U.S. Food and Drug Administration
De Novo Classification Process (Evaluation of Automatic Class III Designation)

OMB Control Number 0910-0844

SUPPORTING STATEMENT—Revision Request

Terms of Clearance: n/a.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The authorizing statute for this information collection is section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

The "Draft Guidance for Industry and Food and Drug Administration Staff – De Novo Classification Process (Evaluation of Automatic Class III Designation)" provides guidance on the process for the submission and review of a De Novo classification request (hereafter a "De Novo request") under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), also known as the De Novo classification process. This process provides a pathway to Class I or Class II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

A device may be classified in class III and be subject to premarket approval (PMA) via several different regulatory vehicles. In accordance with the criteria at section 513(a)(1)(C) of the FD&C Act, FDA may promulgate a regulation classifying, or issue an order reclassifying, a device type into class III based on the risks posed by the device and the inability of general and special controls to provide reasonable assurance of the safety and effectiveness of the device. All particular devices of such a type are considered to be in class III and such devices are not eligible for the De Novo classification process.

Alternatively, devices of a new type that FDA has not previously classified based on the criteria at section 513(a)(1) of the FD&C Act are "automatically" or "statutorily" classified into class III by operation of section 513(f)(1) of the FD&C Act, regardless of the level of risk they pose or the ability of general and special controls to assure safety and effectiveness. This is because, by definition, a new type of device would not be within a type that was on the market before the 1976 Medical Device Amendments or that has since been classified into class I or class II. Thus, there would be no available predicate device.

This second scenario is what Congress targeted when it enacted section 513(f)(2) of the FD&C Act as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The process created by this provision, which was referred to in FDAMA as

the Evaluation of Automatic Class III Designation, will be referred to as the "De Novo classification process" throughout this guidance document. Congress included this section to limit unnecessary expenditure of FDA and industry resources that could occur if devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness were subject to premarket approval under section 515 of the FD&C Act. Section 513(f)(2) of the FD&C Act has allowed manufacturers to submit a De Novo request to FDA for devices "automatically" classified into Class III by operation of section 513(f)(1). As enacted by FDAMA, in order to submit a De Novo request, a device first had to be found not substantially equivalent (NSE) to legally-marketed predicate devices through a premarket notification (510(k)). The 21st Century Cures Act of 2016 removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination.

Section 513(f)(2) was modified by section 607 of FDASIA, which created an alternative mechanism for submitting a De Novo request that does not require that a device be reviewed first under a 510(k) and found NSE prior to submission of a De Novo request. If a person believes their device is appropriate for classification into Class I or Class II and determines, based on currently available information, there is no legally marketed predicate device, they may submit a De Novo request without a preceding 510(k) and NSE (hereafter "Direct De Novo").

FDA issued the guidance to provide updated recommendations for interactions with FDA related to the De Novo classification process, including what information to submit when seeking a path to market via the De Novo classification process.

The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission program.

Requested Revisions to this ICR:

In the Federal Register of October 30, 2017, FDA published a notification of availability of the draft guidance document "Acceptance Review for De Novo Classification Requests." The draft guidance explains the procedures and criteria FDA intends to use in assessing whether a request for an evaluation of automatic class III designation (De Novo classification request or De Novo request) meets a minimum threshold of acceptability and should be accepted for substantive review. The draft guidance discusses De Novo acceptance review policies and procedures, "Refuse to Accept" principles, and the elements of the De Novo Acceptance Checklist and the Recommended Content Checklist and is being issued to be responsive to an explicit deliverable identified in the Medical Device User Fee Amendments of 2017 (MDUFA IV). We request approval of revisions to this ICR to include information collections resulting from recommendations in the draft guidance.

2. Purpose and Use of the Information Collection

A medical device manufacturer may voluntarily submit a De Novo request under 513(f)(2) in order to seek market entry for a new medical device. Section 513(f)(2) was modified by section 607 of FDASIA, which created an alternative mechanism for submitting a De Novo request that does not require that a device be reviewed first under a 510(k) and found NSE prior to submission of a De Novo request. A manufacturer may submit a De Novo request (1) if they have previously submitted a premarket notification in accordance with section 510(k) of the FD&C Act, and for which FDA has "automatically" or "statutorily" classified into class III by operation of section 513(f)(1) of the FD&C Act or (2) if a person believes their device is appropriate for classification into Class I or Class II and determines, based on currently available information, there is no legally marketed predicate device, they may submit a De Novo request without a preceding 510(k) and NSE. FDA is issuing this guidance to provide updated recommendations for interactions with FDA related to the De Novo classification process, including what information to submit when seeking a path to market via the De Novo classification process.

Utilizing the De Novo classification pathway promotes innovation and decreases regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market the same type of device unless the new device has a new intended use or technological characteristics that raise different questions of safety or effectiveness (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

FDA uses the information in the De Novo request to evaluate whether the medical device may be reclassified from Class III to Class I or II, and if applicable, to determine the general and/or special controls necessary to sufficiently regulate the medical device.

Respondents to this information collection are private sector or other for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

For De Novo requests, sponsors must submit at least one valid electronic copy (eCopy). See section 745A(b) of the FD&C Act and FDA's eCopy guidance, "eCopy Program for Medical Device Submissions", available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf. Therefore, FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only federal agency responsible for premarket review of medical devices; as such, there is no duplication of effort.

The information related to the De Novo request may, in some cases, overlap with information previously included in a related 510(k) submission for the medical device. Wherever possible, FDA will not require that this information be re-submitted but instead may rely on the 510(k) submission as a reference. Therefore, duplication with other data sources available to FDA is expected to be minimal.

5. Impact on Small Businesses or Other Small Entities

Approximately 95% of U.S. medical device manufacturing establishments have fewer than 500 employees and would, therefore, be considered small businesses.

Submission of a De Novo request is voluntary. Any impact on small businesses should be offset by the guidance and consumer assistance available through CDRH Learn training tools and the information posted on FDA's website. FDA aids small business by providing guidance and information through the Division of International and Consumer Education (DICE) within the Center for Devices and Radiological Health. DICE provides technical and non-financial assistance to small manufacturers, through a comprehensive program that includes seminars, workshops, and educational conferences, information materials, contact via email and the use of a toll-free telephone number. Other members of the Center staff are also available to respond to questions at any time.

Additionally, the Manufacturers Assistance Branch in the Center for Biologics Evaluation and Research (CBER) provides assistance and training to industry, including large and small manufacturers and trade associations, and responds to requests for information regarding CBER policies and procedures.

6. Consequences of Collecting the Information Less Frequently

The frequency of FDA's receipt of De Novo requests will be determined by the frequency with which medical device manufacturers submit the requests (i.e., occasionally). Because the information in the De Novo request provides a basis for FDA's decision regarding whether to grant market entry for the subject device, the frequency of the information collection is appropriate. The consequence of collecting the information less frequently would potentially be a delay of market entry for the subject device.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA provided an opportunity for public comment on the information collection requirements of the draft guidance document "Acceptance Review for De Novo Classification Requests; Draft Guidance for Industry and Food and Drug Administration Staff" that published in the FEDERAL REGISTER of 10/30/2017 (82 FR 50135). We received various comments on the draft guidance. We describe and respond to the comments related to the proposed information collection in the following paragraphs. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have

separated different issues discussed in the same set of comments and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

(Comment 1) One comment proposed that, in section VII.B of the draft guidance ("Prior Submission(s) Relevant to the De Novo Request Under Review"), FDA revise the phrase "For certain De Novo requests, the requester may have previously provided other submissions for the same device for which FDA provided feedback related to the data or information needed to support De Novo classification (e.g., a Pre-Submission request, Investigational Device Exemption (IDE), prior Not Substantially Equivalent (NSE) determination, or prior 510(k) or De Novo that was deleted or withdrawn)" to read, "For certain De Novo requests, the requester may have previously provided other submissions, or there may be related FDA correspondence or other relevant information for the same device, for which FDA provided feedback related to the data or information needed to support De Novo classification..." The commenter noted that there may be informal correspondence that is pertinent to the De Novo and this should be explicitly requested in the "Recommended Content Checklist" in Appendix B.

(Response 1) FDA does not agree with the proposed revision. This element was intended to specifically focus on pertinent premarket submissions and formal communications that have undergone supervisory review.

(Comment 2) One comment suggested that elements identified as "N/A" should require an accompanying rationale because an inadvertent selection of a N/A answer may result in a "Refuse to Accept" (RTA) decision.

(Response 2) We do not agree with this comment. Selection of "N/A" for any element would not lead to an RTA decision. As explained in Section VI.C of the guidance, "… the item should receive an answer of "yes" or "N/A" for the De Novo request to be accepted for substantive review."

(Comment 3) Two commenters suggested that the preliminary questions in Appendix A ("Acceptance Checklist for De Novo Classification Requests") of the guidance should be removed and included in a document to be used by FDA reviewers or should clarify that these are to be completed by FDA personnel only. FDA recommends that requesters complete the checklists in Appendices A and B ("Recommended Content Checklist for De Novo Classification Requests"); however, the preliminary questions are intended for FDA reviewers.

(Response 3) We do not agree with these commenters. The instructions for the Preliminary Questions within the checklist in Appendix A clearly state that "Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review."

(Comment 4) Two commenters proposed that the Organizational Elements in Appendix A be removed or included in Appendix B instead. The commenters noted that these organizational elements should not result in an RTA designation and, as such, should not be present in Appendix A.

(Response 4) We decline to make this change. These are important administrative elements that will allow the FDA reviewer to determine if the submission is sufficiently organized in order to perform the subsequent RTA review.

(Comment 5) Two commenters proposed that, in Appendix A of the draft guidance, under the section "Elements of a Complete De Novo Request," we remove the second and third paragraphs from Question 1a, or move them to Appendix B. Question 1a requests "[a] description of the technology (features, materials, and principles of operation) for achieving the intended effect." The commenters assert that the second and third paragraphs begin to assess "the sufficiency" of the device description by necessitating detailed device information for acceptance of the De Novo request. In addition, the commenter believes the language in the second paragraph ("Where necessary to describe the device,…") is subjective and would necessitate a substantive review of the device description to determine adequacy.

(Response 5) We do not agree with the commenters description. Because of the wide variety of device types reviewed through the De Novo Program, the reviewer needs flexibility to determine if engineering or representative drawings are necessary for a complete device description. This element is only requesting the inclusion of such information; it is not asking the reviewer to determine the adequacy of the information.

(Comment 6) One comment proposed that, in Appendix A of the draft guidance, under section C of "Elements of a Complete De Novo Request," FDA remove the phrase "detailed information and" in the prefaces to questions 3 through 7. The commenter believes that this request for "detailed information" exceeds the intention of the RTA review which would simply assess the presence of information or a rationale, if not present.

(Response 6) We do not agree with this suggestion. The language in question states "To the extent that the submission relies upon the following information to provide detailed information and reasons for the recommended classification, the De Novo request provides the following…" – therefore the request for the purposes of the Checklist is not for the "detailed information," per se, but rather identifying aspects of the submission for which detailed information will be evaluated during substantive review. Consistent with the policy outlined in the guidance, reviewers will not conduct a detailed review of such information during the RTA phase.

(Comment 7) A comment requested clarity on the extent of information, and location of such information, to be included regarding clinical studies conducted =outside the United States.

(Response 7) The element requesting a summary and full study report for clinical studies (Appendix B, Section E, Question 6) does not require or specify the source of clinical study information. Therefore, we disagree that additional revision to this element is necessary – this pertains to clinical data from studies conducted either within or outside the United States.

(Comment 8) A comment proposed we remove questions 2b and 2c from section D of the Acceptance Checklist, requesting information to be included as part of the Financial Certification (3454) and Financial Disclosure (3455) forms. The commenter believes that the requested information in these questions should be reviewed during substantive review of the De Novo request.

(Response 8) We do not agree. These questions are ensuring that required content in the Financial Certification Forms are included for review. We are not assessing the adequacy of the content.

(Comment 9) A comment proposed that we move element 1 in Appendix B, Section A, requesting "all content used to support the De Novo request is written in English," to the Acceptance Checklist in Appendix A. One would expect that content be provided in English in order to conduct a substantive review of the De Novo request.

(Response 9) We decline to make this change. There is no statutory requirement for providing documentation in English.

(Comment 10) A comment recommends that further guidance "explicitly and specifically incorporate least burdensome concepts." The commenter believes that the draft guidance outlines processes that may not embody least burdensome principles.

(Response 10) We have not made changes based on this comment. FDA defines least burdensome to be the minimum amount of information necessary to adequately address a regulatory question or issue through the most efficient manner at the right time. The least burdensome provisions and guiding principles do not change the applicable regulatory or statutory requirements. We believe the recommendations in the guidance are consistent with the least burdensome provisions and guiding principles, and we apply them in identifying what FDA believes to be the minimum information that the Agency relies on to complete premarket submission review in the most efficient manner. For information on the least burdensome provisions, refer to FDA's Draft guidance, "The Least Burdensome Provisions: Concept and Principles."

(Comment 11) A comment requested that FDA provide clarification on the RTA process, as the draft guidance suggests a De Novo request could be refused based upon "immaterial issues." The commenter recommends addition of a "materiality standard" that would limit refusal to accept a De Novo request "to instances where the missing information is both material and relevant to the assessment of the safety or efficiency [sic] of the device."

(Response 11) We consider the "materiality standard" that the commenter proposes, i.e., that the scope for denial of a review is limited to instances where the missing information is both material and relevant to the assessment of the safety or effectiveness of the device, to be the fundamental basis for the Acceptance Checklist in Appendix A. Elements requested in Appendix A are required by statute and applicable regulations and, as such, we consider these to be material and relevant to the substantive review of the De Novo request.

(Comment 12) One comment proposed that FDA staff should be able to use discretion in order to request missing checklist items interactively, rather than to RTA when there are one or more items missing from the Acceptance Checklist as described in Section III.A of the guidance. This would aid in ensuring a least burdensome approach was applied to this process.

(Response 12) We do not believe that revisions are necessary in response to this comment. Within Section III.A, the guidance states that "FDA staff also has discretion to request missing checklist items interactively from requesters during the RTA review. Interaction during the RTA reviews is dependent on FDA staff's determination that outstanding issues are appropriate for interactive review and that adequate time is available for the requester to provide supporting information and for FDA staff to assess responses."

We believe the recommendations in the guidance are consistent with the least burdensome provisions and guiding principles, and we apply them in identifying what FDA believes to be the minimum information that the Agency relies on to complete premarket submission review in the most efficient manner. For information on the least burdensome provisions, refer to FDA's Draft guidance, "The Least Burdensome Provisions: Concept and Principles."

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

This ICR is not collecting personally identifiable information (PII) or other data of a personal nature. This ICR provides guidance on the process for the submission and review of a De Novo request, also known as the De Novo classification process.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA determined that PII is not collected and the Privacy Act of 1974 does not apply.

Information provided under this collection is handled in a manner to comply with the FDA regulations on public information in 21 CFR part 20. Data will be kept private to the fullest extent allowed by law.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1)-(b)(9)). One such provision, 5 U.S.C. 552(b)(4), exempts "trade secrets and commercial or financial information that is privileged or confidential" from the requirement of public disclosure. Section 520(c) of the FD&C Act prohibits FDA from disclosing any information exempted from public disclosure under 5 U.S.C. 552(b)(4).

Proposed § 860.5(g), Confidentiality and use of data and information submitted in connection with classification and reclassification, states that confidentiality of data and information in a De Novo file is as follows:

(1) A "De Novo file" includes all data and information from the requester submitted with or incorporated by reference in the De Novo request, any De Novo supplement, or any other related submission relevant to the administrative file, as defined in 21 CFR 10.3(a). Any record in the De Novo file will be available for public disclosure in accordance with the provisions of (proposed) § 860.5 and 21 CFR part 20.

(2) The existence of a De Novo request may not be disclosed by FDA before an order granting the De Novo request is issued unless it previously has been publicly disclosed or acknowledged by the De Novo requester.

(3) Before an order granting the De Novo request is issued, data or information contained in the De Novo request is not available for public disclosure, except to the extent the existence of the De Novo request is disclosable under paragraph (2) of this section and such data or information has been publicly disclosed or acknowledged by the De Novo requester.

(4) After FDA issues an order granting a De Novo request, the data and information in the De Novo request that are not exempt from release under 21 CFR 20.61 are immediately available for public disclosure.

11. Justification for Sensitive Questions

This information collection does not include questions that are of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates from past experience with the De Novo classification program that the complete process involved with the program under section 513(f)(2)(i) of the FD&C Act takes approximately 100 hours and the complete process under section 513(f)(2)(ii) FD&C Act takes approximately 180 hours. We estimate that it will take approximately 1 hour to prepare an Acceptance Checklist and 1 hour to prepare a Recommended Content Checklist. Our estimate assumes that each De Novo request will include both checklists. We estimate that requests for withdrawal take approximately 10 minutes. The average burdens per response are based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a De Novo request (and related

materials), have consulted and advised manufacturers on submissions, and have reviewed the documentation submitted.

Respondents to the information collection are medical device manufacturers seeking to market medical device products that have been classified into class III under section 513(f)(2) of the FD&C Act. Based on updated program data and trends, we expect to receive approximately 60 De Novo requests per year. We expect that we will receive approximately five requests for withdrawal per year.

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
De Novo request under 21 U.S.C. 513(f)(2)(i)					
CDRH	2	1	2	100	200
CBER	1	1	1	100	100
De Novo request under 21 U.S.C. 513(f)(2)(ii)					
CDRH	56	1	56	180	10,080
CBER	1	1	1	180	180
Acceptance Checklist	60	1	60	1	60
Recommended Content Checklist	60	1	60	1	60
Total De Novo requests			60		10,680
Request for withdrawal	5	1	5	10	50
Total					10,730

12b. Annualized Cost Burden Estimate

To estimate the wage rate for the industry personnel that prepare the De Novo submissions, we used median hourly wage rates from the Bureau of Labor Statistics (BLS) May 2016 National Occupational Employment and Wage Estimates for the Medical Equipment and Supplies Manufacturing industry (North American Industry Classification, NAICS, code 339100) of $61.20.* To account for benefits and overhead, we doubled this value to $122.40 (= $61.20 x 2). Therefore, we estimate that the annualized cost burden is $1,313,352 ($122.40 x 10,730 hours).

* Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Occupational Employment Statistics, General and Operations Managers (North American Industry Classification, NAICS, code 339100, occupation code 11-1021) May 2016. https://www.bls.gov/oes/current/naics4_339100.htm#11-0000, accessed June 30, 2017.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General and operations managers	10,730	$122.40	$1,313,352

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital or start-up costs associated with this information collection.

The operating and maintenance cost for a De Novo request includes the cost of printing, shipping, and the eCopy. We estimate the cost burden for a De Novo request to be $121.30 ($90 printing + $30 shipping + $1.30 eCopy).

We estimate that printing a submission requires an average of 2 reams of paper, or 1,000 pieces of paper. A piece of paper costs $0.03 per page on average. The cost of printing a single page is $0.06 on average.[1] The average total cost of printing per page is, therefore, $0.09 per page ($0.03 paper + $0.06 printing). Therefore, we estimate that printing an average De Novo request will cost approximately $90.

The Agency's eCopy guidance recommends sending all applications using priority shipping. Using shipping calculators on the websites of the US Postal Service, UPS, and FedEx, FDA finds the shipping cost of a single piece of paper to range from $0.01 to $0.05, with an average of $0.03. The average cost of shipping a full paper copy of submissions is, therefore, $30 (1,000 pages shipped × $0.03 per page).

The least expensive type of eCopy media is a CD, which costs on average $0.25 per CD. DVDs cost $0.48 per unit on average and flash drives cost an average of $2.50 per unit. All forms of eCopy media cost roughly $0.22 to ship. Therefore, the cost per eCopy ranges from $0.47 to $2.72 per eCopy. If eCopies are one-third CDs, one-third DVDs, and one-third flash drives, the average cost per eCopy is $1.30.

We estimate the cost for a request for withdrawal to be $1 (rounded) ($0.09 printing 1 page + $0.03 shipping + $1.30 eCopy).

We have updated the operating and maintenance costs to account for the updated burden estimate for De Novo requests (resulting in an increase of $970 to the total estimated operating and maintenance costs). However, we believe any increase of the operating and maintenance cost resulting from the addition of the Acceptance Checklist and Recommended Content Checklist to be de minimis.

The annual cost estimate for De Novo requests is $7,278 (rounded) (60 submissions x $121.30). The annual cost estimate for requests for withdrawal is $5. Therefore, we estimate the total annual operating and maintenance costs of this information collection to be $7,283.

14. Annualized Cost to the Federal Government

[1] Quality Logic, "Cost of Ink Per Page Analysis, United States," available at https://www.qualitylogic.com/wp-content/uploads/2016/07/QualityLogic-Cost-of-Ink-Per-Page-Analysis_US_1-Jun-2012.pdf, June 2012.

Using FDA's Fully Loaded FTE Cost Model (Domestic) for FY 2016, we estimate that the total cost including pay, information and management technology, general and administrative overhead, and rent for a medical device reviewer is $260,286 annually. FDA estimates that an average of 20 full time equivalent employees (FTEs) will review and process De Novo requests and related information. Therefore, the burden to government of this information collection is projected to cost approximately $5,205,720 per year ($260,286 x 20 FTEs).

15. Explanation for Program Changes or Adjustments

    Our estimated burden for the information collection reflects an overall increase of 3,400 hours. We attribute this adjustment to the addition of the Acceptance Checklist and the Recommended Content Checklist and to an increase in the number of submissions we received during the approval period.

16. Plans for Tabulation and Publication and Project Time Schedule

    No publication of information for statistical use is planned.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

    FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.