

FDA DETAIL SHEET

Article Item Name or Number: _____
(Use separate sheet for each name or number)

Packaging (smallest unit): _____

Size of above packaging: _____
(include unit of measure)

Number of above packages: _____

Net Weight: _____

Manufacturer Name and Address: _____

**Manufacturer Registration/
Establishment No:** _____

Additional requirements by FDA regulated product type:

Biologics¹

Biologic Product No: _____(BPL)

Drugs¹

Drug Listing No²: _____(DLS/NDC)

New Drug Application No: _____(AND/NDA)

Investigational New
Drug No: _____(IND)

Devices³

Medical Device Listing No: _____(DEV/LST)

Pre-Market Notification/
510(k) No: _____(PMN)

Pre-Market Approval No: _____(PMA)

Investigational Device
Exemption No: _____(IDE)

Radiation Emitting Products^o

Accession No: _____(ACC)

Veterinary Products

New Animal Drug
Application No: _____(ANANAD)

Investigational New Animal
Drug No: _____(INA)

Medicated Feed
Application No: _____(MFA)

Food Additives

Food Additive Chemical
Abstract System/CAS No: _____(AIN)

Food Additive Petition No: _____(FAP)

Color Additive No: _____(CIN)

Canned Foods^a

Low Acid Canned Food
Process Submission ID No: _____(FCE)

Cosmetics

Cosmetic Registration No: _____(COS)

¹ - Also requires an intended use statement

² - Also required for sunscreen and self tanning lotions

³ - An Impact Resistant Lens Certificate (Drop Ball Test) is required for glasses, sunglasses, and unmounted lenses

^o - Requires FDA form FDA-2877 (often completed by US Importer)

^a - Fishery Certificate (NOAA370) required for all canned fish and seafood products

Other Details, such as product labeling, export country government inspection certificates, processing information, ingredients and directions for use may be required. Requirements for Prescription Drugs (including eyewear) for personal use are not covered by this document.

Please note that failure to provide complete and accurate information for your FDA regulated product will delay U.S. Customs and U.S. Food & Drug clearance, and may incur storage or other charges.