**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
Food and Drug Administration

# New Inquiry Form
# CDER Import Compliance Branch

1. DATE *(mm/dd/yyyy)*

| **INQUIRER DETAILS** | |
|---|---|
| 2. SOURCE OF INQUIRY | 3. ORGANIZATION NAME |
| 4. CONTACT NAME | 5. E-MAIL ADDRESS |

**INQUIRY DETAILS**

6. DESCRIPTION

| **DRUG DETAILS** | |
|---|---|
| 7. DRUG TYPE | 8. APPLICATION NUMBER *(If applicable)* |

9. PRODUCT NAME

***Please make sure to attach any additional documentation to your e-mail.***

*(continued on next page)*

## INSTRUCTIONS FOR COMPLETION OF FORM FDA 5054 – NEW INQUIRY FORM

*(The item numbers below correspond to the numbered areas on New Inquiry Form)*

1. **Date** – Enter the date that you are submitting the initial inquiry request. For follow-up requests or a request for inquiry termination, enter the date the initial request was submitted to FDA. Enter the date in MM/DD/YYYY format. For any follow-up on previous inquiries, if you do not have the initial assigned inquiry number, then providing the date of the initial request will allow FDA to associate any follow-ups or requests for termination with the initial request.
2. **Source of Inquiry** – Select the appropriate classification of the inquiry:
   - **Consumer** – Inquiry request coming from public stakeholders, that does not include business/industry or government entities
   - **Industry** – Inquiry request coming from business entities and corporations, and/or their representatives
   - **Government** – Inquiry request coming from any official, employee, agent or representative acting on behalf of any domestic or international government department or agency
   - **FDA Internal** – Inquiry request coming from a FDA office
   - **Other** – Inquiry request from a source not listed
3. **Organization Name** – Provide the name of the organization that is responsible for making the inquiry request.
4. **Contact Name** – Provide the name of the contact person that is responsible for making the inquiry request.
5. **E-mail Address** – Provide the e-mail address of the contact person that is responsible for making the inquiry request.
6. **Description** – Describe the circumstances surrounding the inquiry request including:
   - What is the issue, timeframe, supply chain roles, product details, etc.
   - Please provide any specific information like entry numbers, FEI numbers, application numbers, etc. (if applicable).
   - If you are a trading partner other than a manufacturer, please indicate who is the manufacturer of the product.
   - If a previous inquiry request is no longer needed, explain why, and include any corrective actions taken (if applicable).
   - If expedited consultation with FDA is requested, please indicate the rationale here.
7. **Drug Type - Select the appropriate classification of the drug product:**
   - **Finished Dosage Form (FDF)** – A drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application.
   - **Active Pharmaceutical Ingredient (API)** – An Active Pharmaceutical Ingredient (API) is any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance.
   - **Over the Counter (OTC)** – Over-the-counter medicine is also known as OTC or nonprescription medicine. All these terms refer to medicine that you can buy without a prescription.
   - **Unapproved- Drug Efficacy Study Implementation (DESI) and Grandfathered** – DESI products may remain on the market without final approval while the hearing requests are pending. Grandfathered drugs are those that would not be considered "new" under section 201(p) of the FD&C Act.
   - **New Drug Application (NDA)** – A New Drug Application (NDA) contains data that provides for the review and ultimate approval of a new drug product.
   - **Abbreviated New Drug Application (ANDA)** – An Abbreviated New Drug Application (ANDA) contains data that provides for the review and ultimate approval of a generic drug product.
   - **Intermediates** – A material produced during the synthesis of an API that must undergo additional molecular change or processing before it becomes an API.
   - **Inactive Ingredient** – An inactive ingredient is any component of a drug product other than the active ingredient.
   - **Investigational New Drug (IND)** – An Investigational New Drug is a new drug or biological drug that is used in a clinical investigation. It also includes a biological product that is used in vitro for diagnostic purposes.
   - **Biological Licensing Application (BLA)** – A Biological Licensing Application (BLA) contains data that provides for the review and ultimate approval of a biological product.
   - **Pre-Investigational New Drug (PIND)** – An IND that has not been submitted to FDA and the drug offered for import is solely intended for non-human research to generate data to support submission of an IND to FDA (e.g., to collect chemistry, manufacturing, and control information for the IND submission).
8. **Application Number (If applicable)** – Provide the drug application number for the product, if applicable.
9. **Product Name** – Please indicate the name of the product, as it appears on the label.

*** Additional Documentation** – Please make sure to attach any additional documentation to your e-mail.