Current Good Manufacturing Practices for Positron Emission Tomography Drugs
OMB Control Number 0910-0667
SUPPORTING STATEMENT

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection is intended to ensure that Positron Emission Tomography (PET) drug products meet the requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) regarding safety, identity, strength, quality, and purity. Positron emission tomography is a medical imaging modality involving the use of a unique type of radiopharmaceutical drug product. The majority of PET drug products are injected intravenously into patients for diagnostic purposes. Most PET drugs are produced using cyclotrons and other production equipment at locations that are close to the patients to whom the drugs are administered (for example, in hospitals or academic institutions). Due to their short half-lives, PET drugs usually are administered to patients within a few minutes or hours of production.

Under section 501(a)(2)(B) of the act, a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with Current Good Manufacturing Practice (CGMP) regulations to ensure that such drug meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess. FDA has the authority under section 701(a) of the act to issue regulations for the efficient enforcement of the act regarding CGMP procedures for manufacturing, processing, and holding drugs and drug products. Our CGMP requirements for non-PET drug products are set forth in 21 CFR parts 210 and 211. The CGMP regulations help ensure that drug products meet the statutory requirements for safety and have their purported or represented identity, strength, quality, and purity characteristics. The recordkeeping requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to protect public health and safety. CGMP requirements establish accountability in the manufacturing and processing of drug products, provide for meaningful FDA inspections, and enable manufacturers to improve the quality of drug products over time. The CGMP recordkeeping requirements also serve preventive and remedial purposes and provide crucial information if it is necessary to recall a drug product.

2. Purpose and Use of the Information Collection

The information collection includes the following CGMP recordkeeping requirements: Batch Production and Control Records; Equipment and Facilities Records; Records of Components, Containers, and Closures; Process Verification; Laboratory Testing Records; Sterility Test Failure Notices; Conditional Final Releases; Out-of-Specification Investigations; Reprocessing

Procedures; Distribution Records; and Complaints.

3. Use of Improved Information Technology and Burden Reduction

Generally, records required by CGMP regulations are designed and maintained by drug manufacturers. Because the CGMP regulations provide great latitude on how these requirements are to be achieved, manufacturers are allowed to establish their own methods of recordkeeping. FDA accepts any recordkeeping method which meets the objectives of 21 CFR parts 210, 211, and 212. For example, drug manufacturing establishments may use automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, to comply with these recordkeeping requirements.

4. Efforts to Identify Duplication and Use of Similar Information

Other FDA regulations affecting drug manufacturers do not duplicate the PET CGMP regulations. The information required by the PET CGMP regulations is not available from any other source except the manufacturer. No other government agency collects these data.

5. Impact on Small Businesses or Other Small Entities

Section IV of the December 10, 2009, PET CGMP final rule (74 FR 65409), Analysis of Economic Impacts, analyzes the rule's impact on small businesses and other small entities:

> The rule affects producers of PET drugs, including certain hospitals, clinics, colleges and universities, and producers of in vivo diagnostic substances. According to the Small Business Administration (SBA), pharmaceutical preparation manufacturers with 750 or fewer employees, electromedical and electrotherapeutic apparatus manufacturers with 500 or fewer employees, drugs and druggists' sundries wholesalers with 100 or fewer employees, and for-profit hospitals, clinics, colleges, and universities with $29 million or less in revenue are considered small businesses or entities. To estimate the number of U.S. establishments producing PET drugs, we combined a list of PET centers with cyclotrons from the Academy of Molecular Imaging (AMI) with a list of PET manufacturing facilities from the Society of Nuclear Imaging in Drug Development, which has since merged with the AMI, and added additional facilities that we identified. We have identified 101 establishments operated by 51 PET drug producers. In over one-third of the cases, the PET drug is produced by a hospital. In other instances, a corporate producer manages production under contract at one or more hospitals with cyclotrons. PET drugs are also produced at independent establishments by corporate producers or small regional producers. Total producer numbers continue to increase as the current corporate producers expand their number of establishments and more independent regional producers enter the market.
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> Using information from the American Hospital Association (AHA), we characterized 28 of the hospital producers as one of the following establishment types:

- Government, non-Federal;
- Government, Federal;
- Non-Government not-for-profit;
- Investor-owned (for-profit).[1]

The AHA data did not include information for eight hospitals associated with large colleges or universities, but for this analysis, these were assumed to be not-for-profit because approximately 93 percent of all 4-year higher education institutions are public or nonprofit institutions.[2] Census data reports indicate that private hospitals (with more than 100 employees) average gross revenues of about $36.8 million in 1997. This figure inflates to about $57.7 million using the Consumer Price Index (CPI) for medical care from 1997 to 2007. Considering that hospitals producing PET drugs probably are larger than the average private hospital, we consider it very likely that the two private hospitals producing PET drugs have annual revenues over $29 million and are therefore not considered small entities.[3] In instances where PET drug producer information is not available, this analysis assumes that the PET drug producer is owned by the hospital in which it is located.

Two of the three domestic corporate PET drug producers exceed the SBA employee limits within their respective business classifications to qualify as small businesses. Employee data were not available for the other domestic corporation or any of the 11 regional commercial producers, and we therefore assume that these may be small businesses.

In total, the 51 identified producers of PET drugs are classified as follows: 6 Federal, 6 State, 34 small entities, and 5 large entities. Most of those that were considered small entities were classified as such because they are not-for-profit organizations, not because they met the employee or revenue limits for small businesses. It should be noted that an entity's identification as small or large in this analysis does not necessarily indicate the volume of PET drugs it produces or the share of the market it holds.

Most, if not all, of the PET drug producers currently employ individuals who possess skills necessary to establish written procedures and prepare documentation as required by this rule. Some may choose, as mentioned above, to contract with an outside consultant to manage their compliance with the rule.

At most, a single PET drug producer may incur one-time and annual costs of approximately $57,900 and $32,400, respectively, per production facility. The hospital and regional commercial producers will incur these higher per-facility costs because

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1 "AHA Guide to the Health Care Field, 1997-98 Edition," Healthcare Infosource, Inc., a subsidiary of the American Hospital Association.

2 "The Nation: Colleges and Universities," The Chronicle of Higher Education, 1999-2000, Almanac Issue, volume XVI, no. 1, p. 7, August 27, 1999.

3 "Hospital Statistics," table 3, pp. 8-9, Health Forum, An American Hospital Association Company, 1999.

these establishments are expected to have higher noncompliance rates with the written procedure and recordkeeping requirements. The total of the maximum one-time and annual costs per producer equates to significantly less than 1 percent of the $111 million ($70.8 million inflated by the CPI for medical care from 1997 to 2007) average annual gross revenue per nonprofit hospital. In addition, most of the hospitals that are affected by this rule are affiliated with large universities whose total revenues are expected to be much higher than the $111 million figure cited. The estimated compliance cost represents an even smaller portion of a percent of the entire university's revenues. Revenue data were not available for the one possibly small corporate producer. This company is expected to incur annual costs of approximately $70,100 and one-time costs of about $16,800. The 11 regional commercial producers are expected to incur one-time and annual costs of approximately $57,900 per producer and $32,400 per production facility. We lack sufficient data to estimate the expected compliance costs as a percentage of revenues for the regional commercial producers. Although no comments on the proposed rule directly addressed our estimates of the expected impact of compliance costs on small facilities, it is possible that this final rule will have a significant effect on these small entities.

6. Consequences of Collecting the Information Less Frequently

FDA assures compliance with CGMP recordkeeping requirements by conducting drug establishment inspections, as authorized by section 704 (21 U.S.C. 374) of the act, to review and evaluate the adequacy of records. Drug manufacturers are, in general, scheduled for these comprehensive on-site inspections once every two years. Inspections are scheduled more frequently when there have been compliance problems. FDA investigators are authorized to examine and to copy and verify these records in order to document evidence of deviation should an enforcement case go to litigation. It would be impossible to ensure compliance with section 501(a)(2)(B) of the act (21 U.S.C.351 (a)(2)(B)) if industry were not required to maintain these records.

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

There is no inconsistency with the requirements of section 1320.5.

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

In the Federal Register of March 20, 2013 (78 FR 17215), FDA published a 60 day notice requesting public comment on the proposed collection of information. We received 2 comments, each raising several issues.

(Comment 1) One comment said that the two tables in the Federal Register notice were unclear because only the part 212 section was cited and not the records pertaining to that section.

(Response) FDA appreciates the comment and we have revised the tables accordingly.

(Comment 2) One comment said that the collection of information will not have any practical utility unless the reason for the proposed collection is to provide better FDA understanding of the PET drug production industry, to facilitate upcoming inspections, and to work with PET facilities in meeting areas of compliance under part 212. Another comment said that FDA has not adequately explained the purpose of these regulations.

(Response) FDA's CGMP regulations in part 212 are useful and necessary because they help ensure that PET drug products meet the requirements of the FD&C Act regarding safety, identity, strength, quality, and purity. The requirements are specifically designed to take into account the unique characteristics of PET FDA drugs, including their short half-lives and the fact that most PET drugs are produced at locations that are very close to the patients to whom the drugs are administered. As mentioned by the comment, the collection of information also provides FDA with a better understanding of the PET production industry.

(Comment 3) One comment said that the number of PET drug production facilities estimated by FDA is not reflective of the current number of registered PET production facilities operating in the United States, and that the burden estimates are based on 129 PET drug production facilities surveyed. The comment said that the actual number of PET producers is over 150. The comment said that FDA did not divide the PET drug production facilities into commercial sites and academic sites, and questioned whether the data are a fair representation of both. The comment also said that commercial facilities are able to hire a team of personnel dedicated to regulatory compliance, whereas the individual sites, like the academic labs, must perform the same functions with a much smaller staff. The comment said that FDA's burden estimates for academic labs are too low and unrealistic.

(Response) The 129 PET drug production facilities are based on facilities listed in new drug applications (NDAs) and abbreviated new drug applications (ANDAs) submitted to FDA. These 129 sites are producing PET drugs and are seeking approval from FDA for commercial distribution for clinical use (not for investigational or research use). It is unclear from the comment if the 150 sites include sites producing PET drugs for investigational use. FDA requests that the commenter provide any updated data on the number of PET drug sites. In addition, FDA believes it is fair to make a general estimate across academic and commercial sites because the number of academic sites that apply for drug applications is a relatively small percentage.

(Comment 4) One comment said that the burden hour estimates are not accurate because each facility will compile their records differently and will use either a paper-based method or an electronic method. The comment said that FDA did not specify how many PET drug facilities are using paper-based records compared with electronic-based records, and that the burden hours for those using paper-based records would be higher than those using electronic recordkeeping. The comment said that the burden hour estimate is not a fair representation of the time needed for all PET facilities to comply with the recordkeeping requirements.

(Response) All commercial PET drug manufacturers are currently utilizing electronic records for recordkeeping as well as paper-based records. Commercial PET drug manufacturers comprise approximately 90 percent of the manufacturing sites. Many academic PET facilities still choose to use paper-based records. However, academic PET sites produce fewer batches for clinical use compared to commercial sites, and have fewer records. Sufficient resources and personnel are needed to perform the PET drug production activities, and we do not agree that

academic PET drug sites limited in personnel and resources bear more of the regulatory burden. After a firm's recordkeeping process is established, the burdens are generally the same for entering records into an electronic system or a paper-based system. In addition, we question whether it is worthwhile to prepare separate estimates for commercial versus academic sites because academic sites are a small percentage of the total.

(Comment 5) One comment said that the estimate of 30 minutes per batch production and control record should be increased to 90 minutes because of the following responsibilities: Recording the identification number, tracking number, and lot number of each equipment item, component, or reagent utilized in the production of the PET drug; reviewing and recording daily sterility data for 14 days after release and inoculation; and quality assurance review of all batch record entries.

(Response) FDA agrees that some of the responsibilities may take additional time, and we have increased the burden estimate to 1 hour.

(Comment 6) One comment said that the recordkeeping estimate of 10 minutes for components, containers, and closures should be increased to 60 minutes because of the following responsibilities: To document the receipt, quarantine, and release of each component at separate and distinctly timed intervals; to recover certificates of analysis; contacting vendors; requesting documents; receiving and printing documents and maintaining files for documents; and acceptance, which requires performing and recording lab results. For media, this includes completing packaging and shipping documents for offsite testing as well as specifying testing parameters to the contract lab.

(Response) To log in each incoming component may take 10 minutes, but the time needed to perform all procedures as described by the commenter, including verifying that the component meets the firm's internal specifications, will take longer. Therefore, we have we have increased the burden estimate to 30 minutes.

(Comment 7) One comment said that the estimate of 36 out-of-specification investigations per year should be increased to 120 investigations because FDA requires an investigation of not only those that are most serious but also every incident involving an unexpected result.

(Response) FDA disagrees that 36 out-of-specification investigations per year are too low based on the information from our field alert reporting system. Out-of-specification investigations pertain to those products not meeting one or more of its release specifications. On the other hand, certain deviations in manufacturing also warrant investigations in order to prevent future recurrence. It is unlikely that a firm could have 120 total investigations per facility.

(Comment 8) One comment said that the use of automated collection techniques and other forms of information technology increase costs to producers: Software solutions with necessary validation costs could cost $100,000; support and maintenance could cost $20,000 per year; and applications training and implementing the electronic methods require several months of effort.

(Response) There will be initial costs to establish an electronic recordkeeping system, but once the system is set up, the annual costs will be minimal. FDA requires electronic records (i.e., batch records and analytical test records) to comply with the basic electronic records requirements at 21 CFR part 11, namely, record security and an audit trail. Those sites that are

under corporate management can apply their electronic recordkeeping system to all sites within the same corporation.

(Comment 9) One comment asked to see the list of questions from the survey that was used to determine the time spent to comply with the recordkeeping requirements.

(Response) In making our estimates of the time spent in complying with these information collection requirements, we relied on communications we have had with PET producers, visits by our staff to PET facilities, and our familiarity with both PET and general pharmaceutical manufacturing practices. There was no formal survey to industry.

(Comment 10) One comment suggested that FDA establish an "on-line database" requiring a username and password for access to minimize the burden of the collection of information on respondents.

(Response) FDA believes the information collection burden is reasonable at this time, and we have no plans to implement an online database.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Certain data and information collected during an inspection of a drug manufacturing establishment for the purpose of enforcing compliance with the CGMP regulations are considered confidential and not releasable to the public. Confidentiality is maintained for trade secret or confidential, commercial, or financial information under 21 CFR 20.61 and investigatory records under 21 CFR 20.64. In addition, certain sections of 21 CFR 314.430 provide confidentiality of information contained in NDAs and ANDAs.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden and Costs

12a. Annualized Hour Burden Estimate

The CGMP regulations establish several recordkeeping requirements and a third-party disclosure requirement for the production of PET drugs. In making our estimates of the time spent in complying with these information collection requirements, we relied on communications we have had with PET producers, visits by our staff to PET facilities, and our familiarity with both PET and general pharmaceutical manufacturing practices. The estimated annual recordkeeping and third-party disclosure burden is based on there being approximately 129 PET drug production facilities. Table 1 provides an estimate of the annual recordkeeping burdens. Table 2 provides an estimate of the annual third-party disclosure burdens associated with this collection.

A. Investigational and Research PET Drugs

Section 212.5(b) provides that for investigational PET drugs produced under an investigational new drug (IND) and research PET drugs produced with approval of a Radioactive Drug Research Committee (RDRC), the requirement under the FD&C Act to follow current good manufacturing practice is met by complying with the regulations in part 212 or with United States Pharmacopoeia (USP) 32 Chapter 823. We believe that PET production facilities producing drugs under INDs and RDRCs are currently substantially complying with the recordkeeping requirements of USP 32 Chapter 823 (see section 121(b) of FDAMA), and accordingly, we do not estimate any recordkeeping burden for this provision.

B. Batch Production and Control Records

Sections 212.20(c) through (e), 212.50(a) through (c), and 212.80(c) set forth requirements for batch and production records as well as written control records. We estimate that it would take approximately 20 hours annually for each PET production facility to prepare and maintain written production and control procedures and to create and maintain master batch records for each PET drug produced. We also estimate that there will be a total of approximately 221 PET drugs produced, with a total recordkeeping burden of approximately 4,420 hours. We estimate that it would take a PET production facility an average of 1 hour to complete a batch record for each of approximately 501 batches. Our estimated burden for completing batch records is approximately 64,629 hours.

C. Equipment and Facilities Records

Sections 212.20(c), 212.30(b), 212.50(d), and 212.60(f) contain requirements for records dealing with equipment and physical facilities. We estimate that it would take approximately 1 hour to establish and maintain these records for each piece of equipment in each PET production facility. We estimate that the total burden for establishing procedures for these records would be approximately 1,935 hours. We estimate that recording maintenance and cleaning information would take approximately 5 minutes a day for each piece of equipment, with a total recordkeeping burden of approximately 40,237 hours.

D. Records of Components, Containers, and Closures

Sections 212.20(c) and 212.40(a), (b), and (e) contain requirements on records regarding receiving and testing of components, containers, and closures. We estimate that the annual burden for establishing these records would be approximately 259 hours. We estimate that each facility would receive approximately 36 shipments annually and would spend approximately 30 minutes per shipment entering records. The annual burden for maintaining these records would be approximately 2,322 hours.

E. Process Verification

Section 212.50(f)(2) requires that any process verification activities and results be recorded. Because process verification is only required when results of the production of an entire batch are not fully verified through finished-product testing, we believe that process verification will be a very rare occurrence, and we do not estimate any recordkeeping burden for

documenting process verification.

F. Laboratory Testing Records

Sections 212.20(c), 212.60(a), (b), and (g), 212.61(a) and (b), and 212.70(a), (b), and (d) set out requirements for documenting laboratory testing and specifications referred to in laboratory testing, including final release testing and stability testing. Each PET drug production facility will need to establish procedures and create forms for the different tests for each product they produce. We estimate that it will take each facility an average of 1 hour to establish procedures and create forms for one test. The estimated annual burden for establishing procedures and creating forms for these records is approximately 3,225 hours, and the annual burden for recording laboratory test results is approximately 10,728 hours.

G. Sterility Test Failure Notices

Section 212.70(e) requires PET drug producers to notify all receiving facilities if a batch fails sterility tests. We believe that sterility test failures might occur in only 0.05 percent of the batches of PET drugs produced each year. Therefore, we have estimated in Table 2 that each PET drug producer will need to provide approximately 0.25 sterility test failure notice per year to receiving facilities. The notice would be provided using email or facsimile transmission and should take no more than 1 hour.

H. Conditional Final Releases

Section 212.70(f) requires PET drug producers to document any conditional final releases of a product. We believe that conditional final releases will be fairly uncommon, but for purposes of the Paperwork Reduction Act, we estimated that each PET production facility would have one conditional final release a year and would spend approximately 1 hour documenting the release and notifying receiving facilities. The estimate of one conditional final release per year per facility is an appropriate average number because many facilities may have no conditional final releases while others might have only a few.

I. Out-of-Specification Investigations

Sections 212.20(c) and 212.71(a) and (b) require PET drug producers to establish procedures for investigating products that do not conform to specifications and conduct these investigations as needed. We estimate that it will take approximately 1 hour annually to record and update these procedures for each PET production facility. We also estimate, for purposes of the PRA, that 36 out-of-specification investigations would be conducted at each facility each year and that it would take approximately 1 hour to document the investigation, which results in an annual burden of 4,644 hours.

J. Reprocessing Procedures

Sections 212.20(c) and 212.71(d) require PET drug producers to establish and document procedures for reprocessing PET drugs. We estimate that it will take approximately 1 hour a year to document these procedures for each PET production facility. We do not estimate a separate burden for recording the actual reprocessing, both because we believe it would be an uncommon event and because the recordkeeping burden has been included in our estimate for

batch production and control records.

K. Distribution Records

Sections 212.20(c) and 212.90(a) require that written procedures regarding distribution of PET drug products be established and maintained. We estimate that it will take approximately 1 hour annually to establish and maintain records of these procedures for each PET production facility. Section 212.90(b) requires that distribution records be maintained. We estimate that it will take approximately 15 minutes to create an actual distribution record for each batch of PET drug products, with a total burden of approximately 16,157 hours for all PET producers.

L. Complaints

Sections 212.20(c) and 212.100 require that PET drug producers establish written procedures for dealing with complaints, as well as document how each complaint is handled. We estimate that establishing and maintaining written procedures for complaints will take approximately 1 hour annually for each PET production facility and that each facility will receive approximately one complaint a year and will spend approximately 30 minutes recording how the complaint was dealt with.

Table 1.--Estimated Annual Recordkeeping Burden

21 CFR Section	Number of Record-keepers	Number of Records per Record-keeper	Total Annual Records	Average Burden per Record-keeper	Total Hours
Batch Production and Control Records 212.20(c) and (e); 212.50(a) and (b)	129	1.71	221	20	4,420
Batch Production and Control Records 212.20(d) and (e); 212.50(c); 212.80(c)	129	501	64,629	1	64,629
Equipment and Facilities Records 212.20(c); 212.30(b); 212.50(d); 212.60(f)	129	15	1,935	1	1,935
Equipment and Facilities Records 212.30(b); 212.50(d); 212.60(f)	129	3,758	484,782	.08 (5 minutes)	38,783
Records of Components, Containers, and Closures 212.20(c); 212.40(a) and (b)	129	2	258	1	258
Records of Components, Containers, and Closures 212.40(e)	129	36	4,644	.5 (30 minutes)	2,322

Laboratory Testing Records 212.20(c); 212.60(a) and (b); 212.61(a); 212.70(a), (b), and (d)	129	25	3,225	1	3,225
Laboratory Testing Records 212.60(g); 212.61(b); 212.70(d)(2) and (d)(3)	129	501	64,629	.16 (10 min.)	10,341
Conditional Final Releases 212.70(f)	129	1	129	1	129
Out-of-Specification Investigations 212.20(c); 212.71(a)	129	36	4,644	1	4,644
Out-of-Specification Investigations 212.71(b)	129	1	129	1	129
Reprocessing Procedures 212.20(c); 212.71(d)	129	1	129	1	129
Distribution Records 212.20(c); 212.90(a)	129	1	129	1	129
Distribution Records 212.90(b)	129	501	64,629	.25 (15 min.)	16,157
Complaints 212.20(c); 212.100(a)	129	1	129	1	129
Complaints 212.100(b) and (c)	129	1	129	.5 (30 min.)	65
Total					147,456

Table 2.--Estimated Annual Third-Party Disclosure Burden

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Sterility Test Failure Notices 212.70(e)	129	.25	32	1	32

12b. Annualized Cost Burden Estimates

For this extension, we have updated the estimate of costs provided in the Supporting Statement for the December 10, 2009, PET CGMP final rule (74 FR 65409):

Annual Costs By Recordkeeping Requirement				
	Number of Establishments	Labor (Months)	Wage (Year Salary)[1]	Cost[2]
-- Records Daily Implementation, Audits, Updates				
Academic PET Producers	18	2.25	$164,300	$554,512.23
Commercial PET Producers	111	1.0	$164,300	$1,519,774.26
-- Training				
Academic PET Producers	18	.11	$164,300	$27,109.49
Commercial PET Producers	111	.11	$164,300	$167,175.17
-- Total Annual Costs				$194,284.66

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

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

14. Annualized Cost to the Federal Government

FDA costs for this information collection consists of periodic inspections of PET drug production facilities. We estimate that there are approximately 60 inspections annually at 40 hours per inspection, resulting in 5 FTEs X $145,000/FTE = $725,000 annual cost to FDA.

15. Explanation for Program Changes or Adjustments

The information collection burden has changed from 90,216 to 147,546 as a result of updated data used by FDA and increases in response to the public comments we received on the 60-day notice.

16. Plans for Tabulation and Publication and Project Time Schedule

Information collected under this requirement will not be published.

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

The agency does not seek an exemption from displaying the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.