

JUSTIFICATION FOR NONMATERIAL/NONSUBSTANTIVE CHANGE
(Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence
Disclosures)
OMB Control Number 0651-0024

Background

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. Applicants submit copies of sequence listings for both U.S. and international biotechnology patent applications. The USPTO uses the sequence listings during the examination process to determine the patentability of the associated patent application. The USPTO also uses the sequence listings to support publication of patent applications and issued patents. Sequence listings are searchable after publication.

This information collection covers the submission of the sequence listing information itself. Information pertaining to the filing of the initial U.S. patent application is collected under OMB Control Number 0651-0032, and information pertaining to the filing of the initial international application is collected under OMB Control Number 0651-0021.

In particular, this information collection accounts for sequence listings submitted on paper, compact disc (CD), or through EFS-Web, the USPTO's online filing system. Sequence listings may be submitted via EFS-Web as an ASCII text file or in Portable Document Format (PDF). For U.S. applications, § 1.821(c) permits all modes of submission: paper, CD, or EFS-Web. Sequence listings for international applications may be submitted on paper or through EFS-Web only, though sequence listings that are too large to be filed electronically through EFS-Web may be submitted on CD.

This request is to remove the paper-based Sequence Listing in Application (IC No. 1) in response to rulemaking 0651-AD53 (Standard for Presentation of Nucleotide and Amino Acid Sequence Listings Using eXtensible Markup Language (XML) in Patent Applications to Implement WIPO Standard ST.26; Incorporation by Reference), because the Rule amends the rules of practice for these submissions by incorporating by reference certain provisions of World Intellectual Property Office Standard ST.26 (WIPO Standard ST.26) into the USPTO rules of practice. Other conforming changes to accommodate the new rules of practice based on the new standard are also included. In addition to simplifying the process for applicants filing in multiple countries, the requirement to submit a single sequence listing in eXtensible Markup Language (XML) format, or "Sequence Listing XML," will result in better preservation, accessibility, and sorting of the submitted sequence data for the public.

The removal of the paper-based Sequence Listing in Application will result in a reduction of burden, outlined in the table below.

Responses (Year)	Annual Burden (Year)	Annual Non-Hourly/Fee Respondent Cost Burden
-5,000	-30,000	-\$309,667

Summary of Changes

The annual number of responses will decrease by 5,000 and the annual time burden will decrease by 30,000 in this request. The annual non-hour cost burden will decrease by \$309,667 because of the removal of fees and postage associated with the removed item.