



OPA DATABASE GUIDE

FOR

PUBLIC USERS - MANUFACTURERS

MARCH 2013
VERSION 5.0

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MANUFACTURERS

Objectives:

- Registering a Manufacturer
- Searching for a Manufacturer
- Viewing Manufacturer Details

DETAILS	EXAMPLE
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Manufacturers

- Manufacturers menu provides two links:
 - Search Manufacturers
 - Register a Manufacturer
- Links are located on toolbar or from Manufacturers menu.



The screenshot shows the HRSA Office of Pharmacy Affairs website. At the top right, there is a 'Log In | Help' link. Below the header, there is a navigation menu with 'Home', 'Covered Entities', 'Contract Pharmacies', 'Manufacturers', and 'Reports'. The 'Manufacturers' menu is highlighted with a red box, and it contains two sub-links: 'Search Manufacturers' and 'Register a Manufacturer', also highlighted with a red box. Below the navigation menu, there are several sections: 'Covered Entities', 'Contract Pharmacies', 'Manufacturers', 'What's New', and 'Important Notifications'. The 'Manufacturers' section is highlighted with a red box. The 'What's New' section contains a 'HEALTH CENTER RECERTIFICATION UPDATE (09/2013)' and a 'DATABASE ENHANCEMENTS (10/4/2012)'. The 'Important Notifications' section contains an 'UPDATE FOR COVERED ENTITY/CONTRACT PHARMACY REGISTRATIONS (12/20/2013)'. At the bottom of the page, there is a 'HSR Privacy Policy Notice' and a 'U.S. Department of Health and Human Services (HHS)' logo.

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Registering a Manufacturer

- Registering Manufacturer form is in .pdf format and requires Adobe reader.
 - Registering a Manufacturer requires the Manufacturer must be in compliance and agreement with the *Pharmaceutical Pricing Agreement (PPA)*.
 - Email notifications are generated to the contacts, once OPA has reviewed and approved.
1. Click on Register a Manufacturer link.
 2. Print the document and carefully review the instructions and detailed agreement.
 3. Using a computer, enter all applicable information on the last page of the Pharmaceutical Pricing Agreement, which includes contact information and signatures.



The document cannot be completed, saved, and submitted for future use.

Complete the document and print out.

4. Submit the original printed form to the Office of Pharmacy Affairs Branch (OPA).



If you want a signed original for your records, submit two signed copies to OPA.

General Instructions for Completing the Pharmaceutical Pricing Agreement (PPA)

In accordance with the guidance found in the May 7, 1993, *Federal Register*, [\(link here\)](#) Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement (the "Agreement") with the Secretary of Health and Human Services (the "Secretary") in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price ("AMP") decreased by a rebate percentage.

Manufacturer is defined in the guidance listed above, as follows:

The term "Manufacturer" has the meaning as set forth in section 1927(k)(5) of the Social Security Act and includes all entities engaged in –

- (1) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or
- (2) the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. A manufacturer must hold legal title to or possession of the NDC number for the covered outpatient drug. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"Manufacturer" also includes an entity, described in (1) or (2) above, that sells outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program. Furthermore, the Pharmaceutical Pricing Agreement provides that the term also includes any contractor who fulfills the responsibilities pursuant to the PHS drug pricing agreement.

Please print the attached Pharmaceutical Pricing Agreement (PPA) in its entirety and have it signed by a corporate officer, such as the Chief Executive Officer. The form utilizes Adobe Acrobat Reader in an interactive format allowing you to input all applicable information on the computer. However, the form cannot be saved with your information for future use. You must print the form to submit it to the Office of Pharmacy Affairs Branch (OPA).

If your organization would like to receive a signed original, please ensure that you submit TWO signed originals to the OPA. Otherwise, the OPA will send you a copy of the document once it is counter-signed by the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration.

If you have any questions, please contact the Pharmacy Services Support Center at 1-800-628-6297 or via e-mail at pssc@aphanel.org.

Section 340B of the Public Health Service Act
Pharmaceutical Pricing Agreement
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IX. SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____
 Title: Associate Administrator
 Healthcare Systems Bureau
 Health Resources and Services Administration

Date: _____

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments, or other changes to this pricing agreement.

By: _____ Printed Name: _____
 (Signature)

Title: _____

Phone Number: _____ Ext. _____ FAX Number: _____

e-Mail Address: _____

Date: _____

Manufacturer Labeler Code(s): _____

Name of Manufacturer: _____

Manufacturer Address: _____

Contact Person: _____

Title: _____

Phone Number: _____ Ext. _____ FAX Number: _____

e-Mail Address: _____

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Search Manufacturers

- Search Manufacturers screen provides navigation to select and view Manufacturer records, export data for reports, and create data export spreadsheets.
- The more criteria entered, the more filtered the Results.
- Each Label Code links to a Manufacturer Detail record.

- A message displays if no results are returned based on the search criteria entered.

Advanced Search Options

- Advanced Search Option provides advanced query options for specific criteria, which is an option.
- **Show Advanced Options** provides date range searches for:
 - Signed Date
 - Edit Date
 - OPA Termination Date
 - CMS Termination Date
- **Hide Advanced Options** button removes the Advanced Options from view.
- **Clear** button clears information entered.

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Searching for Manufacturers

1. Click the **Show Advanced Options** button to expand search.
2. Enter applicable search criteria.
3. Click the **Search Manufacturers** button and the Manufacturers Results table displays.

The screenshot shows the HRSA 340B search interface. At the top, there are navigation tabs: Home, Covered Entities, Contract Pharmacies, Manufacturers, and Reports. Below this is a 'Search Manufacturers' section with 'Filter Criteria' including fields for Label Code, City, State (dropdown menu), Zip Code, Signed Date, Edit Date, Manufacturer Name, Contact Name, Status (dropdown menu), OPA Term Date, and CMS Term Date. There are 'Search Manufacturers', 'Hide Advanced Options', and 'Clear' buttons. At the bottom, there is a 'Rows/Page' dropdown set to 10 and a 'Set' button. A footer contains the HHS Privacy Policy Notice, contact information for the U.S. Department of Health and Human Services (HHS) Office of Pharmacy Affairs (OPA) - 340B Program, and a date of May 23, 2011.

Search Results

- Search Results displays in uniform table format.
 - Number of rows display default is 10, can be set be to 10 to 200 rows.

The screenshot shows a 'Rows/Page' dropdown menu with options: 10, 25, 50, 100, 200. A 'Set' button is next to it.

- Columns are sortable. Click on column heading to change sort order to descending. The default is by ascending order.

The screenshot shows a 'Select All' checkbox with a checkmark.

- checkbox selects all records in the Search Results table.
- Click a Label Code (i.e., **49908**) which links to the Manufacturer Detail record.
- Lists number of pages at the bottom, which changes if the number of rows is changed. Click on the next number to move to view the next group of records.

The screenshot shows the search results table with 4 records. The table has columns: Label Code, Manufacturer Name, Contact Name, City, State, Zip, OPA Term, CMS Term, Signed Date, Status, and Edit Date. A 'Select All' checkbox is on the left. Below the table, it says 'Page 1 of 1'. A footer contains the HHS Privacy Policy Notice, contact information for the U.S. Department of Health and Human Services (HHS) Office of Pharmacy Affairs (OPA) - 340B Program, and a date of May 23, 2011.

Select	Label Code	Manufacturer Name	Contact Name	City	State	Zip	OPA Term	CMS Term	Signed Date	Status	Edit Date
<input type="checkbox"/>	27808	Tris Pharma, Inc.	Dalia Moufameg-Petosa	Monmouth Junction	NJ	08852			01/14/2011	Active	03/17/2011
<input type="checkbox"/>	49908	Rochester Pharmaceuticals	John Aubeuf	Rochester	NY	14624			03/11/2011	Active	04/12/2011
<input type="checkbox"/>	52536	Wilshire Pharmaceuticals	Randall Perry	Raleigh	NC	27608			03/14/2011	Active	
<input type="checkbox"/>	64597	Avenir Pharmaceuticals, Inc	Christine Thibault	Aliso Viejo	CA	92656			02/08/2011	Active	

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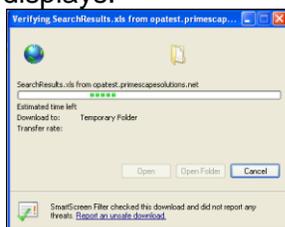
EXAMPLE

Export Results

- To export data for specific Manufacturer records initiates from a Manufacturer Search.

- Enter search criteria and Search Results table displays.
- Click on checkbox(es) for applicable Manufacturer record(s).
- Click the **Export Results** button and the File Download screen displays.

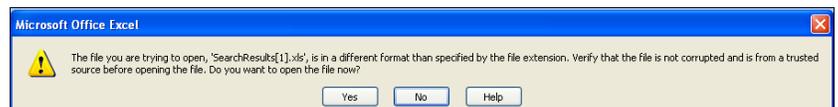
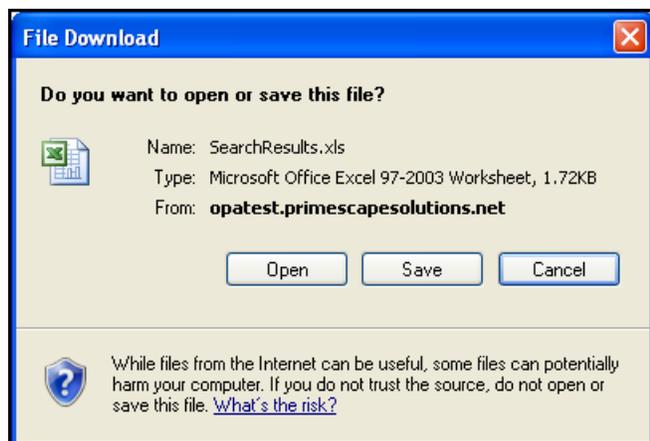
- Select **Open** button to open file, or **Save** button to save file.
- Verify Search Results window displays.



- Click the **Yes** button to and the Excel spreadsheet displays. Or, Click the **No** button to cancel.

- Excel spreadsheet displays. This is a partial view.

Select	Label Code	Manufacturer Name	Contact Name	City	State	Zip	OPA Term	CMS Term	Signed Date	Status	Edit Date
<input checked="" type="checkbox"/>	27808	Tris Pharma, Inc.	Dalia Moufameg-Petosa	Monmouth Junction	NJ	08852			01/14/2011	Active	03/17/2011
<input checked="" type="checkbox"/>	49908	Rochester Pharmaceuticals	John Aubeuf	Rochester	NY	14624			03/11/2011	Active	04/12/2011
<input type="checkbox"/>	52536	Wilshire Pharmaceuticals	Randall Perry	Raleigh	NC	27606			03/14/2011	Active	
<input type="checkbox"/>	64597	Avanir Pharmaceuticals, Inc	Christine Thibault	Aliso Viejo	CA	92656			02/09/2011	Active	



1	Label Code	Manufacturer Name	Sub-Division Name	Address 1	Address 2	City	State	Zip	Second Zip	OPA Term	CMS Term
2	27808	Tris Pharma, Inc.		Brunswick Business Park	2033 Route 130, Suite D	Monmouth Junction	NJ	8852			
3	49908	Rochester Pharmaceuticals		3173 Chili Avenue		Rochester	NY	14624			

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Viewing Manufacturer Details

- Manufacturer records are available for viewing using the Search screen.
- Manufacturer Detail records available for view:
 - Approved and approved with a future start date
 - Terminated and terminated with a future start date
 - Manufacturers that have not been approved, cannot be viewed.
- Covered Entity Detail screen displays as view only; edits cannot be made.

1. Conduct search.
2. Click the **Search Manufacturers** button and Search Results displays.
3. Select applicable Label Code and Manufacturer Detail record displays.
4. Click the **Back** button and the Search Manufacturers screen displays.

Select	Label Code	Manufacturer Name	Contact Name	City	State	Zip	OPA Term	CMS Term	Signed Date	Status	Edit Date
<input type="checkbox"/>	27808	Tris Pharma, Inc.	Dalia Moutafeg-Petosa	Monmouth Junction	NJ	08852			01/14/2011	Active	03/17/2011
<input type="checkbox"/>	49908	Rochester Pharmaceuticals	John Aubeuf	Rochester	NY	14624			03/11/2011	Active	04/12/2011
<input type="checkbox"/>	52536	Wilshire Pharmaceuticals	Randall Perry	Raleigh	NC	27600			03/14/2011	Active	
<input type="checkbox"/>	64597	Avanti Pharmaceuticals, Inc.	Christine Thibault	Aliso Viejo	CA	92656			02/09/2011	Active	

Manufacturer Detail

Details

* Label Code: 49908
 * Name: Rochester Pharmaceuticals
 Subdivision Name:
 OPA Termination Dates:
 CMS Termination Dates:
 Status: Active
 Comments: 4/12/11 updated name and addr (was G4W Labs, 111 Coolidge St., South Plainfield, NJ, 07080);

Address

* Address Line 1: 3173 Chili Avenue
 Address Line 2:
 * City: Rochester
 * State: New York
 * Zip: 14624

Authorizing Official Information

* Signed by: John Aubeuf
 * Title: VP
 * Signed Date: 3/11/2011
 * Phone: 585-739-0626 Ext:

Contact Information

Contact same as Authorizing Official
 * Contact Name: John Aubeuf
 Title: National Account Manager
 * Phone: 585-739-0626 Ext:

[Back](#)