UNITED STATES FOOD & DRUG ADMINISTRATION

Investigational New Drug Application Requirements

OMB Control No. 0910-0014 - Revision

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) and of the licensing provisions of the Public Health Service Act (42 U.S.C. 201 et seq.) that govern investigational new drugs and investigational new drug applications (INDs). Implementing regulations are found in part 312 (21 CFR part 312), and provide for the issuance of guidance documents (see § 312.145 (21 CFR 312.145)) to assist persons in complying with the applicable requirements. The information collection applies to all clinical investigations subject to section 505 of the FD&C Act and includes the following types of INDs:

- An Investigator IND is submitted by a physician who both initiates and investigates, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug or an approved product for a new indication or in a new patient population.

- Emergency Use IND allows FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with § 312.23 or § 312.20 (21 CFR 312.23 or 312.20). It is also used for patients who do not meet the criteria of an existing study protocol or if an approved study protocol does not exist.

- Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and FDA's review takes place.

The two categories of INDs are commercial and research (non-commercial). General IND requirements include submitting an initial application as well as amendments to that application; submitting reports on significant revisions of clinical investigation plans; submitting information to the clinical trials data bank (https://clinicaltrials.gov) established by the National Institutes of Health/National Library of Medicine, including expanded information on certain clinical trials and information on the results of these clinical trials; and reporting information on a drug's safety or effectiveness. In addition, sponsors are required to provide to FDA an annual summary of the previous year's clinical experience. The regulations also include recordkeeping requirements regarding the disposition of drugs, records regarding individual case histories, and certain other documentation verifying clinical investigators' fulfillment of responsibilities.

To facilitate the review of information and provide a uniform format for submission, we have developed Form FDA 1571 entitled "*Investigational New Drug Application (IND)*" and Form FDA 1572 entitled "*Statement of Investigator*." The information is required to be submitted electronically. Individuals who are interested in receiving printed forms may send an email request to the FDA Forms Manager at formsmanager@OC.FDA.GOV. Fees may apply. Sponsors (including sponsor-investigators) interested in filing or updating a research IND may use a new web-based interface developed for use by mobile device or desktop to help in completing Form FDA 1571. The web-based interface also allows respondents to electronically submit completed Form FDA 1571 and associated files. For more information regarding Forms FDA 1571 and 1572 visit https://www.fda.gov/news-events/expanded-access/how-complete-form-fda-1571-and-form-fda-1572.

Human drug, biological product, and device product submissions must be accompanied by Form FDA 3674, "*Certification To Accompany Drug, Biological Product, and Device Applications or Submissions*." The guidance document "*Form FDA 3674 – Certifications To Accompany Drug, Biological Product, and Device Application*" (November 2017) is available from our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/form-fda-3674-certifications-accompany-drug-biological-product-and-device-applicationssubmissions and provides instruction on completing and submitting this information to FDA. As communicated in the instructions, the certification must accompany the application or submission and be included at the time of submission to FDA.

The information collection also includes burden attendant to provisions in 21 CFR 320.31 with regard to the applicability of bioavailability (BA) and bioequivalence (BE) requirements in IND application submissions. Specifically, recordkeeping and record retention requirements in 21 CFR 312.57 provide for the retention of certain test article samples, to be released upon FDA request. Finally, we also include burden that may result from recommendations found in the following guidance documents:

- The guidance document entitled "Oversight of Clinical Investigations" (August 2013) communicates risk-based monitoring strategies and recommends plans for investigational studies of medical products, including human drug and biological products, medical devices, and combinations thereof. The guidance document is intended to enhance human subject protection and the quality of clinical trial data by focusing sponsor oversight on the most important aspects of study conduct and reporting. The guidance also communicates that sponsors can use a variety of approaches to fulfill responsibilities for monitoring clinical investigator conduct and performance in IND studies, and provides a description of strategies for monitoring activities to reflect a modern, risk-based approach. The guidance document recommends that respondents develop a written comprehensive monitoring plan and describes monitoring approaches for respondents to consider (Guidance Section IV.D.).

- The guidance document entitled "Pharmacogenomic Data Submissions" (March 2005) provides recommendations intended to assist sponsors submitting or holding INDs, NDAs, or biologics license applications (BLAs) with submission requirements for

relevant data regarding drug safety and effectiveness (including §§ 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12 (21 CFR 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2 and 601.12)). Because the regulations were developed before the advent of widespread animal or human genetic or gene expression testing, the regulations do not specifically address when such data must be submitted. The guidance document includes content and format recommendations regarding pharmacogenomic data submissions. Although we have not received any pharmacogenomic submissions since 2013, we assume an average of 50 hours for preparing and providing information to FDA as recommended in the guidance and estimate one submission annually.

- The guidance document entitled "*Adaptive Designs for Clinical Trials of Drugs and Biologics*" (December 2019) was developed to assist sponsors and applicants submitting INDs, NDAs, BLAs, or supplemental applications on the appropriate use of adaptive designs for clinical trials to provide evidence of the effectiveness and safety of a drug or biologic. The guidance document describes important principles for designing, conducting, and reporting the results from an adaptive clinical trial, and advises sponsors on the types of information to submit to facilitate FDA evaluation of clinical trials with adaptive designs, including Bayesian adaptive and complex trials that rely on computer simulations for their design. The guidance document also helps to fulfill FDA Commitment Goals under the Prescription Drug User Fee Act pertaining to the enhancement of regulatory decision tools.

As previously noted, the guidance documents are issued consistent with 21 CFR 312.145 and are intended to help respondents comply with the requirements in part 312.

We are therefore requesting OMB approval of the information collection provisions in 21 CFR Part 312, subparts A through G, and the associated guidance documents, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Information collection associated with IND applications (and any supplements thereto) is reviewed by agency staff responsible for overseeing a specific study. The details and complexity of the review requirements are dictated by the scientific procedures and human subject safeguards that must be followed when conducting clinical tests of investigational new drugs. Review of an IND application, as well as pre-submission information, enables us to monitor clinical investigations of unapproved new drugs and biological products. Upon receipt of the IND by FDA, an IND number will be assigned, and the application will be forwarded to the appropriate reviewing division. The reviewing division will send a letter to the Sponsor-Investigator providing notification of the IND number assigned, date of receipt of the original application, address where future submissions to the IND should be sent, and the name and telephone number of the FDA person to whom questions about the application should be directed. Studies shall not be initiated until 30 days after the date of receipt of the IND by FDA unless you receive earlier notification by FDA that studies may begin.

3. Use of Improved Information Technology and Burden Reduction

FDA utilizes the "*Electronic Submission Gateway*" (ESG) to receive most submissions. We encourage preparing submissions in an "*Electronic Common Technical Document*" (eCTD) format, a standardized format for applications, amendments, supplements, and reports to FDA's Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER). In this way, reviewers can easily find and access requisite information, whether part of an original submission or an amendment. We continue to develop and provide resources for submitting information to FDA using the ESG, including the fact sheet available at https://www.fda.gov/media/98901/download.

Additionally, we utilize administrative cover sheets pursuant to 21 CFR 312.23, which sets forth format and content requirements, to facilitate the processing of submissions. Cover sheets are included within the "*Administrative Module*" of the eCTD. We also provide resource information regarding eCTD technical specifications and submission requirements. We estimate 76% of IND submissions will be completed electronically. We are unaware of any legal or technological obstacles to reducing burden.

4. Efforts to Identify Duplication and Use of Similar Information

Although we maintain OMB control no. 0910-0814 to account for burden attributable to information collection activities stemming from regulations in 21 CFR part 312, subpart I (*Expanded Access to Investigational Drugs for Treatment Use*) and our Expanded Patient Access program, we are not aware of duplication.

5. Impact on Small Businesses or Other Small Entities

The IND regulations provide for certain waivers and exemptions but are otherwise intended to enable FDA to fulfill its mandate to ensure the safe study and use of investigational drugs. At the same time, we assist small businesses in complying with our regulations through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. A Small Business Guide is also available at http://www.fda.gov/.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements, as well as commitment goal timeframes established with industry.

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

The information collection requirements under § 312.32 (IND safety reporting) provide for more-than-quarterly reporting with regard to the submission of safety information (i.e., information on adverse drug reactions as well as other information on new studies or modifications of existing studies). However, we believe this is necessary for ensuring the safety of clinical investigations. The regulations also prescribe a specific format for the IND application and follow-up amendments that may not be the same format as that employed by sponsors for their own purposes. These formatting requirements are intended to expedite FDA review and to save Agency resources that can be invested in assisting sponsors in developing approvable marketing applications.

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

In the Federal Register of November 24, 2021 (86 FR 67060), we published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, neither discussed the information collection topics solicited in our 60-day notice or suggested we revise our burden estimate.

9. Explanation of Any Payment or Gift to Respondents

No incentives, payments or gifts are associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 1571 (Investigational New Drug Application (IND)) is name, address, telephone number, fax number, and email address. The PII submitted via Form FDA 1572 (Statement of Investigator) is name, address, and education. The PII submitted via Form FDA 3926 (Individual Patient Expanded Access Investigational New Drug Application (IND)) is patient's initials, brief medical history, physician's name, physician's IND number, address, email address, telephone number, and fax number.

The PII submitted via Form FDA 3674 (Certification of Compliance) is name, address, country, telephone number, and fax number. Sometimes investigators include Form FDA 3455 (Disclosure: Financial Interests and Arrangements of Clinical Investigators). The PII submitted via Form FDA 3455 is name, title, and financial information. We have determined that the PII collected is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use names or any other personal identifiers to routinely retrieve records from the information collected. FDA minimizes the PII collected to protect the privacy of the individuals.

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)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden for Biologics

21 CFR Section; Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Subpart A--General Provisions: §§ 312.1 through 312.10					
§ 312.2(e); requests for FDA advice on the applicability of part 312 to a planned clinical investigation	454	1.528	694	24	16,656
§ 312.8; requests to charge for an investigational drug	14	1.64	23	48	1,104
§ 312.10; waiver requests	5	1	5	24	120
Subtotal Subpart A Center for Biologics Evaluation and Research (CBER)			722		17,880
Subpart B--Investigational New Drug Application (IND): §§ 312.20 through 312.38 (Including Forms FDA 1571, 1572, 3674, and applicable cover sheet or checklist)					
§ 312.23(a) through (f); IND content and format	2,075	3.382	7,018	300	2,105,400
§ 312.30(a) through (e); Protocol amendments	1,781	4.6692	8,316	284	2,361,744
§ 312.31(b); information amendments	169	2.48	419	100	41,900
§ 312.32(c) and (d); IND Safety reports	224	10.59	2,372	32	75,904
§ 312.33(a) through (f); IND Annual reports	971	2.2739	2,208	360	794,880
§ 312.38(b) and (c); notifications of withdrawal of an IND	712	3.057	2,177	28	60,956
Subtotal Subpart B CBER			22,510		5,440,784
Subpart C--Administrative Actions: §§ 312.40 through 312.48					
§ 312.42; clinical holds and requests for modification	154	1.65	254	284	72,136
§ 312.44(c) and (d); sponsor responses to FDA when IND is terminated	86	1.22	105	16	1,680
§ 312.45(a) and (b); sponsor requests for or responses to an inactive status determination of an IND by FDA	48	1.48	71	12	852
§ 312.47; meetings, including “End-of-Phase 2” meetings and “Pre-NDA” meetings	157	1.80	283	160	45,280
Subtotal Subpart C CBER			713		119,948
Subpart D--Responsibilities of Sponsors and Investigators: §§ 312.50 through 312.70					
§ 312.53(c); investigator reports submitted to the sponsor, including Form FDA -1572, curriculum vitae, clinical protocol, and financial disclosure	1,068	5.23	5,586	80	446,880
§ 312.54(a); sponsor submissions to FDA concerning investigations involving an exception from informed consent under § 50.24	4	4.25	17	48	816
§ 312.54(b); sponsor notifications to FDA and others concerning an institutional review board determination that it cannot approve research because it does not meet the criteria in the exception from informed consent in § 50.24(a)	1	1	1	48	48
§ 312.55(a); number of investigator brochures	473	2.224	1,052	48	50,496

21 CFR Section; Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
submitted by the sponsor to each investigator					
§ 312.55(b); number of sponsor reports to investigators on new observations, especially adverse reactions and safe use	243	4.95	1,203	48	57,744
§ 312.56(b), (c), and (d); review of ongoing investigations and associated notifications; sponsor notifications	915	2.948	2,698	80	215,840
§ 312.58; inspection of records and reports by FDA	7	1	7	8	56
§ 312.64; number of investigator reports to the sponsor, including progress reports, safety reports, final reports, and financial disclosure reports	2,728	3.816	10,411	24	249,864
§ 312.70; disqualification of a clinical investigator by FDA	5	1	5	40	200
Subtotal Subpart D CBER			20,980		1,021,944
Subpart F--Miscellaneous: §§ 312.110 through 312.145					
§ 312.110(b)(4) and (b)(5); number of written certifications and written statements submitted to FDA relating to the export of an investigational drug	18	1	18	75	1,350
§ 312.120(b); number of submissions to FDA of "supporting information" related to the use of foreign clinical studies not conducted under an IND	280	9.82	2,750	32	88,000
§ 312.120(c); number of waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	7	2.29	16	24	384
§ 312.130; number of requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	350	1.342	470	8	3,760
Subtotal Subpart F CBER			3,254		93,494
Total			48,179		6,694,050

Table 2.--Estimated Annual Recordkeeping Burden for Biologics

21 CFR Section; Information Collection Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Subpart D--Responsibilities of Sponsors and Investigators: §§ 312.50 through 312.70					
§ 312.52(a); sponsor records for the transfer of obligations to a contract research organization	94	2.26	212	2	424
§ 312.57; sponsor recordkeeping showing the receipt, shipment, or other disposition of the investigational drug, and any financial interest	335	2.70	904	100	90,400
§ 312.62(a); investigator recordkeeping of the disposition of drugs	453	1	453	40	18,120
§ 312.62(b); investigator recordkeeping	453	1	453	40	18,120

21 CFR Section; Information Collection Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
of case histories of individuals					
Subtotal Subpart D CBER			2,022		127,064
Subpart G--Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests					
§ 312.160(a)(3); records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests	111	1.40	155	0.5 (30 minutes)	78
§ 312.160(c) shipper records of alternative disposition of unused drugs	111	1.40	155	0.5 (30 minutes)	78
Subtotal Subpart G CBER			310		156
Total			2,332		127,220

Table 3.--Estimated Annual Reporting Burden for Human Drugs

21 CFR Section; Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Subpart A--General Provisions					
§ 312.2(e); requests for FDA advice on the applicability of part 312 to a planned clinical investigation	419	1	419	24	10,056
§ 312.8; requests to charge for an investigational drug	25	1.28	32	48	1,536
§ 312.10; requests to waive a requirement in part 312	68	1.5	102	24	2,448
Subtotal Subpart A Center for Drug Evaluation and Research (CDER)			553		14,040
Subpart B--Investigational New Drug Application (IND)					
§ 312.23(a) through (f); IND content and format (including Forms FDA 1571 and 3674)	4,886	1.4662	7,164	300	2,149,200
§ 312.30(a) through (e); protocol amendments	11,847	3.2367	38,346	284.25	10,899,850
§ 312.31(b); Information amendments	8,094	3.30899	26,783	100	2,678,300
§ 312.32(c) and (d); IND safety reports	892	15.848	14,137	32	452,384
§ 312.33(a) through (f); IND annual reports	3,777	2.9097	10,990	360	3,956,400
§ 312.38(b) and (c); notifications of withdrawal of an IND	1,549	1.834	2,841	28	79,548
Subtotal Subpart B CDER			100,261		20,215,682
Subpart C--Administrative Actions: §§ 312.40 through 312.48					
§ 312.42; clinical holds and requests for modifications	181	1.28	232	284	65,888
§ 312.44(c) and (d); sponsor responses to FDA when IND is terminated	1	1	1	16	16
§ 312.45(a) and (b); sponsor requests for or responses to an inactive status determination of an IND by FDA	213	1.72	367	12	4,404
§ 312.47; meetings, including “End-of-Phase 2” meetings and “Pre-NDA” meetings	174	2.885	502	160	80,320

Subtotal Subpart C CDER			1,102		150,628
Subpart D--Responsibilities of Sponsors and Investigators					
§ 312.54(a); sponsor submissions to FDA concerning investigations involving an exception from informed consent under § 50.24	7	1.14	8	48	384
§ 312.54(b); sponsor notifications to FDA and others concerning an institutional review board determination that it cannot approve research because it does not meet the criteria in the exception from informed consent in § 50.24(a)	2	1	2	48	96
§ 312.56; review of ongoing investigations and associated notifications	4,570	5.4689	24,993	80	1,999,440
§ 312.58; inspection of records and reports by FDA	73	1	73	8	584
§ 312.70; disqualification of a clinical investigator by FDA.	5	1	5	40	200
Subtotal Subpart D CDER			25,081		2,000,704
Subpart F--Miscellaneous: §§ 312.110 through 312.145					
§ 312.110(b)(4) and (b)(5); written certifications and written statements submitted to FDA relating to the export of an investigational drug	8	22.375	179	75	13,425
§ 312.120(b); submissions to FDA of "supporting information" related to the use of foreign clinical studies not conducted under an IND	1,964	7.352	14,440	32	462,080
§ 312.120(c); waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	68	1.5	102	24	2,448
§ 312.130; requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	3	1	3	8	24
§ 312.145; Guidance Documents:					
Oversight of Clinical Investigations (2013)	88	1.5	132	4	528
Pharmacogenomic Data Submissions (2005)	1	1	1	50	50
Adaptive Designs for Clinical Trials of Drugs and Biologics (2019)	55	4.727	260	50	13,000
Subtotal Subpart F CDER			15,117		491,555
Total			142,114		22,872,609

Table 4.--Estimated Annual Recordkeeping Burden for Human Drugs

21 CFR Section; Information Collection Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Subpart D--Responsibilities of Sponsors and Investigators					
§ 312.52(a); transfer of obligations to a contract research organization	466	3.107	1,448	300	434,400
§ 312.57; records showing the receipt, shipment, or other disposition of the investigational drug and any financial	13,000	1	13,000	100	1,300,000

Table 4.--Estimated Annual Recordkeeping Burden for Human Drugs

21 CFR Section; Information Collection Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
interests					
§ 312.62(a); records on disposition of drugs	13,000	1	13,000	40	520,000
§ 312.62(b); records on case histories of individuals	2,192	6.587	14,439	40	577,560
Subtotal Subpart D CDER			41,887		2,831,960
Subpart G--Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests					
§ 312.160(a)(3); records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests	547	1.43	782	0.50 (30 minutes)	391
§ 312.160(c); shipper records of alternative disposition of unused drugs	547	1.43	782	0.50 (30 minutes)	391
Subtotal			1,564		782
Total			43,451		2,832,742

12b. Annualized Cost Burden Estimate

To estimate average costs to respondents we assume a wage rate of **$28.87**, the median hourly wage across all occupations within the *Pharmaceutical and Medicine Manufacturing* labor category.[1] We then multiplied this figure by the subtotal of reporting hours, shown in tables 1 and 3 above, for 21 CFR part 314, subpart B – application submissions (5,440,784 hours for biological products (CBER); 20,215,682 for drug products (CDER)) and calculated a total of $740,702,173.42.

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

No capital costs or operating or maintenance costs are associated with this information collection.

14. Annualized Cost to the Federal Government

Costs of administering the information collection are absorbed through existing resource allocations and the payment of industry user fees authorized by the Prescription Drug User Fee Act.

15. Explanation for Program Changes or Adjustments

The information collection reflects program changes and adjustments. We have revised the information collection to account for burden that may be incurred by respondents who choose to adopt or implement recommendations discussed in referenced agency guidance documents intended to assist respondents in complying with regulatory requirements in part 312. We have also made adjustments to individual collection elements. As a result of these changes and adjustments, the information collection reflects an overall decrease in both annual responses and burden hours. Finally, we have removed burden we attribute to provisions in part 312, subpart I: Expanded Access to Investigational Drugs for Treatment Use and are revising OMB control

[1] Bureau of Labor Statistics, National Industry-Specific Occupational Employment and Wage Estimates; North American Industry Classification System (NAICS), 2020.

number 0910-0814 to include burden associated with information collection applicable to these regulatory provisions for efficiency of Agency operations.

16. Plans for Tabulation and Publication and Project Time Schedule

We will not tabulate or publish the information collected.

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

FDA will display the OMB control number as required by 5 CFR 1320.5 (and 21 CFR 1320.8(b)(1)); however, because documents are more frequently being accessed electronically we are considering technological changes that will enable us to display the expiration date by linking to approval information found at www.reginfo.gov. We intend to include the OMB control number and expiration date on the guidance landing page, allowing those who download the document an easily identifiable option to view this information. This also allows the agency to more easily update the expiration date upon renewal and/or revision of OMB approval. We are taking this approach to improve compatibility with our current website platform (Drupal).

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certifications associated with this information collection.