|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Customer Product Information for STERIS Drug Listing**  *As a contract sterilizer, STERIS is required to list with the FDA, under our own NDC#s, each approved drug product that we sterilize. To ensure compliance, STERIS will not process drug product until this information is obtained. It is your (our Customer) responsibility to notify STERIS when information on this form changes. Information on this form should be provided by your regulatory resource*. | | | | | | | | | | | |
| **Drug Name** | |  | | | | | | | | | |
| **STERIS Customer Name** | |  | | | | | **Drug Owner/Labeler:** | | |  | |
| **Regulatory Contact**  *(Customer name, email, phone and address)* | |  | | | | | **Importer of Record FDA Registration #** *(only required if STERIS site not in U.S. and drugs imported to US)* | | |  | |
| **1. GENERAL INFORMATION** (for product processed at STERIS AST site(s) identified above) | | | | | | | | | | | |
| **Product Type Processed by STERIS AST**  *(check only one – if multiple product types, complete a form for each)* | | | Non-Drug component of drug product  API  Drug in Primary Packaging   Final Packaged Drug | | | | | | | | |
| **Product Description** *(description of product processed by STERIS AST)* |  | | | | | | | | | | |
| **Item ID(s)** |  | | | | | | | | | | |
| **STERIS AST Processing Site**  *(city and street address)* |  | | | | | **Backup AST Site(s):** | |  | | | |
| **Current Product Disposition** | Processed product will not be used in commercial distribution *(testing, validation, dose audit, etc.)*  Processed product will be used in commercial distribution | | | | | | | | | | |
| **Intended for U.S. Market?** | YES  NO | | | **Imported to U.S. Market?** | YES  NO | | | | **Approved for the U.S. market?** | | YES  NO |
| **Drug Type Processed by STERIS AST**  *(check all that apply)* | Human  Generic FDF  Generic API  OTC Approved  OTC Monograph  Animal Prescription  Animal OTC  Animal OTC Type A Medicated Article | | | | | | | | | | |
| **U.S. Submission Information** | Application Type: | | | | | Application Number(s): | | | | | |
| Application Status:  Approved  Submitted Actual/Planned Submission Date: | | | | | | | | | | |
| Is STERIS identified in application?  YES  NO If YES, how?  DMF  FEI  Name/Address | | | | | | | | | | |
| **2. DETAIL INFORMATION FOR DRUG PRODUCT PROCESSED** *(skip to section 3 if Product Type Processed is non-drug component or Drug Type is Animal drug.* | | | | | | | | | | | |
| **NDC#s for Product** |  | | | | | | | | | | |
| **Drug Manufacturer** |  | | | | | | | Manufacturer DUNS#: | |  | |
| **Part information for product processed by AST**  *(complete if Drug in Primary Packaging checked for Product Type processed by STERIS AST* | |  |  |  |  | | --- | --- | --- | --- | | NDC# | Proprietary Name | Non-proprietary Name | Dosage Form | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | | | | | | | | | | | |
| **API information**  *(complete if API checked for Product Type processed by STERIS AST)* | API Name: | | | | | | | | | | |
| API Form: | | | | | | | API Unit of Measure: | | | |
| How packaged for processing at STERIS AST *(weight, Unit of Measure and Packaging)*: | | | | | | | | | | |
| 3**. CUSTOMER SIGNATURE**  *Signature indicates attestation of data accuracy and agreement to notify STERIS if/when information provided on this form changes* | | | | | | | | | | | |
| **Name (Printed):** |  | | | | **Title:** | | |  | | | |
| **Signature:** |  | | | | **Date signed:** | | |  | | | |