SUPPORTING STATEMENT
Internal Revenue Service (IRS)
Branded Prescription Drugs
OMB #1545-2209

1. CIRCUMSTANCES NECESSITATING COLLECTION OF INFORMATION

Internal Revenue Code (IRC) section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111-148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111-152 (124 Stat. 1029 (2010)) imposes an annual fee on manufacturers and importers of branded prescription drugs (covered entities) that have gross receipts of over $5 million from the sales of these drugs to certain government programs.

The Treasury Decision (TD) 9544 temporary regulations were superseded by TD 9684 temporary and final regulations (79 FR 43639) dated July 28, 2014, and by TD 9823 final regulations (82 FR 34611) dated July 24, 2017. The final regulation supersedes the temporary regulations and describes how the IRS will administer the branded prescription drug fee. 26 CFR Section 51.6(b) of the Branded Prescription Drug Fee regulations provides that the IRS will send each covered entity notification of its preliminary fee calculation. If a covered entity chooses to dispute the IRS' preliminary fee calculation, the covered entity must follow the procedures for submitting an error report that are established in 26 CFR Section 51.7 and Notice 2014-42.

2. USE OF DATA

The IRS will use the data voluntarily supplied by a covered entity that disputes its preliminary fee calculation to verify the accuracy of the data and the calculation used to determine the covered entity's fee.

3. USE OF IMPROVED INFORMATION TECHNOLOGY TO REDUCE BURDEN

IRS has no plans to offer electronic filing due to the low number of filers.

4. EFFORTS TO IDENTIFY DUPLICATION

The information obtained through this collection is unique and is not already available for use or adaptation from another source.

5. METHODS TO MINIMIZE BURDEN ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

The collection of information requirement will not have a significant economic impact on a substantial number of small entities.

6. CONSEQUENCES OF LESS FREQUENT COLLECTION ON FEDERAL PROGRAMS OR POLICY ACTIVITIES

A less frequent collection of taxes and tax information could adversely affect the government's effectiveness and would reduce the oversight of the public in ensuring compliance with Internal Revenue Code and hinder the IRS from meeting its mission. Additionally, less frequent collection would hinder the taxpayer's ability to dispute of the fee.

7. SPECIAL CIRCUMSTANCES REQUIRING DATA COLLECTION TO BE INCONSISTENT WITH GUIDELINES IN 5 CFR 1320.5(d)(2)

There are no special circumstances requiring data collection to be inconsistent with Guidelines in 5 CFR 1320.5(d)(2).

8. CONSULTATION WITH INDIVIDUALS OUTSIDE OF THE AGENCY ON AVAILABILITY OF DATA, FREQUENCY OF COLLECTION, CLARITY OF INSTRUCTIONS AND FORMS, AND DATA ELEMENTS

In response to the Federal Register notice January 23, 2025, (90 FR 8103), we received no comments during the comment period regarding TD 9544, Branded Prescription Drugs.

9. EXPLANATION OF DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS

No payment or gift has been provided to any respondents.

10. ASSURANCE OF CONFIDENTIALITY OF RESPONSES

Generally, tax returns and tax return information are confidential as required by section 6103.

11. JUSTIFICATION OF SENSITIVE QUESTIONS

No sensitive personally identifiable information is being collected.

12. ESTIMATED BURDEN OF INFORMATION COLLECTION

A covered entity that disputes its preliminary fee calculation will need to submit supporting data to the IRS. We estimate that 45 covered entities will dispute the IRS' preliminary fee calculation. The estimated burden per covered entity will be 40 hours.

The burden estimate is as follows:

Authority	Description	# of Respondents	# Responses per Respondent	Annual Responses	Hours per Response	Total Burden
Treasury Regulation § 51.7	TD 9684	45	1	45	40	1,800
Total				45		1,800

13. ESTIMATED TOTAL ANNUAL COST BURDEN TO RESPONDENTS

To ensure more accuracy and consistency across its information collections, IRS is currently in the process of revising the methodology it uses to estimate burden and costs. Once this methodology is complete, IRS will update this information collection to reflect a more precise estimate of burden and costs.

14. ESTIMATED ANNUALIZED COST TO THE FEDERAL GOVERNMENT

There is no developing, printing, or distribution cost to the Federal government for the error report statements.

15. REASONS FOR CHANGE IN BURDEN

There is no change in the paperwork burden previously approved by OMB. IRS is making this submission to renew the OMB approval.

	Total Approved	Change Due to New Statute	Change Due to Agency Discretion	Change Due to Adjustment in Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	**45**	0	0	0	0	**45**
Annual Time Burden (Hr)	**1,800**	0	0	0	0	**1,800**

16. PLANS FOR TABULATION, STATISTICAL ANALYSIS AND PUBLICATION

There are no plans for tabulation, statistical analysis, and publication.

17. REASONS WHY DISPLAYING THE OMB EXPIRATION DATE IS INAPPROPRIATE

The IRS believes that displaying the OMB expiration date is inappropriate because it could cause confusion by leading taxpayers to believe that the regulation expires as of the expiration date. Taxpayers are not likely to be aware that the IRS intends to request renewal of the OMB approval and obtain a new expiration date before the old one expires.

18. EXCEPTIONS TO THE CERTIFICATION STATEMENT

There are no exceptions to the certification statement for this collection.