in response to EPA's 2006 final rule may elect to submit the information either on paper, or electronically, via email, CD, or DVD.

a. What do you think of electronic alternatives to hard-copy data submissions?

The AHETF is almost paperless in its documentations, so it definitely prefers electronic submissions.

b. Are you keeping your records electronically? If yes, in what format?

Yes, records are kept in several forms including MS Word, Excel, Adobe Acrobat, E-mail files, and CDs. Key documents are also stored on a task force server for easy access by AHETF members and EPA.

c. Does electronic submission benefit you by reducing your burden or permitting greater efficiency in compiling the information?

Most of the information is generated electronically, so converting this to hard copy for the submission is an additional burden. The AHETF submits final reports "electronically", although two hard copies of each report are submitted prior to the electronic sending. It is with the hard copy submission that the MRID number is assigned. Reducing the effort to ***only*** *the electronic submission (and*

somehow obtaining the necessary MRID number prior to this) would be helpful to the efficiency of the overall submission process.

5. Burden and Costs

a. The labor rates EPA will use to estimate costs for regulated entities are taken from the May 2010 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 541710 (Research and Development in the Physical, Engineering, and Life Sciences), published by the Bureau of Labor Statistics. The BLS fully-loaded hourly rates for this industry are $153/hour for management, $79/hour for technical staff, and $45/hour for clerical staff. Do you think these labor rates are appropriate? Can you suggest another NAICS code that would be more appropriate?

The rates used by EPA are less than that incurred by the AHETF, especially for the technical people. The professional technical and management work of the AHETF is done by highly specialized research scientists who work for the AHETF on a consulting basis, so a classification for researchers with MS or PhD degree requirements would be more appropriate. The more applicable rates are $225, $175, and $50 per hour for the management, technical, and clerical classifications. This does not account for the sweat equity that goes into these programs by representatives of the member companies whose time is not charged to the AHETF.

b. EPA will estimate annual costs by multiplying the estimated average cost of burden hours associated with each of several classes of activities by the estimated number of times each year that class of activity is expected to be performed.

Please enter in Table 1 on the next page your estimates of the incremental paperwork burden in hours by management, technical, and clerical staff associated with each occurrence of each activity listed. Base your estimates on your experience since the rule became effective in 2006, and on your projections for the paperwork and recordkeeping burden of each activity over the period covered by the ICR renewal—i.e., between September 1, 2012 and August 31, 2015.

Please explain how you arrived at your estimates, and please estimate only the incremental burden imposed by the paperwork requirements associated with the rule, not the costs of conducting the research or costs you would have incurred if the rule were not in effect.

Table 1
Respondent Burden Estimates:
Unit Costs of Discrete Activities Required by the New Rule

Activities	Average Burden Hours Per Occurrence			Total Per Response		
	Mgt $153[1]	**Technical $79**	**Clerical $45**	**Total Hours**	**Cost ($) Estimated by EPA**	**Actual Cost ($) to AHETF**
Rule familiarization and training (per protocol)[2]	*5*	*5*	*5*	*15*	*1,385*	*2,250*
Prepare and submit protocol for IRB review[3]	*25*	*300*	*50*	*375*	*29,775*	*60,625*
Prepare and submit protocol for EPA and HSRB review[4]	*40*	*900*	*60*	*1000*	*79,920*	*169,500*
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[5]	*60*	*2500*	*50*	*2610*	*208,930*	*453,500*
Store, file, and maintain records[6]	*5*	*5*	*5*	*15*	*1,385*	*2,250*
TOTALS	*135*	*3,710*	*170*	*3,515*	*321,395*	*688,125*

Notes for Table 1:

[1] Rates are from the May 2010 National Industry-Specific Occupational Employment and Wage Estimates for NAICS code 541710 (Research and Development in the Physical, Engineering, and Life Sciences), published by the Bureau of Labor Statistics.

A column was added that reflects the actual costs to the AHETF.

[2] Consider this a one-time activity. Enter your estimate of what your total burden will be for rule familiarization and training during 2012-2015. Since you are already familiar with the rule, you may have little additional burden for this activity.

This is not totally a one-time activity due to new people coming on board, normal turn-over of personnel, and training personnel on changes in the process as they occur.

[3] Estimate your average paperwork burden of preparing for a single IRB review which would not have occurred but for the requirements of the human studies rule. Consider IRB reviews both before and after EPA/HSRB review.

The costs have decreased slightly since 2006 largely due to decreases in the volume of documentation associated with IRB correspondence.

[4] Estimate your average paperwork burden of preparing a single submission to EPA of a protocol proposing research involving intentional exposure of human subjects. Treat each repellent testing protocol as a single protocol, however many test materials may be involved.

The amount of background research required for designing and documenting the studies as currently required by the Agency and the HSRB, has markedly increased. Without substantive change this aspect is expected to become even more time-consuming as the AHETF addresses more difficult scenarios.

[5] Estimate your average paperwork burden to document the ethical conduct of a single study for submission to EPA when the protocol has already been reviewed by EPA and the HSRB. Treat all reports reflecting a single execution of one protocol as a single activity, however many test materials may be involved.

This cost is increasing significantly and continually due to difficulties in recruiting study participants under the ethics rules established by the Agency and the HSRB. Some changes in the recruitment process are being implemented, but it is not yet known how successful they will be. The recruitment process requires very extensive documentation.

[6] Estimate your average paperwork burden for managing and archiving records of each submitted protocol or study report.

c. Please estimate in Table 2 below the frequency with which you expect to incur the paperwork burden associated with each class of activity described in Table 1. Your responses will be combined with those from others in EPA's revised burden estimate. Please explain any assumptions underlying your estimates.

Table 2
Respondent Burden Estimates: Estimated Frequency of Activities

Activities	Projected Number of Occurrences by Year		
	Sept 2012-Aug 2013	Sept 2013-Aug 2014	Sept 2014-Aug 2015
Prepare and submit protocol for IRB review[1]	*1*	*1*	*1*
Prepare and submit protocol for EPA and HSRB review[2]	*1*	*1*	*1*
Document ethical conduct of a completed study for which EPA and the HSRB have reviewed the protocol[3]	*5*	*5*	*5*
Store, file, and maintain records	*7*	*7*	*7*

Notes for Table 2:

[1] Count IRB submissions that would not have occurred but for the requirements of the human studies rule, including those both before and after EPA/HSRB review.

[2] Count each repellent testing protocol as a single occurrence, however many test materials it may involve.

[3] Count each executed repellent protocol only once, however many test materials or physical study volumes it may involve.

d. The Agency assumes there are no capital costs within the scope of this Information Collection Request. Do you agree?

The AHETF agrees.

e. Are there other activities or incremental costs associated with the paperwork burden imposed by the human studies rule, not listed in the tables but which should be accounted for?

The AHETF is not immediately aware of applicable activities.