ORA Partners Portal (ORAPP) Firm Inventory Reconciliation Submission 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 use the **Firm Inventory Reconciliation Template** to verify firm inventory data in FDA's database for firms within their state. Regulatory partners can 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. It is recommended that you read the ORA Partners Portal (ORAPP) Firm Inventory Reconciliation (IR) Overview Knowledge Article before reading this article.

Firm IR File Requirements

Firm IR file submissions must meet the following criteria:

- Unique File Name (75 characters max)
- Not Password-Protected
- Maximum of 5,000 records
- Firm inventory data for one firm per row

Perform Firm IR Data Submission

To perform a firm inventory reconciliation data submission:

- 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 Firm Inventory Reconciliation on the submenu.



- 3. Select the Download Firm Inventory Reconciliation Template link.
- 4. The template will appear in the Downloads folder of the web browser. **Note:** The location of the Downloads folder will vary based on the browser used. Open the template, populate it with the



firm inventory data, and save it with a unique file name. Reference the Firm Inventory Reconciliation (IR) Overview knowledge article for more information on the template fields.

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- 5. On the Firm Inventory Reconciliation page, select Choose File.
- 6. In the populated window, select the file to be submitted and choose **Open**.
- 7. Then, select **Submit** on the page. The file will begin to process, and the **Status** column will display **In progress** until processing completes.

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- 8. Once the file has been processed, the **Status** and **Status Summary** columns will be updated on the Firm Inventory Reconciliation page in ORAPP.
 - a. The Status column will display one of four statuses:



- i. In Progress The submission file is currently being processed in ORAPP.
- ii. **Success** All firm inventory records within the submission file were successfully matched.
- iii. **Review** Some or all firm inventory records within the submission files were not matched and require review.
- iv. Rejected The submission file could not be processed due to formatting or data issues.
- b. The Status Summary column will display:
 - i. The number of successfully matched firm inventory records.
 - ii. The number of firm inventory records that need review.
 - iii. The number of firm inventory records that received data errors that must be corrected and resubmitted.

OR

- i. If the entire submission was rejected due to unauthorized template modifications, an error message and instructions for correction will display. Note: If the file was rejected due to unauthorized template modifications, download a new copy of the Firm Inventory Reconciliation Template from the ORAPP Firm Inventory Reconciliation page to perform the submission.
- 9. Select the download arrow next to the file name to download the processed file.
- 10. Open the downloaded file.

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- Select the Inventory Reconciliation Data worksheet tab and review the Match Status and FDA Firm Data Results / Error Explanation to determine if any firm inventory data must be reconciled.
 - a. The Match Status column will display one of the following statuses:
 - i. **Match** The firm inventory record on the submission file matched a single record in FDA's database.



- ii. Match on DBA The firm inventory record on the submission file matched a single record in FDA's database using the Doing Business As (DBA) name and not the Firm Legal Name.
- iii. **Multiple Matches** The firm inventory record matched multiple records in the FDA database.
- iv. **No Match** There was no match in the FDA database for the firm inventory records.
- v. **Review** The firm inventory record data received an error explanation that must be reviewed before taking next steps.
- Results Info Match Status ILEAVE BLANK, FIELDS WILL BE FDA Firm Data Results / Error Explanation [LEAVE BLANK. FIELDS WILL BE AUTO-POPULATED AUTO-POPULATED DU g Business As (DBA (Optional) Address Lines (Required) City Name (Required) Zip Code (Required) FEI (Optional) Code Number (Optional) (Optional) ROCESSING. AFTER PROCESSING DO NOT CLEAR OR ALTER FIELD DURING PROCESSING. AFTER PROCESSING, DO NOT CLEAR OR ALTER FIELD CONTENTS] Legal Name: Mirabella Specialty Food DBA: Physical Address: 625 St Louis St Ste 31 Hopkins, MN 55343-4429 Country:US State Identification Number: 27213 55343-4429 91458 Mirabella Specialty Food 625 St Louis S FEI: 3008994110 Legal Name: Harry's Frozen Food DBA: Physical Address: 211 Main St Elrosa, MN 56325 Country:US State Identification Num Harry's Frozen Food 211 Main St 56325 Inventory Reconciliation Data Example DataValues : ∢ Data Requirements Disclaimer Instructions
- vi. **Rejected** ORAPP could not process the submission due to data errors.

- 12. Firm inventory records that received a **Multiple Matches**, **No Match**, **Review**, or **Rejected** status, must be reviewed to determine the next steps.
 - a. If a Multiple Matches status was returned:
 - i. Review the information in the FDA Firm Data Results/Error Explanation column for the multiple firms that matched the submission and identify the accurate firm inventory record.
 - ii. Submit an email request to the state liaison to have the firm inventory records merged in the FDA database. The email should contain the following information:
 - 1. The FDA Establishment Identifier (FEI) for the accurate firm inventory record.
 - 2. The accurate firm inventory record details to include Firm Legal Name, DBA, Physical Address, DUNS Number *(if applicable)*, and State Identification Number *(if applicable)*.
 - 3. A list of the **multiple firm inventory records** provided in the **Firm Data Results/Error Explanation** column of the submission file.
 - 4. A **request to merge** the multiple firm inventory records with the accurate firm inventory record.
 - b. If a **No Match** status was returned:
 - i. Review the submitted firm inventory data to ensure that complete and accurate data was submitted.
 - 1. If errors were found, correct the data, rename the file with a unique file name, and perform resubmission.



- 2. If the original submission data was accurate but a **No Match** status was returned, send an email to the state liaison requesting to add the firm inventory record to the FDA database. The email should contain the following information for the firm:
 - a. **FEI** (If known)
 - b. Firm Legal Name
 - c. **DBA** (If applicable)
 - d. **Physical address** to include street address, suite/floor/room number, city, state, zip code, and country code (i.e. US)
 - e. DUNS Number (If known)
 - f. State Identification Number (If known)
- ii. If a Rejected status was returned:
 - Review the details in the FDA Firm Data Results/Error Explanation column to determine the cause of the error. Note: Firm inventory reconciliations submissions are prohibited for firms outside of the loggedin the user's state and will return a Rejected status.
 - 2. Update the necessary data using the **Data Requirements** and **Example** worksheets of the **Firm Inventory Reconciliation Template** as a guide to ensure that the data is properly formatted.
 - 3. **Rename** the submission file with a unique name and perform a **resubmission**.

More Information

To learn more information about the Firm IR capability, review the Firm IR knowledge articles and e-Learning courses 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.