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Form **8947**

(Rev. August 2016)

Department of the Treasury
Internal Revenue Service

Report of Branded Prescription Drug Information

▶ **Information about Form 8947 and its instructions is at *www.irs.gov/form8947*.**

Read the instructions before you complete Form 8947.

OMB Number
1545-0123

Item A: Check only one box below (see instructions)

- ☐ **1** First-Time Filer (Complete this page and page 7; attach Schedule A)
- ☐ **2** Subsequent Year Filer with Changes (Complete this page and page 7; attach Schedules B, C, and D as needed)
- ☐ **3** Subsequent Year Filer with No Changes and Reporting Rebates (Complete this page and page 7; attach Schedule D)
- ☐ **4** Subsequent Year Filer with No Changes and Not Reporting Rebates (Complete this page and page 7)

Item B: Check only one box below (see instructions)

Single-person ☐ 1 Single-person covered entity

Designated entities ☐ 2a Agent of an affiliated group ☐ 2b Other designated entity

Information report for sales year

2015

Entity name

Employer Identification Number (EIN)

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

City, town, or post office (Foreign addresses should also complete fields below — see instructions)

State

ZIP code

Foreign country name

Foreign province/state/county

Foreign postal code

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, 2015, 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 2014	(a) EIN	(b) Entity Name	(c) Address of entity	
1					
	☐				X
	☐				X

Add new member — Click on the button to add a new member of the controlled group

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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).

	(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 nonorphan drug marketing, if applicable (mmddyyyy)	
			$				X
			$				X

Add a new row to Schedule A — Click on this button to add a new row to Schedule A.

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Schedule B Branded Prescription Drug Information NDC Additions and Deletions (see instructions)

Schedule B, Section I - Page of

Caution: Use Schedule B only for additions and deletions of National Drug Codes (NDCs) at the covered entity level. NDCs reported here cannot be shown on Schedule C or Schedule D. 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 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 BA1 of BA5).

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 nonorphan drug marketing, if applicable (mmddyyyy)	
			$				X
			$				X

Add a new row to Schedule B, Section I — Click on this button to add a new row to Schedule B, Section I, Additions

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Schedule B Branded Prescription Drug Information NDC Additions and Deletions (see instructions)

Schedule B, Section II - Page of

Caution: Use Schedule B only for additions and deletions of National Drug Codes (NDCs) at the covered entity level. NDCs reported here cannot be shown on Schedule C or Schedule D. Do not report the movement of NDCs between members of the controlled group.

Entity name	Employer Identification Number (EIN)

If you have more NDC 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 BD1 of BD5).

Section II Deletions

Enter the NDC of any branded prescription drug you listed on your report for sales year 2014 but is no longer applicable (see instructions).

NDC	NDC	NDC	NDC	NDC	NDC	NDC	NDC	NDC	NDC
NDC	NDC	NDC	NDC	NDC	NDC	NDC	NDC	NDC	NDC

Add a new row to Schedule B, Section II — Click on this button to add a new row to Schedule B, Section II, Deletions.

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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 or Schedule D) (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).

	(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 nonorphan drug marketing, if applicable (mmddyyyy)	
			$				X
			$				X

Add a new row to Schedule C — Click on this button to add a new row to Schedule C.

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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 or Schedule C) (see instructions)

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).

(a) NDC	(b) Medicaid state supplemental rebate amount, if applicable	(a) NDC	(b) Medicaid state supplemental rebate amount, if applicable	(a) NDC	(b) Medicaid state supplemental rebate amount, if applicable	
	$		$		$	X
	$		$		$	X

Add a new row to Schedule D — Click on this button to add a new row of NDCs to Schedule D.

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, Agent of an Affiliated Group, or Other Designated Entity) and Consent by the Agent 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 agent 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 person that is a controlled group member at the end of the day on December 31, 2015, is jointly and severally liable for this fee. I further declare that each controlled group member identified on this report consents to the choice of the designated entity indicated on this report.

Sign Here ▶

Signature of official	Date signed	Phone number	FAX number
Printed name of signing official		Title of signing official	

PART III Alternate Contact Person Designee (see instructions)

Do you want to designate an employee to discuss this report with the IRS? ☐ Yes ☐ No

Name of designee	Designee phone number
Title of designee	Designee fax number

Where To File

If you are not filing electronically, send your paper Form 8947 to:

Internal Revenue Service
1973 Rulon White Boulevard
Mail Stop 4916 BPDF
Ogden, UT 84201-0051

Send the forms in a flat mailing envelope (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, FedEx, and UPS.

Instructions

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

Future Developments

For the latest information about developments related to Form 8947 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/form8947*.

How To File

You can file Form 8947 electronically (with Form 8453-R, Declaration and Signature for Electronic Filing of Forms 8947 and 8963) by accessing IRS *e-file* using your own computer, or you can file a paper Form 8947.

If you file Form 8947 electronically, do not sign it. Instead, complete Form 8947 online. Before uploading it, separately print and sign Form 8453-R, scan it, and include it in your upload. Scan Form 8453-R only. Do not scan Form 8947.

If you file a paper Form 8947, you must sign it, and you do not need to file Form 8453-R. You can file Form 8947 as an enhanced fillable PDF document.

If you would like to request an acknowledgment that we received your Form 8947, please email *it.bpd.fee@irs.gov* with the company information and/or certified tracking number and we will reply when we receive the form. If you use an overnight service, add the email address *it.bpd.fee@irs.gov* in the recipient email and we will reply when we receive the form.

IRS *e-file*: It's Convenient, Safe, and Secure. IRS *e-file* is the IRS's electronic filing program. For more information about IRS *e-file*, visit IRS.gov. By filing electronically, you will receive an electronic acknowledgment once you complete the transaction. Keep it with your records.

General Instructions

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 2015.

- 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").

Alternate Contact Person Designee. If you want to designate your employee to discuss your report with the IRS, check the "Yes" box on page 7, under *Alternate Contact Person Designee*. Also, enter the designee's name, title, and phone number.

If you check the "Yes" box, you are authorizing the IRS to call the designee to answer any questions that may arise and the designee to call the IRS with any questions related to the administration of the 2017 branded prescription drug fee year. You are also authorizing the designee to:

- Receive copies of IRS letters upon request,
- Respond to IRS letters, and
- Receive and provide information regarding the status of a payment or an amount due back to you.

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

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 controlled group that is treated as a single covered entity is requested to file one Form 8947, providing all requested information for each manufacturing and reporting entity within the group, as described in these instructions.

Schedules A, B, C, D, and E. All filers must complete page 1 and page 7, which includes Schedule E, Summary of Form 8947, and Part II, Signature of Official Signing On Behalf of the Covered Entity (Single-Member, Agent of an Affiliated Group, or Other Designated Entity) and Consent by the Agent or Designated Entity (if applicable).

Completing Pages 1 and 7, 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				
Schedule A				
Schedule B				
Schedule C				
Schedule D				
Schedule E Schedule E, Line 1				
Schedule E, Line 2				
Schedule E, Line 3				
Schedule E, Line 4				
Schedule E, Line 5				
Schedule E, Line 6				
Schedule E, Line 7				
Schedule E, Line 8				
Schedule E, Line 9				
Part II				

(1) NDCs reported on Schedule B cannot be shown on Schedules C or D.
(2) On Schedule B, 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.
(4) NDCs reported on Schedule C cannot be shown on Schedules B or D.
(5) NDCs reported on Schedule D cannot be shown on Schedules B or C.

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 2015 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 7, and the Correct Schedule(s),* earlier.

When To File

File Form 8947 by November 1, 2016, to report sales year 2015 information.

Definitions

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

Branded prescription drug. 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. Branded prescription drug sales are sales of branded prescription drugs made to specified government programs (or sales due to coverage under the programs).

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 tax year, and there has not been a final assessment or a court disallowance of the full section 45C credit taken for the drug.

Nonorphan 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 nonorphan drug marketing, regardless of whether a section 45C credit was allowed for an orphan drug either before or after the nonorphan drug designation. Nonorphan 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.

If a covered entity transfers ownership rights to manufacture or import a branded prescription drug to a new entity but does not change the Labeler Code of the NDC for that drug, all post-transfer sales of that drug will continue to be treated as sales by the transferring entity until the Labeler Code reflects the new owner. The entities must change the Labeler Code before the change of ownership is recognized.

A covered entity is either a single-person covered entity or a controlled group. A single-person covered entity is a covered entity that is not affiliated with a controlled group. A controlled group is a group of at least two covered entities that are treated as a single employer under section 52(a), 52(b), 414(m), or 414(o). 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 person is treated as being a controlled group member if it is a member of the group at the end of the day on December 31, 2015.

Box 1. Check box 1 if you are a single-person covered entity. You must sign Part II on page 7.

Designated entity. Generally, the designated entity is one of the following.

- The agent of the affiliated group (when the controlled group, without regard to foreign corporations, is also an affiliated group whose common parent files a consolidated return for federal income tax purposes).
- 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 **all** of the following for the group.

- Filing Form 8947.
- Receiving IRS communications about the fee.
- Filing any necessary error report (as described in Regulations section 51.7).
- Paying the fee to the IRS.
- If the designated entity is chosen by the members of a controlled group that is not an affiliated group: (1) obtaining consents from all controlled members that are required to be listed in Part I of this form; and (2) providing (to the IRS upon request) the consents obtained from controlled group members that are required to be listed in Part I of this form.

Box 2a. Check box 2a if you are an agent 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, 2015, 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), listing the designated entity's name first. You must also sign Part II on page 7.

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, 2015, 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), listing the designated entity's name first. You must also sign Part II on page 7.

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.

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

Foreign Address. Enter the full name of the country using uppercase letters in English. Follow the country's practice for entering the postal code. In some countries the postal code may come before the city or town name.

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 2014, do not use Schedule A for sales year 2015. 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 2015.

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 2015. For this purpose, enter Medicaid state supplemental rebates invoiced by states and paid by the covered entity for drugs in sales year 2015 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 nonorphan drug marketing. Enter the date of FDA approval for nonorphan 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 2014, use Schedule B (check Item A, box 2) to report the following for sales year 2015.

- Additions include the following.
  - (a) NDCs that you **did not** report on your Form 8947 for sales year 2014.
  - (b) NDCs of a newly acquired controlled group member (even if a prior filer) as of the end of the day on December 31st of sales year 2015.
  - (c) New NDCs even if there is no associated reporting for Medicaid State Supplemental Rebates.
- Deletions include NDCs that are no longer in the covered entity. An NDC is no longer in the covered entity if you reported it on your Form 8947 for sales year 2014 and it ceases to be described in the definition of branded prescription drugs for the covered entity's 2015 sales year (see *Branded prescription drug* under *Definitions,* earlier).

Deletions **do not** include the following.

(a) Expired drugs: There is no exclusion for sales of branded prescription drugs that have expired because these drugs continue to meet the definition of a branded prescription drug in Regulations section 51.2(c) (see *Branded prescription drug* under *Definitions*, earlier).

(b) Divested NDCs: A covered entity may not exclude a divested NDC if the covered entity is still the person identified in the Labeler Code of the NDC (see *Covered Entity* under *Item B. Covered Entity Information,* earlier).

Do not report the movement of NDCs between members of the controlled group. Do not include NDCs or orphan drug information on your Schedule B if it is reported on your Schedule C or Schedule D attached to this report.

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

If you filed Form 8947 for sales year 2014, 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 on your Schedule C if it is reported on your Schedule B or Schedule D attached to this report.

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

If you filed Form 8947 for sales year 2014, 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 2015. Enter rebates only for NDCs which you reported when you filed Form 8947 for sales year 2014. For this purpose, enter Medicaid state supplemental rebates invoiced by states and paid by the covered entity for drugs in sales year 2015 and paid before you file Form 8947. Do not include NDCs or rebate information reported on the Schedule B attached to this report.

Do not include NDCs or orphan drug information on your Schedule D if it is reported on your Schedule B or Schedule C attached to this report. Changes in orphan drug information for previously reported NDCs should be reported on Schedule C. Unless the status of the orphan drug is being changed so that the drug is no longer eligible to be excluded as an orphan drug, it should not be listed on Schedule D.

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 hr., 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 send us comments from *www.irs.gov/formspubs*. Click on "More Information" and then on "Give us feedback." You can also send your comments to:

Internal Revenue Service
Tax Forms and Publications
1111 Constitution Ave. NW, IR-6526
Washington, DC 20224

Do not send Form 8947 to this address. Instead, see *Where To File,* earlier.