Supporting Statement

Environmental Impact Considerations - 21 CFR Part 25 -

(OMB Control Number 0910-0322)

A. **Justification**

1. Circumstances of Information Collection

FDA is requesting OMB approval for the reporting requirements contained in the FDA regulation "Environmental Impact Considerations."

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321-4347, states national environmental objectives and imposes upon each Federal agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment.

The FDA NEPA regulations are at 21 CFR part 25. All applications or petitions requesting agency action require the submission of a claim for a categorical exclusion or an environmental assessment (EA). A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. Section 25.15(a) and (d) specifies the procedures for submitting

to FDA a claim for a categorical exclusion. Extraordinary circumstances (§ 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Sections 25.40(a) and (c) specifies the content requirements for EAs for nonexcluded actions.

This collection of information is used by FDA to assess the environmental impact of agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse effects cannot be avoided, the agency uses the submitted information as the basis for preparing and circulating to the public an EIS, made available through a Federal Register document also filed for comment at the Environmental Protection Agency (EPA). The final EIS, including the comments received, is reviewed by the agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would

reduce expected environmental impact. Any final EIS would contain additional information gathered by the agency after the publication of the draft EIS, a copy of or a summary of the comments received on the draft EIS, and the agency=s responses to the comments, including any revisions resulting from the comments or other information. When the agency finds that no significant environmental effects are expected, the agency prepares a finding of no significant impact (FONSI).

2. Purpose and Use of Information

This collection of information is used by FDA to assess the environmental impact of agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse effects cannot be avoided, the agency uses the submitted information as the basis for preparing and circulating to the public an EIS, made available through a Federal Register notices also filed for comment at the Environmental Protection Agency (EPA). If the agency finds that no significant environmental effects are

expected, the agency prepares a finding of no significant impact (FONSI).

3. Use of Improved Information Technology

For human drugs, the submissions under 21 CFR part 25 are part of an application for marketing. Some of the steps that FDA has taken to facilitate the electronic submission of marketing applications include:

In the Federal Register of December 11, 2003, FDA issued a final rule amending FDA regulations governing the format in which certain labeling is required to be submitted for review with NDAs, certain BLAs, ANDAs, supplements, and annual reports. The final rule requires the electronic submission of the content of labeling (i.e., the content of the package insert or professional labeling, including all text, tables, and figures) in NDAs, certain BLAs, ANDAs, supplements, and annual reports electronically in a form that FDA can process, review, and archive.

The following guidances for industry are among those that have been developed to improve the use of information technology in the submission of marketing applications for human drugs and related reports:

- "Providing Regulatory Submissions in Electronic Format--NDAs" (January 28, 1999). This guidance provides

information on how to submit a complete archival copy of an NDA in electronic format and applies to the submission of original NDAs as well as to the submission of supplements and amendments to NDAs.

- "Providing Regulatory Submissions in Electronic Format--General Considerations" (January 28, 1999). This guidance includes a description of the types of electronic file formats that the agency is able to accept to process, review, and archive electronic documents. The guidance also states that documents submitted in electronic format should enable the user to: (1) Easily view a clear and legible copy of the information; (2) print each document page by page while maintaining fonts, special orientations, table formats, and page numbers; and (3) copy text and images electronically into common word processing documents.
- “Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format” (November 12, 1999). This guidance provides information to assist applicants in submitting documents in electronic format for review and archive purposes as part of a BLA, product license application (PLA), or establishment license application (ELA).
- "Providing Regulatory Submissions in Electronic Format-— Prescription Drug Advertising and Promotional Labeling" (January 31, 2001). This draft guidance discusses issues related to the

electronic submission of advertising and promotional labeling materials for prescription drug and biological products.

- "Providing Regulatory Submissions in Electronic Format-—ANDAs" (June 27, 2002). This guidance discusses issues related to the electronic submission of ANDAs and supplements and amendments to those applications.
- "Providing Regulatory Submissions in Electronic Format-—Annual reports for NDAs and ANDAs" (August 2003). This guidance discusses issues related to the electronic submission of annual reports for NDAs and ANDAs.
- "Providing Regulatory Submissions in Electronic Format-—Postmarketing Periodic Adverse Drug Experience Reports" (June 2003). This guidance discusses general issues related the electronic submission of postmarketing periodic adverse drug experience reports for NDAs, ANDAs, and BLAs.
- "Providing Regulatory Submissions in Electronic Format-—Human Pharmaceutical Product Applications and Related Submissions" (August, 2003). This draft guidance discusses issues related to the electronic submission of ANDAs, BLAs, INDs, NDAs, master files, advertising material, and promotional material.
- "Providing Regulatory Submissions in Electronic Format-—General Considerations" (October 2003). This draft guidance discusses general issues common to all types of electronic regulatory submissions.

• "Providing Regulatory Submissions in Electronic Format-—Content of Labeling" (February 2004). This draft guidance discusses issues related to the submission of the content of labeling in electronic format for marketing applications for human drug and biological products.

These guidance documents are available at FDA's web site http://www.fda.gov/cder/guidance/index.htm.

4. Efforts to Identify Duplication

FDA avoids duplication by encouraging applicants to reference in their environmental documents data and information presented in other documents that are available to FDA and the public (21 CFR 25.40(d)). FDA intends to focus environmental reviews on the use and disposal from use of FDA regulated articles. Because FDA actively works to ensure the consistency of its protocols with those prescribed by EPA, the American Society for Testing and Materials (ASTM), and Organization for Economic Co-operation and Development (OECD), FDA avoids unnecessary duplication of environmental testing. Thus, environmental testing that has already been performed will not have to be repeated by a different protocol when applicants move from one regulatory agency to another and from one country to another for approvals of the same chemical substance.

Where possible, existing data are used by FDA in evaluating the environmental impact of an industry-sponsored application or petition. To the extent publicly available, data in FDA files may be cross-referenced, data available in the scientific literature may be submitted, and data gathered for other government agencies, such as EPA, may be used in support of the environmental review of an application to FDA.

FDA recognizes that there are instances where the same substance may be the subject of separate environmental analyses by another agency, for example by EPA. FDA has determined that separate environmental review is not necessary for FDA approval of a food additive petition or FDA granting a request for an exemption from regulations as a food additive if the substance is already registered by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for the same use requested in the petition. Although both agencies have worked to eliminate duplication of effort, applications submitted to FDA sometimes involve a different use of a chemical substance than the use(s) reviewed by EPA and the patterns of environmental introduction often vary. Therefore, in some circumstances, a document prepared by FDA or another agency may not suffice as the NEPA document.

5. Involvement of Small Entities

For both large and small entities, FDA has identified the types of information necessary to review the environmental impact of a new product and, where possible, provides case-by case guidance on the specific types of information required for a particular action. FDA does not have the resources to perform a firm=s environmental studies and the information gathering necessary for the evaluation of a new product. However, small manufacturers may request help in applying for approval from the FDA office that works with small manufacturers. Because FDA has identified categories of actions that are categorically excluded from the requirement to prepare an EA and EIS, fewer EA's and EIS's are likely to be required from small businesses.

6. <u>Consequences If Information Collected Less Frequently</u>

Industry-sponsored applications and petitions are submitted to obtain permission to market a new product or to expand the usage of a currently regulated product. If the frequency of collection for environmental impact data were reduced, the agency could not assess the environmental impact of approving applications. Failure to take environmental factors into account in the agency decision making would leave the agency susceptible to court challenge and may result in unnecessary delays in the approval for marketing of products.

7. Consistencies with Guidelines in 5 CFR 1320.5(d)(2)

Data collection for applications is consistent with these guidelines.

8. Consultations Outside the Agency

In the Federal Register of March 29, 2006 (71 FR 15753), FDA requested comments on the proposed collection of information. FDA received one comment. The comment said it supports the current FDA approach to assessing potential environmental impact under NEPA. However, the comment questioned whether one aspect of the collection of information is necessary for the proper performance of FDA's functions, including whether the information has practical utility, and contended that eliminating the collection of information would minimize the burden on respondents.

Specifically, the comment suggested that FDA should "eliminate unnecessary work" related to requests for categorical exclusions for actions on certain INDs. Section 25.31 lists classes of actions that are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS. Section 25.31(e) lists an "action on an IND" as one of these classes of actions. The comment proposed that § 25.31(e) be amended as follows: "Action on INDs where the drug or biologic product is derived from wild plants or animals. Action

on other types of INDs do not require a claim for a categorical exclusion.” The comment proposed that categorical exclusions should be automatically granted for actions on INDs where the drug or biologic products are not derived from wild plants or animals.

The comment proposed this amendment to § 25.31(e) for the following reasons, each of which suggests that claims for categorical exclusion for action on an IND have little practical utility and amending § 25.31(e) as proposed represents a way to minimize the burden of the collection of information:

(1) FDA’s guidance document entitled "Environmental Assessment of Human Drug and Biologics Applications" (July 1998) states:

> "INDs generally involve relatively small quantities of a drug or biologic product and treatment of a limited number of patients. Many INDs never result in the filing of an NDA or application for marketing approval of a biologic product, which would allow for the wide-spread commercial sale of the product. CDER and CBER will evaluate INDs on a case-by-case basis where the drug or biologic product is derived from wild plants or animals to determine whether the extraordinary circumstance provision in 21 CFR 25.21 is invoked." (Section III.C.3.b.ii of the guidance document).

(2) Pharmaceutical companies have been providing claims for

categorical exclusion for action on an IND since the early 1990's for active pharmaceutical ingredients (APIs) in all therapeutic classes, and the companies have no indication that FDA has used these claims as the basis for denials pertinent to potential environmental impact as described under NEPA.

(3) Usage of an API under an IND is “site limited and time bounded,” indicating that “the potential for patient excretion of an API to the environment is extremely limited.”

(4) The potential risk from pharmaceuticals in the environment pertains to long-term, chronic exposure, and usage of an API under an IND will not result in the type of exposure widely accepted as being of potential environmental concern. The comment also stated that prior to marketing approval of an API, FDA will have the opportunity to review potential environmental impact through its EA requirements.

(5) The comment concluded that amending § 25.31(e) as proposed would have “eliminated work on up to 1933 categorical exclusions (15,464 hours) for INDs in 2005 that ultimately had no practical utility."

FDA appreciates the comment requesting that § 25.31(e) be amended so that categorical exclusions could be automatically granted for actions on INDs where the drug or biologic products are not derived from wild plants or animals. The purpose of the March 29, 2006, Federal Register notice and this notice, however,

is to afford an opportunity for comment on the information collection requirements and burden estimates for part 25, and to request that OMB extend approval for that collection. Because the comment requests a rulemaking change, we have forwarded it to the office in each Center that is responsible for the information collection requirements in part 25 so that the comment may be considered for any future amendments to the regulations.

9. Remuneration of Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents under the revisions of part 25.

10. Assurance of Confidentiality

NEPA requires that EA's and EIS's be made available for public review. However, 21 CFR 25.50(b) recognizes that FDA actions involving investigations, review, and approval of applications and premarket notifications for human drugs, animal drugs, biologic products, and devices are protected from disclosure under the Trade Secret Act (TSA), the Federal Food, Drug, and Cosmetic Act (FFDCA), and 21 CFR part 20. Additionally, under 21 CFR 25.51 (a), data constituting trade secrets or confidential information under the TSA or the FFDCA must not be included in the portion of environmental documents that is made public. Thus, environmental information will be

made available to the public to the extent permitted.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature in the environmental impact requirements.

12. Estimates of Annualized Hour Burden

Estimated annual reporting burden for human drugs

Under 21 CFR 312.23(a)(7)(iv)(*e*), 21 CFR 314.50(d)(1)(iii), and 21 CFR 314.94(a)(9)(i), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for categorical exclusion under '' 25.30 or 25.31 or an EA under ' 25.40. In 2005, FDA received 1,933 INDs from 1,517 sponsors, 114 NDAs from 94 applicants, 2,682 supplements to NDAs from 293 applicants, 777 ANDAs from 161 applicants, and 4,318 supplements to ANDAs from 219 applicants. FDA estimates that it receives approximately 9,813 claims for categorical exclusions as required under '' 25.15(a) and (d), and 11 EAs as required under '' 25.40(a) and (c). Based on information provided by the pharmaceutical industry, FDA estimates that it takes sponsors or applicants approximately 8 hours to prepare a claim for a categorical exclusion and approximately 3,400 hours to prepare an EA.

Estimated Annual Reporting Burden for Human Drugs					
CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15 (a)&(d)	2,284	4.32	9,813	8	78,504
25.40 (a)&(c)	11	1	11	3,400	37,400
Total					115,904

There are no capital costs or operating and maintenance costs associated with this collection of information.

Estimated annual reporting burden for human foods

Under 21 CFR 71.1, 171.1, 170.39, and 170.100, food additive petitions, color additive petitions, requests for exemption from regulation as a food additive, and submission of a food contact notification (FCN) for a food contact substance must contain either a claim of categorical exclusion under " 25.30 or 25.32, or an EA under ' 25.40. From 2003 to 2005, FDA received an annual average of 88 industry submissions. FDA estimates that it received an annual average of 57 claims of categorical exclusions as required under " 25.15(a) and (d), and 31 EAs as required under " 25.40(a) and (c). FDA estimates that, on average, it takes petitioners, notifiers, or requestors approximately 3 hours to prepare a claim of categorical exclusion and approximately 210 hours to prepare an EA.

Estimated Annual Reporting Burden for Human Foods					
CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15 (a)&(d)	57	1.4	80	3	240
25.40 (a)&(c)	31	1.3	39	210	8,190

Estimated Annual Reporting Burden for Human Foods					
Total					8,430

There are no capital costs or operating and maintenance costs associated with this collection of information.

Estimated annual reporting burden for medical devices

Under 21 CFR 814.20(b)(11), pre-market approvals (original PMAs and supplements) must contain a claim for categorical exclusion under " 25.30 or 25.34 or an environmental assessment under ' 25.40. In 2005, FDA received 282 claims (original PMAs and supplements) for categorical exclusions as required under " 25.15(a) and (d), and 0 EAs as required under " 25.40(a) and (c). Based on information provided by less than 10 sponsors, FDA estimates that it takes approximately less than 1 hour to prepare a claim for a categorical exclusion and an unknown number of hours to prepare an EA.

Estimated Annual Reporting Burden for Medical Devices					
CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15 (a)&(d)	47	6	282	1	282
25.40 (a)&(c)	0	0	0	0	0

Estimated Annual Reporting Burden for Medical Devices					
Total					282

There are no capital costs or operating and maintenance costs associated with this collection of information.

Estimated annual reporting burden for biological products

Under 21 CFR 312.23(a)(7)(iv)(e) and 601.2(a), IND and biologics license applications (BLAs) must contain a claim for categorical exclusion under " 25.30 or 25.31 or an EA under ' 25.40. In 2005, FDA received 565 INDs from 426 sponsors, 27 BLAs from 12 applicants, and 737 BLA supplements to license applications from 205 applicants. FDA estimates that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA estimates that it received approximately 666 claims for categorical exclusion as required under " 25.15(a) and (d), and 2 EAs as required under " 25.40(a) and (c). Based on information provided by industry, FDA estimates that it takes sponsors and applicants approximately 8 hours to prepare a claim for categorical exclusion and approximately 3,400 hours to prepare an EA for a biological product.

Estimated Annual Reporting Burden for Biological Products					
CFR	Number of	Annual	Total	Hours per	Total

Estimated Annual Reporting Burden for Biological Products					
Section	Respondents	Frequency per Response	Annual Responses	Response	Burden Hours
25.15 (a)&(d)	459	1.45	666	8	5,328
25.40 (a)&(c)	2	1	2	3,400	6,800
Total					12,128

There are no capital costs or operating and maintenance costs associated with this collection of information.

Estimated annual reporting burden for animal drugs

Under 21 CFR ' 514.1(b)(14) (21 CFR 514.1(b)(14)), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADA=s), ' 514.8(a)(1) supplemental NADAs and ANADAs, ' 511.1 (b)(10) investigational new animal drug applications (INADs), ' 570.35 (c)(1)(viii) generally recognized as safe (GRAS) affirmation petitions, and ' 571.1(c) food additive petitions must contain a claim for categorical exclusion under '' 25.30 or 25.33 or an EA under ' 25.40. In 2005, FDA's Center for Veterinary Medicine (CVM) has received approximately 421 claims for categorical exclusion as required under '' 25.15(a) and (d), and 14 EAs as required under '' 25.40(a) and (c). Based on information provided by industry, FDA estimates that it takes sponsors/applicants approximately 8 hours to prepare a claim for

a categorical exclusion and an average of 2,160 hours to prepare an EA.

Estimated Annual Reporting Burden for Animal Drugs					
CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Burden Hours
25.15 (a)&(d)	135	3.9	421	8	3,368
25.40 (a)&(c)	12	1.6	14	2,160	30,240
Total					33,608

There are no capital costs or operating and maintenance costs associated with this collection of information.

Combined Estimated Annual Total Burden Hours for All Centers					
Total					170,352

13. Estimates of Annualized Cost Burden to Respondents

FDA's Economics Staff estimates the average industry wage rate of $50.00 per hour for preparing and submitting the information collection requirements associated with marketing applications. Based on a total industry burden of 170,352 hours, the annualized cost burden to respondents would be $8,517,600.

14. Estimates of Annualized Cost Burden to the Government

FDA estimates that a total of approximately 8 FTEs are devoted to the review of submissions associated with 21 CFR part 25. Based on an estimate of $250,000 per FTE, the annualized cost burden to FDA would be approximately $2,000,000.

15. Changes in Burden

The revised burden estimates are the result of the number of claims for categorical exclusions and EAs submitted mainly during 2004-2005.

16. Time Schedule, Publication, and Analysis Plans

FDA does not intend to publish tabulated results of the information collection requirements that are imposed by 21 CFR part 25.

17. Displaying of OMB Approval Date

There are no forms associated with this collection.

18. Exception to the Certification Statement - Item 19

There are no exceptions to the "Certification for Paperwork Reduction Act Submissions" in item 19 of OMB Form 83-I.

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

1. Agency/Subagency originating request

FDA

2. OMB control number b. [ ] None

a. 0910 - 0322 0910

3. Type of information collection (*check one*)

a. [ ] New Collection

b. [ ] Revision of a currently approved collection

c. [X] Extension of a currently approved collection

d. [ ] Reinstatement, without change, of a previously approved collection for which approval has expired

e. [ ] Reinstatement, with change, of a previously approved collection for which approval has expired

f. [ ] Existing collection in use without an OMB control number

For b-f, note Item A2 of Supporting Statement instructions

4. Type of review requested (*check one*)
a. [X] Regular submission
b. [ ] Emergency - Approval requested by ____/____/____
c. [ ] Delegated

5. Small entities
Will this information collection have a significant economic impact on a substantial number of small entities? [ ] Yes [ ] No

6. Requested expiration date
a. [X] Three years from approval date b. [ ] Other Specify:____/___

7. Title **21 CFR 25 - Environmental Impact Considerations**

8. Agency form number(s) (*if applicable*)

9. Keywords NEPA, Environmental Impact Statement, Environmental Assessment, Categorical Exclusion

10. Abstract
This collection of information is used by FDA to assess the environmental impact of agency actions and to ensure that the public is informed of environmental analyses.

11. Affected public (*Mark primary with "P" and all others that apply with "x")*
a. ___ Individuals or households d. ___ Farms
b. _x_ Business or other for-profit e. ___ Federal Government
c. ___ Not-for-profit institutions f. ___ State, Local or Tribal Government

12. Obligation to respond (*check one*)
a. [ ] Voluntary
b. [ ] Required to obtain or retain benefits
c. [x] Mandatory

13. Annual recordkeeping and reporting burden
a. Number of respondents _____
b. Total annual responses _____
1. Percentage of these responses collected electronically - App.75% of new NDAs have electronic components.
c. Total annual hours requested 170,352
d. Current OMB inventory 210,182_____
e. Difference 39,830_____
f. Explanation of difference
1. Program change _____
2. Adjustment Submissions received during 2003-2005
_____

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*
a. Total annualized capital/startup costs ___0_____
b. Total annual costs (O&M) ___0_____
c. Total annualized cost requested ___0_____
d. Current OMB inventory ___0_____
e. Difference ___0_____
f. Explanation of difference
1. Program change _____
2. Adjustment _____

15. Purpose of information collection (*Mark primary with "P" and all others that apply with "X"*)
a. _ Application for benefits e._ Program planning or management
b. _ Program evaluation f._ Research
c. _ General purpose statistics g.X_ Regulatory or compliance
d. _ Audit

16. Frequency of recordkeeping or reporting *(check all that apply)*
a. [ ] Recordkeeping b. [ ] Third party disclosure
c. [x] Reporting
1. [x] On occasion 2. [ ] Weekly 3. [ ] Monthly
4. [ ] Quarterly 5. [ ] Semi-annually 6. [ ] Annually
7. [ ] Biennially 8. [ ] Other (describe) _____

17. Statistical methods
Does this information collection employ statistical methods
[ ] Yes [x] No

18. Agency Contact (person who can best answer questions regarding the content of this submission)
Name: Karen Nelson
Phone: _____

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal Agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

(a) It is necessary for the proper performance of agency functions;

(b) It avoids unnecessary duplication;

(c) It reduces burden on small entities;

(d) It used plain, coherent, and unambiguous terminology that is understandable to respondents;

(e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;

(f) It indicates the retention period for recordkeeping requirements;

(g) It informs respondents of the information called for under 5 CFR 1320.8(b)(3):

(i) Why the information is being collected;

(ii) Use of information;

(iii) Burden estimate;

(iv) Nature of response (voluntary, required for a benefit, mandatory);

(v) Nature and extent of confidentiality; and

(vi) Need to display currently valid OMB control number;

(h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of instructions);

(i) It uses effective and efficient statistical survey methodology; and

(j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of the provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Senior Official or designee	Date

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