ORA Partners Portal (ORAPP) Firm Inventory Reconciliation Overview Knowledge Article (KA)

Audience

This article is intended for regulatory partners with access to the Office of Regulatory Affairs (ORA) Partners Portal (ORAPP) who manage firm inventory data for firms within their state.

Summary

The ORAPP Firm Inventory Reconciliation (IR) capability allows regulatory partners to perform firm inventory data submissions, to verify the firm inventory data for their state in FDA's database. Regulatory partners can use the **Firm Inventory Reconciliation Template** to submit firm inventory data for up to **5,000 firms per submission** to determine if the firm inventory data in FDA's database matches the state's records or requires reconciliation.

Firm Inventory Reconciliation (IR) Overview

During a Firm IR submission, ORAPP will attempt to match firm inventory data on the Firm Inventory Reconciliation Template with the data in FDA's database. Matching will be attempted using the following criteria or criteria combinations:

- FDA Establishment Identifier (FEI) (if provided)
- Firm Legal Name and physical address
- Doing Business As (DBA) (if provided) and physical address
- DUNS Number (if provided) and physical address

After the submission is processed, the Firm Inventory Reconciliation Template will display a **Match Status** and **FDA Firm Data Results / Error Explanation** for each record. This should be used to determine if reconciliation is needed. The following table displays the match statuses that can be returned for a firm inventory reconciliation submission.

Firm Inventory Reconciliation Match Statuses							
Match Status	Description	Follow-up Action					
Match	A single firm matched the firm inventory record	None Required					
Match on	The DBA name matched FDA's firm inventory	Submit the correct Firm Legal					
DBA	record	Name to state liaison if needed					
No Match	No firms in the FDA database matched the	Submit missing firm inventory					
	submitted data	data to state liaison					
Multiple	There are multiple matches in the FDA	Review the FDA Firm Data					
Matches	database	Results/Error Explanation and					
		submit correct firm inventory data					
		to state liaison to have the					
		multiple firm inventory records					
		merged					
Review	The firm inventory record data needs to be	Review the FDA Firm Data					
	reviewed for errors	Results/Error Explanation and					
		address the error explanation					
		listed for that firm inventory					
		record					
		For example, if the error					
		explanation states, "Returned					



		address is out of state", confirm
		that the address entered in the
		submission file is correct and
		within your assigned state before
		performing a resubmission
Rejected	There are errors with the firm inventory data	Review the FDA Firm Data
	entered in the template that prevent	Results/Error Explanation,
	processing.	correct the error(s) and perform a
		resubmission

Reconciliation is needed for **No Match** and **Review** statuses. To reconcile the inconsistencies between FDA's database and the state records, the regulatory partner must send the correct firm inventory data to their state liaison to be updated in FDA's database.

Access Firm Inventory Reconciliation Capability and Template

To access the **ORAPP Firm IR** capability and template:

- 1. Navigate to <u>ORAPP</u> in the web browser and log in using your FDA provided credentials.
- 2. Hover over Firms on the menu bar and select Inventory Reconciliation on the submenu.



- 3. The Firm Inventory Reconciliation contains:
 - a. Link to Download the Firm Inventory Reconciliation Template.
 - b. Option to select and submit firm inventory data.
 - c. File submission status information.



Firm Inventory Reconciliation								
Submit Firm Inventory Reconciliation data using the FDA Firm Inventor Beconciliation Template that is available to download below.								
Download Firm Inventory Reconciliation Template v2.0								
To submit Firm Inventory Reconciliation data for processing, the Excernte must NOT:								
Contain more than 5000 records Reuse a	previously submitted f	lename						
Be password-protected Use a fi	lename longer than 75 o	haracters or containin:	g * " : ? / \ < >	•				
Click the Refresh icon to view the latest processing inform	nation for the submitted	files.						
Processed files can be down clicking the Downlo	Processed files can be down b clicking the Download icon. The processed files will be available for download for 2 years from the Submission Date.							
Select File Choose File No file chosen X Submit				C ^t Refresh				
	Mi	nnesota Department of A	griculture - Foo	d Division				
Filename	Submission Date	Submitted By	Status	Status Summary				
IR_T003_MD_V1.xlsx	7/31/2023	Dennis Shats	Success	The processed file resulted in 2 firm record match(es) on state firm name or DBA and 0 firm record(s) for review. 0 firm record(s) contained data errors that require the record(s) to be corrected and resubmitted. Download and open the file and view the last two columns for the Match Status and the FDA Firm Data Results/Error Explanation for each firm.				
IR_T002_MD_V1.xlsx	7/31/2023	C	Success	The processed file resulted in 2 firm record match(es) on state firm name or DBA and 0 firm record(s) for review. 0 firm record(s) contained data errors that require the record(s) to be corrected and resubmitted. Download and open the file and view the last two columns for the Match Status and the FDA Firm Data Results/Error Explanation for each firm.				
IR Excel Template_07262023-1 xlsx	7/26/2023	Prasanthi Velaga	A Review	The processed file resulted in 4 firm record match(es) on state firm name or DBA and 0 firm record(s) for review. 2 firm record(s) contained data errors that require the record(s) to be corrected and resubmitted. Download and open the file and view the last two columns for the Match Status and the FDA Firm Data Results/Error Explanation for each firm.				

- 4. To download the template, select the **Download Firm Inventory Reconciliation Template** link at the top of the page.
- 5. The template will appear in the Downloads folder within the web browser. **Open** the downloaded template. **Note:** The location of the Downloads folder will vary based on the web browser used

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FDA U.S. FOOD & DRUG	ORA Partners Portal							IR Excel Template_v2.0 (3).xisx Per 208 K8 • Done		
		Н	ome Inspection	ns - Sam	ples - NFSDX -	Firms -	Training +	About	Contact U	5
Firm Inventory Reconciliation Submit Firm Inventory Reconciliation data using the FDA Firm Inventor Reconciliation Template that is available to download below. Download Firm Inventory Reconciliation data for processing, the Excel file must NOT: Contain more than 5000 records Reuse a previously submitted filename Reuse a previously submitted filename Be password-protected See a filename longer than 75 characters or containing *" : ? / \< > Click the Refresh icon to view the latest processing information for the submitted files. Processed files can be downloaded by clicking the Download icon. The processed files will be available for download for 2 years from the Submission Date.										
Minnesota Department of Agriculture - Food Division										
Filename		Submission Date	Submitted By	Status	Status Summary					
IR_T003_MD_V1.xlsx	Ť	7/31/2023	Dennis Shats	Success	The processed file resulted i 0 firm record(s) contained da open the file and view the la Explanation for each firm.	n 2 firm record ma ta errors that requ at two columns for	tch(es) on state firm nam- ire the record(s) to be con the Match Status and the	e or DBA and 0 firm rrected and resubm FDA Firm Data Re	record(s) for revie itted. Download an sults/Error	w. d
IR_T002_MD_V1.xlsx	Ŧ	7/31/2023	Dennis Shats	Success	The processed file resulted i 0 firm record(s) contained da open the file and view the la Explanation for each firm.	n 2 firm record ma ta errors that req at two columns for	atch(es) on state firm nam- uire the record(s) to be con the Match Status and the	e or DBA and 0 firm rrected and resubm FDA Firm Data Re	record(s) for revie itted. Download an sults/Error	w. d

Firm Inventory Reconciliation Template Overview

The Firm Inventory Reconciliation Template consists of six worksheets:

- **Disclaimer** FDA disclosure about authorized usage of the template.
- **Instructions** Instructions on how to use the template to perform a firm inventory reconciliation submission.
- Data Requirements A list of all data elements within the template with guidance on proper formatting.
- Inventory Reconciliation Data <u>Data entry worksheet</u> used by the regulatory partner to enter firm inventory data.



- **Example** Sample firm inventory data that can be used as a reference when populating the template.
- Data Values A list of all dropdown menus in the template and the menu options.

				FirmDetails						Results Info		
FEI (Optional)	Firm Legal Name (Required)	Doing Business As (DBA) (Optional)	Address Line1 (Required)	Address Line2 (Optional)	City Name (Required)	State Code (Required)	Zip Code (Required)	Country Code (Required)	DUNS Number (Optional)	State Identification Number (Optional)	Match Status [LEAVE BLANK. FIELDS WILL BE AUTO-POPULATED DURING PROCESSING, AFTER PROCESSING, DO NOT CLEAR OR ALTER FIELD CONTENTSI	FDA Firm Data Results / Error Explanation [LEAVE BLANK. FIELDS WILL BE. AUTO-POPULATED DURING PROCESSING. AFTER PROCESSING, DO NOT CLEAR OR ALTER FIELD CONTENTS]
3006312713	JJ Road Feeder, LLC		1432 Nw 82nd Ave		Miami	FL	32401	US		STID984563450345		
	El Reglano Seafood, Corp		911 Nw 7th Street Rd		Miami	FL	33101	US		46456456456		
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< >	Disclaimer Ins	tructions Data Re	equirements Inventor	y Reconciliation Data	Example D	ataValue	s +		:	•		

Firm inventory data is entered on the Inventory Reconciliation Data worksheet which contains two sections: Firm Details and Results Info. Regulatory partners should only enter data in columns within the Firm Details section. The Results Info section should never be modified as it is used by ORAPP to autogenerate the Match Status and FDA firm Data Results/Error Explanation post-submission. The following table contains a list of the data elements on the Inventory Reconciliation Data Worksheet of the template and their descriptions.

Inventory Reconciliation Data Worksheet Data Elements								
Data Element Name	Required or Optional?	Description						
FEI Number	Optional	Unique number assigned to a firm by the FDA which is involved in an FDA regulated activity with the agency						
Legal Name	Required	Firm name used on legal documents such as the incorporation charters and tax filings						
DBA	Optional	Doing Business As (DBA) name for the firm						
Address	Required	Physical address of the firm						
Street – Line 1	Required	Physical street address of the firm						
Street – Line 2	Optional	Suite number, room number, office number, etc. (<i>if applicable</i>)						
City	Required	City for the firm's physical address						
State	Required	State for the firm's physical address						
Zip Code	Required	Zip code for the firm's physical address						
Country	Required	International Organization for Standardization (ISO) Country						
DUNS number	Optional	Nine-digit identifier number assigned to businesses by Dun & Bradstreet						
State Identification Number	Optional	State Identification Number – assigned by state agency						
Matching Status	System Generated Post- Submission	Match status returned for firm inventory data submission						
FDA Firm Data Results/Error Explanation	System Generated Post- Submission	Firm inventory data returned from FDA database or error explanation (based on match status)						



Firm Inventory Reconciliation Submission

To learn how to perform a <u>Firm IR submission, reference the ORAPP Inventory Reconciliation</u> <u>Submission Knowledge Article</u> or the <u>Firm Inventory Reconciliation e-Learning courses</u> available within the ORAPP Training tab.

Contact Us

For assistance with ORAPP or ORA DX, contact the ORA DX Team via the ORAPP Contact Us page.