Form 8947: Report of Branded Prescription Drug Information

Read the instructions before you complete Form 8947.

OMB No. 1545-2192

(Rev. October 2011)

Department of the Treasury — Internal Revenue Service

Item A: Check one

1 First time Filer (Complete this page and page 6; attach Schedule A) . . . . . ☐

2 Subsequent Year Filer with Changes (Complete this page and page 6; attach Schedules B, C, and D as needed) . . . . . ☐

3 Subsequent Year Filer with No Changes and Reporting Rebates (Complete this page and page 6; attach Schedule D) . . . . . ☐

4 Subsequent Year Filer with No Changes and Not Reporting Rebates (Complete this page and page 6) . . . . . ☐

Information report for sales year: 2010

Item B: Check one (see instructions)

1 Single-person covered entity ☐

Designated entities:

2a Common parent of an affiliated group . . . ☐

2b Other designated entity . . ☐

Entity name

Address (number and street). If you have a P.O. box, see instructions.

City, town or post office, state, and ZIP code. If you have a foreign address, see instructions.

Employer identification number (EIN).

Part I Controlled Group Members

If you checked Item B, box 2a or 2b: Beginning with the name of the designated entity, list the information for all members of the controlled group who, as of the end of the day on December 31, 2010, are manufacturers or importers with gross receipts from the sale of branded prescription drugs to specified government programs (or sales due to coverage under the programs).

Check if the entity was not listed on your report for sales year 2009	(a) Name of entity	(b) Address of entity	(c) Employer identification no.
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Schedule A **Branded Prescription Drug Information – First Time Filers Only** (see instructions)

Entity name

Employer identification number (EIN).

If you have more National Drug Codes (NDCs) to report than can be shown on this page, complete and attach as many Schedules A as you need to list them all, numbering each page (for example, Page A1 of A5). Page ___ of ___

(a) Controlled group member EIN	**(b)** NDC	**(c)** Medicaid state supplemental rebate amount, if applicable (if none, enter -0-)	**(d)** Latest tax year section 45C orphan drug credit allowed, if applicable (yyyy)	**(e)** Name of section 45C orphan drug, if applicable	**(f)** Date of FDA approval for non-orphan drug marketing, if applicable (mmddyyyy)
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Schedule B Branded Prescription Drug Information NDC Additions and Deletions (see instructions)

Caution: Use Schedule B only for additions and deletions of National Drug Codes (NDCs) at the covered entity level. Do not report the movement of NDCs between members of the controlled group.

Entity name

Employer identification number (EIN).

If you have more NDC additions and deletions to report than can be shown on this page, complete and attach as many Schedules B as you need to list them all, numbering each page (for example, Page B1 of B5). Page ___ of ___

Section I Additions

(a) Controlled group member EIN	(b) NDC additions	(c) Medicaid state supplemental rebate amount, if applicable (if none, enter -0-)	(d) Latest tax year section 45C orphan drug credit allowed, if applicable (yyyy)	(e) Name of section 45C orphan drug, if applicable	(f) Date of FDA approval for non-orphan drug marketing, if applicable (mmddyyyy)
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Section II Deletions

Enter the NDC of any branded prescription drug you listed on your report for sales year 2009 but is no longer applicable (see instructions).	NDC	NDC	NDC	NDC	NDC
	NDC	NDC	NDC	NDC	NDC

Schedule C **Branded Prescription Drug Information Orphan Drug Changes—Previously Reported NDCs** (do not include National Drug Codes (NDCs) or orphan drug information reported on Schedule B - see instructions)

Entity name

Employer identification number (EIN).

If you have more orphan drug changes to report than can be shown on this page, complete and attach as many Schedules C as you need to list them all, numbering each page (for example, Page C1 of C5). Page___ of ___

(a) Controlled group member EIN	(b) NDC	(c) Latest tax year section 45C orphan drug credit allowed, if applicable (yyyy)	(d) Name of section 45C orphan drug, if applicable	(e) Date of FDA approval for non-orphan drug marketing, if applicable (mmddyyyy)

Schedule D **Branded Prescription Drug Medicaid State Supplemental Rebates—Previously Reported NDCs (**do not include National Drug Codes (NDCs) or rebate information reported on Schedule B**)**

Entity name

Employer identification number (EIN).

If you have more rebate information to report than can be shown on this page, complete and attach as many Schedules D as you need to list them all, numbering each page (for example, Page D1 of D5). Page ___ of ___

(a) NDC	(b) Medicaid state supplemental rebate amount, if applicable (if none, enter -0-)	(a) NDC	(b) Medicaid state supplemental rebate amount, if applicable (if none, enter -0-)	(a) NDC	(b) Medicaid state supplemental rebate amount, if applicable (if none, enter -0-)
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Schedule E Summary of Form 8947

Entity name

Employer identification number (EIN).

1	Total number of controlled group members, including the designated entity, from page 1, Part I	
2	Total National Drug Codes (NDCs) from Schedule(s) A, column (b)	
3	Total Medicaid state supplemental rebate amounts from Schedule(s) A, column (c)	
4	Total NDC additions from Schedule(s) B, Section I, column (b)	
5	Total Medicaid state supplemental rebate amounts from Schedule(s) B, Section I, column (c)	
6	Total NDC deletions from Schedule(s) B, Section II	
7	Total NDCs from Schedule(s) C, column (b)	
8	Total NDCs from Schedule(s) D, column (a)	
9	Total Medicaid State supplemental rebate amounts from Schedule(s) D, column (b)	

Part II Signature of Official Signing On Behalf of the Covered Entity (Single-Member, Common Parent of an Affiliated Group, or Other Designated Entity) and Consent by the Common Parent or Designated Entity (if applicable)

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.

[If you checked Item B, box 2a or 2b, on page 1] I also declare that I identified myself as the common parent of an affiliated group or other designated entity (as per the instructions). I understand that the designated entity will receive IRS communications relating to the fee imposed by section 9008 of the Act and is to pay 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. I further declare that each entity in the controlled group identified on this report consents to the choice of the designated entity indicated on this report.

Sign Here

Signature of official | Date | Title

Print name of signing official | Daytime telephone number

Email address

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 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).

General Instructions

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

What's New

If you are filing this report for the second year (a subsequent year filer), you are not required to resubmit all of the branded prescription drug information submitted on your report filed for sales year 2009. For reporting sales year 2010 information, Form 8947 is expanded with new Schedules A, B, C, D, and E, allowing subsequent year filers to report entity information and branded prescription drug information changes only. See *Schedules A, B, C, D, and E* under *Who Files* below.

Medicare Part D rebate information is now directly reported to the IRS by the Centers for Medicare and Medicaid Services and is no longer reported on this form. However, it is still necessary for covered entities to report Medicaid state supplemental rebate information on Schedules A, B, D, and E, as applicable.

Purpose of Form

Use Form 8947 to report the following information for branded prescription drugs sold by covered entities to specified government programs (or sales due to coverage under the programs) during sales year 2010.

- National Drug Codes (NDCs).
- Medicaid state supplemental 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").

For more information, see *Definitions* and *Item B. Covered Entity Information* below. Also, see Temporary Regulations sections 51.1T through 51.12T, and section 51.6302-1T.

Who Files

Generally, each manufacturer or importer of branded prescription drugs with sales to specified government programs (or sales due to coverage under the programs) may submit Form 8947. Each entity that is treated as a single covered entity is requested to file one Form 8947, providing all requested information for each such manufacturing and reporting entity, as described in these instructions.

Schedules A, B, C, D, and E. All filers must complete page 1 and page 6, which includes Schedule E, Summary of Form 8947, and Part II, Signature of Official Signing On Behalf of the Covered Entity (Single-Member, Common Parent of an Affiliated Group, or Other Designated Entity) and Consent by the Common Parent or Designated Entity (if applicable).

First time filers must also attach Schedule A, Branded Prescription Drug Information—First Time Filers Only.

Subsequent year filers with changes to report must attach Schedule B, Branded Prescription Drug Information NDC Additions and Deletions, or Schedule C, Branded Prescription Drug Information Orphan Drug Changes—Previously Reported NDCs, or both.

Subsequent year filers reporting Medicaid state supplemental rebates for sales year 2010 drug sales must attach Schedule D, Branded Prescription Drug Medicaid State Supplemental Rebates—Previously Reported NDCs, to report NDCs and their Medicaid state supplemental rebates. See *Completing Pages 1 and 6, and the Correct Schedule(s)* below.

When To File

File Form 8947 by December 15, 2011, to report sales year 2010 information.

Definitions

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

Completing Pages 1 and 6, and the Correct Schedule(s)

	First time filer (check Item A, box 1)	Subsequent year filer with changes (check Item A, box 2)	Subsequent year filer with no changes, reporting rebates (check Item A, box 3)	Subsequent year filer with no changes, not reporting rebates (check Item A, box 4)
Page 1	Yes	Yes	Yes	Yes
Schedule A	Yes	No	No	No
Schedule B	No	Yes, if NDC additions or deletions (1), (2), (3)	No	No
Schedule C	No	Yes, if orphan drug changes (1), (3)	No	No
Schedule D	No	Yes, if reporting rebates (1), (3)	Yes	No
Schedule E Schedule E, Line 1	Yes, if Item B, box 2a or 2b, checked	Yes, if Item B, box 2a or 2b, checked	Yes, if Item B, box 2a or 2b, checked	Yes, if Item B, box 2a or 2b, checked
Schedule E, Line 2	Yes	No	No	No
Schedule E, Line 3	Yes	No	No	No
Schedule E, Line 4	No	Yes, if Schedule B attached	No	No
Schedule E, Line 5	No	Yes, if Schedule B attached	No	No
Schedule E, Line 6	No	Yes, if Schedule B attached	No	No
Schedule E, Line 7	No	Yes, if Schedule C attached	No	No
Schedule E, Line 8	No	Yes, if Schedule D attached	Yes	No
Schedule E, Line 9	No	Yes, if Schedule D attached	Yes	No
Part II	Yes	Yes	Yes	Yes

(1) NDCs reported on Schedule B cannot be shown on Schedules C or D.

(2) In Section I, report as additions only NDCs that were not associated with the covered entity for the previous sales year.

(3) On Schedule B, (Section II), Schedule C, or Schedule D, report only NDCs that were associated with the covered entity for the previous sales year.

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)). A prescription drug is any drug that is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

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. Generally, branded prescription drug sales do not include sales of an orphan drug if any person claimed (and was allowed) a section 45C tax credit for the orphan drug on a return or claim for refund for any taxable year, 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. However, a branded prescription drug is not treated as an orphan drug after December 31 of the year in which the drug or biological product was approved by the Food and Drug Administration (FDA) for non-orphan drug marketing, regardless of whether a section 45C credit was allowed for an orphan drug either before or after the non-orphan drug designation. 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 B. 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 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.

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). A covered entity is either a single-person covered entity or a member of a 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). A covered entity is treated as being a member of a controlled group if it is a member of the group at the end of the day on December 31, 2010. Also, a controlled group that is an affiliated group that filed a consolidated federal tax return for tax year 2010 ("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 Part II on page 6.

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. If a controlled group does not select a designated entity, the IRS will select a member of the controlled group as the designated entity for the controlled group.

The designated entity is responsible for the following for the group.

- Filing Form 8947,
- Receiving IRS communications about the fee,
- Filing any necessary error report (as described in Temporary Regulations section 51.7T), and
- Paying 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 only those members of the controlled group who, as of the end of the day on December 31, 2010, are manufacturers or importers with gross receipts from the sale of branded prescription drugs to specified government programs (or sales due to coverage under the program), listing the designated entity's name first. You must also sign Part II on page 6.

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 only those members of the controlled group who, as of the end of the day on December 31, 2010, are manufacturers or importers with gross receipts from the sale of branded prescription drugs to specified government programs (or sales due to coverage under the program), listing the designated entity's name first. You must also sign Part II on page 6.

Name and Address

Entity name

If you checked box 1, 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.

Schedule A. Branded Prescription Drug Information – First Time Filers Only

If you filed Form 8947 for sales year 2009, do not use Schedule A for the 2010 sales year. If you checked Item A, box 1, use Schedule A to report the following.

Controlled group member EIN

Enter the same EIN for each member that was shown in Part I, column (c).

NDC

Enter the 11-digit NDC (omitting hyphens) for any branded prescription drug sold to any specified government program (or sold due to coverage under the programs) during 2010.

Medicaid state supplemental rebate amount

Enter the Medicaid state supplemental rebates for each NDC paid by the covered entity for sales under Medicaid in sales year 2010. For this purpose, enter Medicaid state supplemental rebates invoiced by states and paid by the covered entity for drugs in sales year 2010 and paid before you file Form 8947.

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. The section 45C credit is considered to be allowed if any entity claimed the credit even if that entity was not part of the covered entity at the time the credit was claimed. 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 mmddyyyy.

Schedule B. Branded Prescription Drug Information NDC Additions and Deletions

If you filed Form 8947 for sales year 2009, use Schedule B (check Item A, box 2) to report the following for sales year 2010.

- NDCs that you **did not** report on your Form 8947 for sales year 2009 (additions), and
- NDCs that are no longer in the covered entity (deletions). An NDC is no longer in the covered entity if you reported it on your Form 8947 for sales year 2009 and it ceases to be described in the definition of branded prescription drugs for the covered entity's 2010 sales year (see *Branded Prescription Drugs* under *Definitions* above).

Do not report the movement of NDCs between members of the controlled group.

Schedule C. Branded Prescription Drug Information Orphan Drug Changes—Previously Reported NDCs

If you filed Form 8947 for sales year 2009, use Schedule C (check Item A, box 2) to report changes in orphan drug information for previously reported NDCs. Do not include NDCs or orphan drug information reported on the Schedule B attached to this report.

Schedule D. Branded Prescription Drug Medicaid State Supplemental Rebates— Previously Reported NDCs

If you filed Form 8947 for sales year 2009, use Schedule D (check Item A, box 2 or box 3, as applicable) to report Medicaid state supplemental rebates paid by the covered entity for sales under Medicaid occurring in sales year 2010. Enter rebates only for NDCs which you reported when you filed Form 8947 for sales year 2009. For this purpose, enter Medicaid state supplemental rebates invoiced by states and paid by the covered entity for drugs in sales year 2010 and paid before you file Form 8947. Do not include NDCs or rebate information reported on the Schedule B attached to this report.

Schedule E. Summary of Form 8947

Use Schedule E to report the total number of controlled group members, including the designated entity, shown on page 1, Part I, and the totals from each of the other schedules attached to this report.

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 file Form 8947. If you do not file Form 8947, we will calculate your branded prescription drug fee based on information reported on previously filed Forms 8947 (if any), NDC information maintained by the FDA, sales and rebate information reported by the Agencies, and orphan drug information maintained by the IRS.

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 . . . . . 7 hrs., 24 min.

Preparing, copying, assembling, and sending the form . . . . . 51 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 email us at *taxforms@irs.gov* or write to us at: Internal Revenue Service, Tax Products Coordinating Committee, SE:W:CAR:MP:T:M:S, 1111 Constitution Ave. NW, IR-6526, Washington, DC 20224. Do not send Form 8947 to this address. Instead, see *Where To File* earlier.