SF-83 SUPPORTING STATEMENT
PAPERWORK REDUCTION ACT - OMB CONTROL NUMBER 0651-0024
REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

A. JUSTIFICATION

1. Necessity of Information Collection

Patent applications that contain nucleotide and/or amino acid sequence disclosures must include a copy of the sequence listing in accordance with the requirements in 37 CFR 1.821-1.825. The rules of practice require applicants to submit these sequence listings in a standard international format that is consistent with World Intellectual Property Organization (WIPO) Standard ST.25 (1998) (Attachment A). Under this standard, sequence listings are presented in an international, language-neutral format using numeric identifiers rather than subject headings. Applicants may submit sequence listings for both U.S. and international patent applications. Submissions of nucleotide and amino acid sequence listings in international applications are in accordance with Patent Cooperation Treaty (PCT) Rule 13ter (Attachment B).

The USPTO uses the sequence listings during the examination process to determine the patentability of the associated patent application. Sequence listings are also disclosed as part of the published patent application or issued patent. Sequence listings that are extremely long (files larger than 600K or approximately 300 printed pages) are published only in electronic form and are available to the public on the USPTO sequence data web page.

The USPTO recognizes that the submission of massive paper versions of extremely long sequence listings would place a significant burden on applicants and the USPTO, while also being of minimal utility for examination purposes. Consequently, applicants may submit the sequence listing required by 37 CFR 1.821(c) on paper or compact disc (CD). Applicants may also file sequence listings for U.S. applications electronically using the Electronic Filing System (EFS) software developed by the USPTO for secure transmission of patent applications and related documents over the Internet. Applicants may use EFS to file a sequence listing electronically with a patent application or subsequent to a previously filed application.

Under 37 CFR 1.821(e)-(f), applicants must also submit a copy of the sequence listing in “computer readable form” (CRF) with a statement indicating that the CRF copy of the sequence listing is identical to the paper or CD copy required by 1.821(c). If an applicant later submits an amendment to the paper or CD copy of the sequence listing, the applicant must also submit a new CRF copy of the amended listing. Applicants may submit the CRF copy of the sequence listing to the USPTO on CD or other acceptable

media as provided in 37 CFR 1.824. Sequence listings that are submitted electronically using EFS do not require a separate CRF copy.

This information collection contains the sequence listings that are submitted with biotechnology patent applications. Information pertaining to the filing of the initial patent application itself is collected under OMB Control Number 0651-0032, and international applications submitted under the Patent Cooperation Treaty (PCT) are covered under OMB Control Number 0651-0021. Customers may use a checkbox on Form PTO/SB/05 Utility Patent Application Transmittal, which is covered under OMB Control Number 0651-0032, to indicate the submission of a sequence listing for a U.S. patent application. The USPTO also provides a sample format for the transmittal documentation that must be submitted with a sequence listing on CD for an international patent application. Applicants who submit sequence listings using EFS must complete the electronic transmittal forms included within the submission software.

Table 1 provides the specific statute and regulations requiring the USPTO to collect the information discussed above:

Table 1: Information Requirement for Sequence Disclosures

Requirement	Statute	Rule
Sequence Listing in Application and Electronic Sequence Listing in Application	35 U.S.C. ' 22	37 CFR 1.821-1.825

2. Needs and Uses

The USPTO uses nucleotide and amino acid sequence listing information to determine the patentability of an application during the examination process and to support the publication of issued patents. In addition, the sequences are used by the USPTO to participate with the European and Japanese Patent Offices in a Trilateral Sequence Exchange project to facilitate the international exchange of published sequence data. Upon publication of the application or issued patent, the associated nucleotide or amino acid sequence listings are disclosed to the public and made available on the USPTO web site. Copies of published sequence listings are also forwarded to the National Center for Biotechnology Information (NCBI). Applicants use the sequence data when preparing both national and international patent applications involving nucleotide or amino acid sequences.

The Information Quality Guidelines from Section 515 of Public Law 106-554, Treasury and General Government Appropriations Act for Fiscal Year 2001, apply to this information collection and comply with all applicable information quality guidelines, i.e. OMB and specific operating unit guidelines.

This proposed collection of information will result in information that will be collected, maintained, and used in a way consistent with all applicable OMB

and USPTO Information Quality Guidelines. (See Attachment C, the USPTO Information Quality Guidelines.)

Table 2 outlines how this collection of information is used by the public and the USPTO:

Table 2: Needs and Uses of Information Collected for Sequence Disclosures

Item	Form #	Needs and Uses
Sequence Listing in Application (paper)	No Form Associated	Used by the public when preparing a national or international patent application containing nucleotide and/or amino acid sequence information. Used by the USPTO to determine the patentability of an application. Used by the USPTO to support publication of applications and issued patents. Used by the USPTO during participation with the European and Japanese Patent Offices in a Trilateral Sequence Exchange Project to facilitate the international exchange of published sequence data.
Sequence Listing in Application (CD) (Attachment D)	No Form Associated	Used by the public when preparing a national or international patent application containing nucleotide and/or amino acid sequence information. Used by the USPTO to determine the patentability of an application. Used by the USPTO to support publication of applications and issued patents. Used by the USPTO during participation with the European and Japanese Patent Offices in a Trilateral Sequence Exchange Project to facilitate the international exchange of published sequence data.
Electronic Sequence Listing in Application (EFS) (Attachment E)	No Form Associated	Used by the public to submit a nucleotide and/or amino acid sequence listing with a national patent application or subsequent to a previously filed application. Used by the USPTO to determine the patentability of an application. Used by the USPTO to support publication of applications and issued patents. Used by the USPTO during participation with the European and Japanese Patent Offices in a Trilateral Sequence Exchange Project to facilitate the international exchange of published sequence data.

3. Use of Information Technology

Applicants may submit sequence listings on paper, CD, or electronically over the Internet using EFS. Submissions on CD must follow the guidelines specified in 37 CFR 1.52(e), with the file contents in American Standard Code for Information Interchange (ASCII) format and accompanied by the necessary transmittal documentation to identify, maintain, and interpret the sequence listing. Under Part 8 of the PCT Administrative Instructions promulgated by WIPO, sequence listings for international PCT applications may be submitted on CD as well. Applicants who submit a paper or CD sequence listing are also required to submit a CRF copy of the listing, which facilitates the ability of examiners to search sequences and improves the accuracy and efficiency of the publishing process.

Applicants may use EFS to file a sequence listing electronically with a patent application or subsequent to a previously filed application. The acceptance of CDs and electronic submissions is permitted by 35 U.S.C. ' 22, which provides that the USPTO Amay

require papers filed in the Patent and Trademark Office to be printed, typewritten, or on an electronic medium.@ Sequence listings submitted using EFS do not require a separate CRF copy or any paper documentation. The first EFS filing of a sequence listing for a pending biotechnology patent application occurred on September 29, 1999.

EFS consists of both client and server software that supports the authoring, preparation, secure submission, receipt, and receipt validation of patent applications and certain related documents electronically over the Internet. Applicants prepare the electronic sequence listing submissions by using the Electronic Packaging and Validation Engine (ePAVE) software, which is free and available for download from the USPTO web site. The ePAVE software allows the applicant to enter the necessary identifying information and then attach the sequence listing file for electronic submission. The ePAVE software will also validate the entered data and alert the user of any errors or omissions. When the electronic package is ready to be submitted, the filer must sign and date the package with an electronic mark. The ePAVE software then combines the transmittal information and sequence listing into a single compressed file, encrypts and digitally signs the file, and securely transmits the file to the USPTO over the Internet.

Submissions that exceed 100 megabytes (including all files and attachments) cannot be transmitted electronically over the Internet. If the submission is too large, the ePAVE software will prompt the user to copy the oversized submission onto a CD, which can then be mailed or hand delivered to the USPTO with a printed copy of the transmittal information. Customers are advised to keep a back-up copy of the CD and transmittal information for their own records, and they may also submit a second copy of the CD to the USPTO to be used in case the first copy is unreadable.

To protect the confidentiality, authenticity, and integrity of electronic submissions, the USPTO employs public key infrastructure (PKI) technology for secure electronic communications with its customers. Customers must obtain a customer number and digital certificate from the USPTO that will be used to authenticate the electronic submission. All electronic submissions are automatically encrypted prior to transmission to ensure confidentiality of their contents. After the electronic package has been received by the USPTO, the EFS server uses digital signature technology to verify that the contents of the package have not been altered and generates an electronic acknowledgment receipt that is immediately returned to the customer. If a sequence listing filed using EFS is not usable, the USPTO will notify the customer promptly by phone, fax, or email.

EFS offers many advantages over paper filing. The system immediately sends customers an electronic receipt and ensures that electronic sequence listings are transmitted securely to the USPTO by using PKI technology. The electronic filing of sequence listings also eliminates the inefficiencies of physically mailing, handling, routing, and storing sequence listings on paper or portable electronic media.

The USPTO provides PatentIn authoring software that may be used by applicants to create sequence listings that comply with U.S. and international filing standards for biotechnology patent applications containing nucleotide and amino acid sequence data. The free PatentIn software may be downloaded from the USPTO web site, and the USPTO offers public training sessions on how to use the software. In addition, the USPTO provides a CRF Checker software tool that allows applicants to test sequence listings for compliance with format and content rules before submitting them to the USPTO.

When the sequence listing arrives at the USPTO, the data format is checked for compliance by the CRF receipt system and then uploaded to the Automated Biotechnology Sequence Search (ABSS) System database. ABSS stores electronic sequence listings submitted by applicants and supports searching of biosequences from patent submissions as well as public and commercial databases of published biosequence data. ABSS also supports the publication and dissemination of sequence listings following publication of the associated application or issuance of the patent.

Upon publication of the application or issued patent, the associated nucleotide or amino acid sequence listings are disclosed to the public. Sequence listings that are extremely long (files larger than 600K or approximately 300 printed pages) are published only in electronic form and are available for viewing or download through the Publication Site for Issued and Published Sequences (PSIPS) on the USPTO web site.

4. Efforts to Identify Duplication

This collection requires the duplication of a limited amount of identifying information (such as the applicant=s name, address, and phone number), which is also provided on the patent application. However, the duplication of identification information is the most efficient way of accurately associating the sequence listing with the appropriate application case file.

The sequence listing required by 37 CFR 1.821(c) may be submitted on paper, CD, or electronically over the Internet. For paper and CD submissions, the applicant must also submit a separate CRF copy of the listing. However, if the CRF sequence listing in a new application is identical to the CRF sequence listing of another application that the applicant already has on file at the USPTO, 37 CFR 1.821(e) permits the applicant to refer to the CRF listing in the other application rather than having to submit a duplicate copy of the CRF listing for the new application. In such a case, the applicant may submit a letter identifying the application and CRF sequence listing that is already on file and stating that the sequence listing submitted in the new application is identical to the CRF copy already filed with the previous application.

5. Minimizing Burden to Small Entities

Although the collection may involve small businesses or other small entities, most applications involving sequence listings are filed by other than small entities. This collection does not impose a significant economic impact on small businesses or other small entities. The same information is required from every applicant and is not available from any other source.

The information collection does involve payment of fees by customers who may qualify as small entities. To reduce this cost burden for small entities, the USPTO offers reduced application size fees (by 50%) for persons, small business concerns, or nonprofit organizations that qualify as small entities under 37 CFR 1.27. No significant burden is placed on small entities, in that small entities are simply required to identify themselves as such in order to obtain these benefits. An assertion of small entity status only needs to be filed once in an application or patent.

6. Consequences of Less Frequent Collection

This collection of information is required for the processing and examination of the respondent's patent application involving a nucleotide or amino acid sequence listing. This information could not be collected less frequently. If the information were not collected, the USPTO could not properly examine the associated application as required by 35 U.S.C. ' 131. Further, the collection of this information is necessary in order to publish the sequence listings accurately as part of the application or patent.

7. Special Circumstances in the Conduct of Information Collection

There are no special circumstances associated with this collection of information.

8. Consultations Outside the Agency

The 60-Day Notice was published in the *Federal Register* on June 15, 2006 (71 Fed. Reg. 34601) (Attachment F). The comment period ended on August 14, 2006. No public comments were received.

The USPTO has long-standing relationships with groups from whom patent application data is collected, such as the American Intellectual Property Law Association (AIPLA), as well as patent bar associations, independent inventor groups, and users of our public facilities. Their views are expressed in regularly scheduled meetings and considered in developing proposals for information collection requirements. The USPTO also meets regularly with groups from whom sequence information is collected, such as BIO, the Biotechnology subgroup of the American Intellectual Property Law Association, and the Biotechnology Institute. There have been no comments or concerns expressed by these or similar organizations concerning the time required to provide the information under this program.

9. Payments or Gifts to Respondents

This information collection does not involve a payment or gift to any respondent.

10. Assurance of Confidentiality

The confidentiality of patent applications is governed by statute (35 U.S.C. ' 122) and regulation (37 CFR 1.11 and 1.14). The USPTO has a legal obligation to maintain the confidentiality of the contents of unpublished patent applications and related documents. Upon publication of an application or issuance of a patent, the patent application file is made available to the public, subject to the provisions for providing only a redacted copy of the file contents. The disclosure of the invention in the application is the quid pro quo for the property right conferred by the patent grant and the very means by which the patent statute achieves its constitutional objective of "promot[ing] the progress of science and useful arts." The prosecution history contained in the application file is critical for determining the scope of the property right conferred by a patent grant.

11. Justification for Sensitive Questions

None of the required information in this collection is considered to be of a sensitive nature.

12. Estimate of Hour and Cost Burden to Respondents

Table 3 calculates the burden hours and costs of this information collection to the public, based on the following factors:

$ Respondent Calculation Factors
The USPTO estimates that it will receive 15,382 nucleotide and/or amino acid sequence disclosures per year.

$ Burden Hour Calculation Factors
The USPTO estimates that it will take the public approximately ten minutes (0.17 hours) to one hour and 20 minutes (1.33 hours) to gather the necessary information, prepare the sequence listing, and submit it to the USPTO, depending on whether the listing is submitted on paper, on CD, or electronically.

$ Cost Burden Calculation Factors
The USPTO expects that the information in this collection will be prepared by paraprofessionals at an estimated rate of $90 per hour. This is a fully-loaded, hourly rate.

Table 3: Burden Hour/Burden Cost to Respondents for Sequence Disclosures

Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a) x (b)	Rate ($/hr) (d)	Total Cost ($/yr) (e) (c) x (d)
Sequence Listing in Application (paper)	1.33	11,512	15,311	$90.00	$1,377,990.00
Sequence Listing in Application (CD)	1.0	1,600	1,600	$90.00	$144,000.00
Electronic Sequence Listing in Application (EFS)	0.17	2,270	386	$90.00	$34,740.00
TOTALS	. . . . .	**15,382**	**17,297**	. . . . .	**$1,556,730.00**

The USPTO estimates that approximately 15% of the total responses for this collection will be submitted electronically (through EFS).

13. Total Annualized Cost Burden

There are no maintenance costs associated with this collection. The USPTO provides free software for creating and validating the format of the sequence listings prior to submission. However, this collection does have annual (non-hour) costs in the form of filing fees, capital start-up costs, recordkeeping costs, and postage costs.

There is no separate filing fee for submitting a sequence listing as part of a U.S. patent application, but there is a filing fee of $4,800 for submitting a sequence listing on CD as part of an international PCT application. The USPTO estimates that approximately 200 of the 1,600 CD sequence listings submitted per year will be for international applications, for a total of $960,000 per year. While there is no additional fee for a sequence listing filed on paper in an international application, the basic international filing fee only covers the first 30 pages of the application. As a result, there is a $12 fee per page that is added to the international filing fee for each page over 30 pages. The average length of a paper sequence listing in an international application is 150 pages, which would carry an additional fee of $1,800 if the international application were already at least 30 pages long without the listing. The USPTO estimates that approximately 1,560 of the 11,512 paper sequence listings submitted per year will be for international applications, for a total of $2,808,000 per year. Therefore, this collection has $3,768,000 per year in filing fees that may be associated with paper and CD sequence listings for international applications.

Under 37 CFR 1.16(s) and 1.492(j), both U.S. and international patent applications that include lengthy paper sequence listings may be subject to an application size fee. For applications with paper sequences listings that exceed 100 pages, the application size fee is $250 (or $125 for small entities) for each additional 50 pages or fraction thereof. The USPTO estimates that approximately 400 applications with long paper sequence listings will incur an average application size fee of $750, and approximately 310 applications with long paper listings from small entities will incur an average application

size fee of $375, for a total of $416,250 per year. **Therefore, this collection has total filing fees of $4,184,250 per year.**

There are capital start-up costs associated with submitting sequence listings and CRF copies to the USPTO on CD. Applicants who submit sequence listings on CD must submit two copies of the CD (or three copies for international applications) along with a transmittal letter stating that the copies are identical. This process requires additional supplies, including blank recordable CD media and padded envelopes for shipping. The USPTO estimates that the cost of these supplies will be approximately $3 per CD submission and that it will receive approximately 1,600 CD submissions per year, for a total of $4,800. In addition, customers who submit sequence listings on paper or CD must also submit a separate CRF copy of the listing, which may be submitted on CD. The USPTO estimates that it will receive approximately 13,112 CRF copies for paper and CD sequence listings at an estimated cost of $2 per copy, for a total of $26,224. **Therefore, this collection has total capital start-up costs of $31,024 per year.**

Applicants who submit sequence listings on CD may also incur recordkeeping costs. The USPTO advises applicants to retain a back-up copy of CD submissions and associated documentation for their records. The USPTO estimates that it will take applicants five minutes to produce a back-up CD copy and two minutes to print copies of documentation, for a total of seven minutes (0.12 hours) to make a back-up copy of the CD submission. The USPTO estimates that approximately 1,600 CD submissions will be received per year, for a total of 192 hours for making back-up CD copies. The USPTO expects that these back-up copies will be prepared by paraprofessionals at an estimated rate of $90 per hour, for a recordkeeping cost of $17,280 per year.

There are also recordkeeping costs associated with submitting sequence listings electronically over the Internet using EFS. The USPTO recommends that customers print and retain a copy of the acknowledgment receipt that appears on the screen after a successful submission. Customers will also receive an electronic copy of this receipt via email. The USPTO estimates that it will take 5 seconds (0.001 hours) to print a copy of the acknowledgment receipt and that approximately 2,270 sequence listings per year will be submitted via EFS, for a total of approximately 2 hours per year for printing this receipt. The USPTO expects that these receipts will be printed by paraprofessionals at an estimated rate of $90 per hour, for a recordkeeping cost of $180 per year for printing the acknowledgment receipts. **Therefore, this collection has total recordkeeping costs of $17,460 per year associated with retaining copies of CDs and acknowledgment receipts.**

Customers may incur postage costs when submitting a sequence listing to the USPTO by mail. Mailed submissions may include the sequence listing on either paper or CD, the CRF copy of the listing on CD, and a transmittal letter containing the required identifying information. The USPTO estimates that the average postage cost for a paper or CD sequence listing submission will be $4.05 and that 13,112 sequence listings will be mailed to the USPTO per year. **Therefore, this collection has total**

postage costs of $53,104 per year.

The total annual (non-hour) respondent cost burden for this collection in the form of filing fees ($4,184,250), capital start-up costs ($31,024), recordkeeping costs ($17,460), and postage costs ($53,104) is estimated to be $4,285,838 per year.

14. Annual Cost to the Federal Government

The USPTO estimates that it takes a GS-5, step 1 employee an average of 6 minutes (0.10 hours) to process a sequence disclosure, including paper, CD, and electronic submissions using EFS. The hourly rate for a GS-5, step 1, is currently $14.18. When 30% is added to account for a fully-loaded hourly rate (benefits and overhead), the hourly rate for processing these submissions is $18.43 ($14.18 + $4.25).

Table 4 calculates the burden hours and costs to the Federal Government for processing this information collection:

Table 4: Burden Hour/Burden Cost to the Federal Government for Sequence Disclosures

Item	Hours (a)	Responses (yr) (b)	Burden (hrs/yr) (c) (a) x (b)	Rate ($/hr) (d)	Total Cost ($/yr) (e) (c) x (d)
Sequence Listing in Application (paper)	0.10	11,512	1,151	$18.43	$21,213.00
Sequence Listing in Application (CD)	0.10	1,600	160	$18.43	$2,949.00
Electronic Sequence Listing in Application (EFS)	0.10	2,270	227	$18.43	$4,184.00
TOTALS	.....	**15,382**	**1,538**	.....	**$28,346.00**

15. Reason for Change in Burden

Summary of Changes Since the Previous Renewal

This information collection was previously approved in September 2003 with a total of 23,750 responses and 29,856 burden hours per year.

For this renewal, the USPTO estimates that the total annual responses will be 15,382 and the total annual burden hours will be 17,297, which is a decrease of 8,368 responses and 12,559 burden hours from the currently approved burden for this collection. This decrease in burden hours is due to administrative adjustments from an overall expected net decrease in patent filings with sequence listings. In addition, the USPTO estimates that the proportion of responses submitted electronically (using EFS) will increase from approximately 1% to 15%.

The total annual (non-hour) cost burden for this renewal of $4,285,838 is a net decrease of $3,322,344 from the currently approved total of $7,608,182 in annual costs for this

collection. This net decrease in annual costs is due to both program changes and administrative adjustments.

Changes from the 60-Day Notice

The 60-Day Notice that was published for this renewal reported an estimated annual (non-hour) cost burden of $4,285,658. Since the 60-Day Notice was published, the estimated recordkeeping costs for this collection have been revised to include costs for retaining acknowledgment receipts for electronic submissions of sequence listings using EFS. As a result, the total estimated annual (non-hour) cost burden has increased by $180 to the $4,285,838 in annual (non-hour) cost burden now submitted with this renewal.

Change in Respondent Cost Burden

This collection was previously approved in September 2003 with 29,856 burden hours and an estimated total respondent cost burden of $895,680. That submission used an estimated rate of $30 per hour for paraprofessionals preparing the sequence listings. For this renewal, the estimated rate for paraprofessionals has been revised to $90 per hour. At the revised rate, the 17,297 burden hours for this renewal yield a respondent cost burden of $1,556,730, which is an increase of $661,050 from the total respondent cost burden reported in the September 2003 submission. This increase is due to the increase in the estimated hourly rate for respondents, even though the total burden hours have decreased.

Changes in Responses and Burden Hours

For this renewal, the USPTO estimates that the annual responses for this collection will decrease by 8,368, from 23,750 to 15,382 responses per year. The USPTO also estimates that the total burden hours for this collection will decrease by 12,559, from 29,856 to 17,297 hours per year. This decrease is due to administrative adjustments, as follows:

! The USPTO estimates that the annual responses for paper sequence listings will decrease by 7,368, from 18,880 to 11,512, due to expected decreases in filings. **Therefore, this collection takes a burden decrease of 9,799 hours as an administrative adjustment.**

! The USPTO estimates that the annual responses for CD sequence listings will decrease by 3,120, from 4,720 to 1,600, due to expected decreases in filings. **Therefore, this collection takes a burden decrease of 3,120 hours as an administrative adjustment.**

! The USPTO estimates that the annual responses for sequence listings filed electronically over the Internet using EFS will increase by 2,120, from 150 to

2,270, due to expected increases in electronic filings. **Therefore, this collection takes a burden increase of 360 hours as an administrative adjustment.**

In sum, the decrease in paper and CD filings is partially offset by an increase in electronic filings using EFS. **Therefore, this information collection has a total net burden decrease of 12,559 hours due to administrative adjustments.**

Changes in Annual (Non-hour) Costs

For this renewal, the USPTO estimates that the total annual (non-hour) costs for this collection will decrease by $3,322,344, from $7,608,182 to $4,285,838 per year. The decrease in total annual (non-hour) costs is due to program changes and administrative adjustments, as follows:

! This collection is currently approved with $7,500,000 in filing fees associated with submitting a sequence listing as part of an international PCT application. For this renewal, the USPTO estimates that these fees associated with PCT sequence listings will decrease to $3,768,000 due to net decreases in filings. The USPTO expects that paper PCT sequence listings will decrease from 3,900 to 1,560 per year and that CD PCT sequence listings will increase from 100 to 200, for a net decrease of 2,240 sequence listings for PCT applications. The $4,212,000 decrease in fees associated with paper PCT sequence listings, from $7,020,000 to $2,808,000, is only partially offset by the $480,000 increase in fees associated with CD PCT sequence listings, from $480,000 to $960,000. **Therefore, this collection takes a burden decrease of $3,732,000 in filing fees as an administrative adjustment.**

! The USPTO is adding application size fees to this collection that may apply to some paper sequence listing submissions. For this renewal, the USPTO estimates that the total fees associated with lengthy paper sequence listings will be $416,250 per year. **Therefore, this collection takes a burden increase of $416,250 in filing fees as a program change.**

! This collection is currently approved with $342 in capital start-up costs for the CD burning hardware, software, and supplies associated with the production of CDs for sequence listing submissions. Since the hardware and software for burning CDs may be considered standard office equipment, this estimate has been revised and the capital start-up costs reported for this renewal include only the additional supplies for producing and submitting CDs, such as blank recordable media and shipping envelopes. The estimate has also been recalculated to include these supply costs for each CD sequence listing submission as well as the required CRF copies on CD for paper and CD sequence listings, for a total of $31,024 per year. **Therefore, this collection takes a burden increase of $30,682 in capital start-up costs as an administrative adjustment.**

! This collection is currently approved with a total of $16,980 in recordkeeping costs associated with keeping back-up copies of CD submissions. For this renewal, the USPTO estimates that these recordkeeping costs will increase to $17,280 per year due to an increase in the estimated hourly rate for paraprofessionals preparing the back-up copies, despite the expected decrease in CD filings. The USPTO also estimates that there will be an additional $180 in recordkeeping costs associated with retaining acknowledgment receipts for electronic submissions of sequence listings using EFS. **Therefore, this collection takes a burden increase of $480 in recordkeeping costs as an administrative adjustment.**

! This collection is currently approved with a total of $90,860 in postage costs associated with submitting paper and CD sequence listings to the USPTO by mail. For this renewal, the USPTO estimates that the total postage costs will decrease to $53,104 per year due to expected decreases in paper and CD filings, despite an increase in the estimated postage cost from $3.85 to $4.05 per submission. **Therefore, this collection has a burden decrease of $37,756 in postage costs as an administrative adjustment.**

In sum, this collection has an annual (non-hour) cost burden of $4,285,838, with $4,184,250 in the form of filing fees, $31,024 in capital start-up costs, $17,460 in recordkeeping costs, and $53,104 in postage costs. **Therefore, this collection has a net decrease in annual (non-hour) cost burden of $3,322,344, with an increase of $416,250 due to program changes and a decrease of $3,738,594 due to administrative adjustments.**

16. Project Schedule

The USPTO does not plan to publish this information for statistical use. However, sequence listing information will be published as part of the routine pre-grant publication of applications as well as issued patents.

17. Display of Expiration Date of OMB Approval

There are no forms associated with this collection. Therefore, the display of the expiration date is not applicable.

18. Exception to the Certificate Statement

This collection of information does not include any exceptions to the certificate statement.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.

List of Attachments

A. World Intellectual Property Organization (WIPO) Standard ST.25 (1998)
B. Patent Cooperation Treaty (PCT) Rule 13ter
C. The USPTO Information Quality Guidelines
D. Sample Format for Compact Disc Transmittal Sheet for Submission of Sequence Listing and/or Tables to the United States Receiving Office Under PCT Administrative Instructions - Part 8
E. Screenshots from ePAVE software for filing sequence listings electronically via EFS
F. 60-Day Notice published in the *Federal Register* on June 15, 2006 (71 Fed. Reg. 34601)