

Form 8947: Report of Branded Prescription Drug Information

Read the instructions before you complete Form 8947.

OMB No. 1545-2192

(November 2010)

Department of the Treasury — Internal Revenue Service

Information report for calendar year:
<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> 2009 </div>

Item A: Check one (see instructions)	Entity name
1 Single-person covered entity <input type="checkbox"/>	Address (number and street). If you have a P.O. box, see instructions.
Designated entities:	
2a Common parent of an affiliated group <input type="checkbox"/>	City, town or post office, state, and ZIP code. If you have a foreign address, see instructions.
2b Other designated entity <input type="checkbox"/>	

Employer identification number (EIN).

Part I Controlled Group Members

This section must be completed if you checked Item A, box 2a or 2b. Beginning with the information for the designated entity, list the information for all members (as of the end of the day on December 31, 2009) of the controlled group.

(a) Entity No.	(b) Name of Entity	(c) Address of Entity	(d) Employer Identification No.
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Part III **Controlled Group Designated Entity Consent**

(sign and complete if you checked Item A, box 2b, on page 1) (see instructions)

Entity name _____

Employer identification number (EIN).

The designated entity receives IRS correspondence relating to the fee imposed by section 9008 of the Patient Protection and Affordable Care Act and pays this fee to the IRS on behalf of the controlled group. Each entity that is a member of the controlled group is jointly and severally liable for this fee.

Under penalties of perjury, I declare that each entity in the controlled group identified on this report consents to the choice of the designated entity indicated on this report for this controlled group, and that I have examined this report, including accompanying statements, and to the best of my knowledge and belief, it is true, correct, and complete.

Sign Here ▶

Signature of official

Date

Title

Name of signing official

Daytime telephone number

Part IV **Signature for Single-Person Covered Entity**

(sign and complete if you checked Item A, box 1, on page 1)

Entity name _____

Employer identification number (EIN).

Under penalties of perjury, I declare that I have examined this report, including accompanying statements, and to the best of my knowledge and belief, it is true, correct, and complete.

Sign Here ▶

Signature of official

Date

Title

Name of signing official

Daytime telephone number

Send Form 8947 to: Internal Revenue Service
1973 Rulon White Boulevard
Mail Stop 4916
Ogden, UT 84404

Continuation Sheet for Part II. Branded Prescription Drug Information

Sheet _____ of _____ Use as many Continuation Sheets for Part II as necessary. Number each sheet. For example, sheet 1 of 4, sheet 2 of 4, etc.

Entity name _____

Employer identification number (EIN).

(a) Part I entity no.	(b) National Drug Code	(c) Medicare Part D rebate amount, if applicable (if none, enter -0-)	(d) Medicaid state supplemental rebate amount, if applicable (if none, enter -0-)	(e) Latest tax year section 45C credit allowed, if applicable (yyyy)	(f) Name of section 45C orphan drug, if applicable	(g) Date of FDA approval for non-orphan drug marketing, if applicable (mmddyyyy)
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General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Purpose of Form

Use Form 8947 to report the following information for all branded prescription drugs sold by covered entities to specified government programs (or sales due to coverage under the programs) during calendar year 2009.

- National Drug Codes.
- Medicare and Medicaid rebate information.
- Section 45C orphan drug information.
- Designated entity and controlled group members information, if applicable.

The IRS will use the information you submit on Form 8947 to calculate the annual fee for branded prescription drug sales ("the fee"). The fee is imposed by section 9008 of Public Law 111-148 (Patient Protection and Affordable Care Act), as amended by Public Law 111-152 (Health Care and Education Reconciliation Act of 2010) (the "Act").

See *Item A. Covered Entity Information and Definitions* later. Also, see Notice 2010-71 for more information.

Who Should File

All manufacturers and importers of branded prescription drugs with sales to specified government programs (or sales due to coverage under the programs) should file Form 8947. All entities that are treated as single covered entities are requested to file one Form 8947, disclosing all requested information for each entity, as described in these instructions and Notice 2010-71.

When To File

File Form 8947 by January 20, 2011, for 2009 calendar year sales information.

Where To File

Send Form 8947 to:

Internal Revenue Service
1973 Rulon White Boulevard
Mail Stop 4916
Ogden, UT 84404

Send the forms in a flat mailing (not folded). Do not staple, tear, or tape any of these forms. If you are sending a large number of forms in conveniently sized packages, write your name and EIN on each package and number the packages consecutively. United States postal regulations require forms and packages to be sent by First-Class Mail. However, you may use private delivery services such as DHL, Federal Express (FedEx), and United Parcel Service (UPS).

Definitions

For the definitions of covered entity, single-person covered entity, and designated entity, see *Item A. Covered Entity Information* under *Specific Instructions*.

Branded prescription drug sales. Branded prescription drug sales are sales of branded prescription drugs made to specified government programs (or sales due to coverage under the programs). A branded prescription drug is any prescription drug for which an application was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)), or any biological product the license for which was submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

Branded prescription drug sales do not include sales of section 45C orphan drugs (defined below).

Specified government programs. Specified government programs under the Act are:

- The Medicare Part D program under part D of title XVIII of the Social Security Act;
- The Medicare Part B program under part B of title XVIII of the Social Security Act;
- The Medicaid program under title XIX of the Social Security Act;
- Any program under which branded prescription drugs are procured by the Department of Veterans Affairs;
- Any program under which branded prescription drugs are procured by the Department of Defense; and
- The TRICARE retail pharmacy program under section 1074g of title 10, United States Code.

Section 45C orphan drugs. Branded prescription drug sales do not include sales of orphan drugs if the covered entity claimed the section 45C tax credit for the orphan drugs on a return or claim for refund, and there has not been a final assessment or a court disallowance of the full section 45C credit taken for the drug.

Non-orphan drug marketing. A branded prescription drug is not treated as an orphan drug after December 31 of the year in which the drug or biological was approved by the Food and Drug Administration (FDA) for non-orphan drug marketing. Non-orphan drug marketing is marketing for any indication other than the treatment of the rare disease or condition for which the section 45C tax credit was allowed.

Specific Instructions

Item A. Covered Entity Information

Covered entity

A covered entity is any manufacturer or importer with gross receipts from branded prescription drug sales. A manufacturer or importer is the person identified in the Labeler Code of the National Drug Code (NDC) for the branded prescription drug. The NDC is an identifier assigned by the FDA to a branded prescription drug, as well as other drugs. The Labeler Code is the first five numeric characters of the NDC, or the first six numeric characters when the available five-character code combinations are exhausted.

A covered entity is either unaffiliated (a single-person covered entity) or a member of a controlled group. For purposes of the Act, all persons treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) will be treated as one covered entity (an Act section 9008(d)(2) controlled group). In applying the single employer rules, a foreign entity subject to tax under section 881 is included within a controlled group under section 52(a) or 52(b). Also, a controlled group that is an affiliated group that filed a consolidated federal tax return for tax year 2009 ("affiliated group") will be treated as one covered entity.

Box 1. Check box 1 if you are a single-person covered entity. You must sign and complete Part IV, Signature for Single-Person Covered Entity.

Designated entity

Generally, the designated entity is one of the following.

- The common parent of an affiliated group.
- The member chosen to be the designated entity by the members of a controlled group that is not an affiliated group.

The designated entity files Form 8947, receives IRS correspondence about the fee for the group, and pays the fee to the IRS.

Box 2a. Check box 2a if you are a common parent of an affiliated group. Also complete *Part I, Controlled Group Members*, giving the name, address, and EIN of each member as of the end of the day on December 31, 2009, listing the designated entity's name first. You must also sign and complete Part III, Controlled Group Designated Entity Consent.

Box 2b. Check box 2b if you are the designated entity for a covered entity that is not an affiliated group. Also complete *Part I, Controlled Group Members*, giving the name, address, and EIN of each member as of the end of the day on December 31, 2009, listing the designated entity's name first. You must also sign and complete Part III, Controlled Group Designated Entity Consent.

Name and Address

Entity name

If you checked box 1 in Item A, enter the name of the single-person covered entity. If you checked box 2a or 2b, enter the name of the designated entity.

Address

P.O. box. Enter your box number only if your post office does not deliver mail to your street address.

Foreign address. Enter the information in the following order: city, province or state, and country. Follow the country's practice for entering the postal code. In some countries the postal code may come before the city or town name. Enter the full name of the country using uppercase letters in English.

Third party. If you receive your mail in care of a third party (such as an accountant or an attorney), enter on the street address line "C/O" followed by the third party's name and street address or P.O. box.

Part II. Branded Prescription Drug Information

Entity number

Enter the same entity number for each member that was shown in Part I.

National Drug Code

Enter the 11-digit National Drug Code (omitting hyphens) maintained by the FDA for any branded prescription drug sold to any specified government program (or sold due to coverage under the programs) during 2009.

Medicare Part D rebate amount

Enter the rebates for each NDC paid in the 2009 sales year by the covered entity to Medicare Part D for sales occurring in the 2009 sales year. For this purpose, a rebate is considered paid in the 2009 sales year if it is taken into account on the covered entity's tax return(s) for the 2009 sales year.

Medicaid state supplemental rebate amount

Enter the rebates for each NDC paid in the 2009 sales year by the covered entity for sales under Medicaid occurring in the 2009 sales year. For this purpose, a rebate is considered paid in the 2009 sales year if it is taken into account on the covered entity's tax return(s) for the 2009 sales year.

Latest tax year section 45C orphan drug credit allowed

For the drug listed, enter the latest tax year that the section 45C orphan drug credit was allowed on your tax return, if applicable. Use the format yyyy. Fiscal year filers must show the tax year according to the tax year's beginning.

Name of section 45C orphan drug

Enter the generic or trade name shown on FDA Form 3671, if applicable.

Date of FDA approval for non-orphan drug marketing

Enter the date of FDA approval for non-orphan drug marketing, if applicable. Use the format mmdyyy.

Part III. Controlled Group Designated Entity Consent

Complete this section if you checked Item A, box 2b.

The choice of designated entity must be consented to by all the members of the Act section 9008(d)(2) controlled group that are members as of the end of the day on December 31, 2009. The consent must be signed by a person with the authority to bind the designated entity.

Paperwork Reduction Act Notice. We ask for the information on Form 8947 to carry out the Internal Revenue laws of the United States. We need it to ensure that you are complying with these laws and to allow us to figure and collect the right amount of fees.

You are not required to provide the information requested on a form that is subject to the Paperwork Reduction Act unless the form displays a valid OMB control number. Books or records relating to a form or its instructions must be retained as long as their contents may become material in the administration of any Internal Revenue law. Generally, the information you report on this form is confidential, as required by section 6103.

The time needed to complete and file Form 8947 will vary depending on individual circumstances. The estimated average time is:

Recordkeeping	8 hrs., 51 min.
Preparing, copying, assembling, and sending the form	52 min.
Learning about the law or the form	42 min.

If you have comments concerning the accuracy of these time estimates or suggestions for making Form 8947 simpler, we would be happy to hear from you. You can write to: Internal Revenue Service, Tax Products Coordinating Committee, SE:W:CAR:MP:T:T:SP, 1111 Constitution Ave. NW, IR-6526, Washington, DC 20224. Do not send Form 8947 to this address. Instead, see *Where To File* on page 5.