SUPPORTING STATEMENT
Internal Revenue Service
(TD 9544) (REG-112805-10) Branded Prescription Drugs
OMB #1545-2209

1. CIRCUMSTANCES NECESSITATING COLLECTION OF INFORMATION

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 that have gross receipts of over $5 million from the sales of these drugs to certain government programs (covered entity/covered entities).

The final regulation supersedes the temporary regulations and describes how the IRS will administer the branded prescription drug fee. Section 51.7T(b) of the temporary regulations provides that the IRS will send each covered entity notification of its preliminary fee calculation by May 15 of the fee year. 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 §51.8T.

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 publication, regulations, notices and letters are to be electronically enabled on an as practicable basis in accordance with the IRS Reform and Restructuring Act of 1998. IRS intends to offer electronic filing to the extent it is practicable however in this case it isn't practicable because of the evaluative nature of the determination.

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

Consequences of less frequent collection on federal programs or policy activities would consist of: decreased amount of taxes collected by the Service, inaccurate and untimely filing of tax returns, and an increase in tax violations.

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 INSTRUCTION AND FORMS, AND DATA ELEMENTS

In response to the Federal Register notice dated April 2, 2018 (83 FR 14107), we received no comments during the comment period regarding TD 9544.

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

A covered entity’s submission of information regarding its fee will be treated as return information that is generally confidential as required by 26 USC 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' 2011 preliminary fee calculation. The estimated burden per covered entity will be 40 hours.

Authority	Description	# of Respondents	# Responses per Respondent	Annual Responses	Hours per Response	Total Burden
Treasury Regulation §§ 51.6302-1T(b)	TD 9544	45	1	45	40	1,800
Total				45		**1,800**

Estimates of the annualized cost to respondents for the hour burdens shown are not available at this time.

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

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.

15. REASONS FOR CHANGE IN BURDEN

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

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

IRS believes that displaying the OMB expiration date is inappropriate because it could cause confusion by leading covered entities to believe that the dispute resolution process is available to them until the expiration date.

18. EXCEPTIONS TO THE CERTIFICATION STATEMENT

There are no exceptions to the certification statement.

Note: The following paragraph applies to all of the collections of information in this submission:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of section 9008 of the ACA and any related Internal Revenue Code provision. A covered entity's submission of information regarding its preliminary fee calculation will be treated as return information that is generally confidential as required by 26 USC 6103.