HDA Standard Pharmaceutical (Rx-only) Product and Medical Device Information Short Form Instructions

The information conveyed about existing products has important downstream implications for the appropriate receiving, handling and storage of pharmaceutical product at the distributor’s facility and farther along in the supply chain. This **one-page** form contains a series of questions concerning changes to existing products.

* COMPANY NAME
* GLN DATA
* DSCSA EXEMPTION STATUS
* DRUG NAME
* GTIN PRODUCT INFORMATION
* ITEM AND PACKING INFORMATION

Please note that this is a subset of the form data present on the HDA New Product Form. This short form is intended to capture product packaging and resulting GTIN updates and subsequent updates to DSCSA exemption status. For questions about specific data fields, please check with your trading partner for its requirements. Please note that HDA does not receive copies of these forms or store any product information.

**Please review each section of the form and provide all relevant information. Include only one product or promotion per form. Use the *LEFT* mouse button to select checkboxes and highlight gray areas to write in text or numbers. Blue boxes indicate drop-down menu options.**

*This form was developed for the maintenance of Rx and medical device product information. There may be other information relevant for the maintenance of over-the- counter (OTC) drugs and medical device (e.g. other bases for marketing) product info not referenced on this form.*

**PRODUCT INFORMATION**

**Company Name:** Enter the company name of the manufacturer as defined in the Food and Drug Administration (FDA) [guidance](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/identifying-trading-partners-under-drug-supply-chain-security-act).

**GLN:** Enter the corporate GLN corresponding to the **Company Name** specified above.

**Is this an updated GLN?** Select yes or no. Consult the [GLN Management Rules](https://www.gs1.org/standards/gs1-gln-allocation-rules-standard/current-standard#3-GLN-Management-Rules+3-1-New-party/location-introduction) to determine if an existing GLN can be changed or a new one needs to be assigned.

**Proprietary Name (If Applicable) and Established Name:** Enter the name of the Drug or Biologic.

**Selling Unit NDC:** Specify the selling unit package NDC number.

**Unit of Use NDC:** Specify the unit of use NDC if applicable/different from the selling unit NDC.

**UPC:** Enter the UPC code if the product is barcoded in UPC format. If the linear format GS1-128 is used, enter that.

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) EXEMPTION STATUS**

**Has FDA granted an exemption for the product since it was launched if covered under the DSCSA?** Check YES if an exemption has been approved by FDA, NO if none.

**If an exemption has been granted, specify the effective date of it.** Specify the effective date of the exemption.

**If FDA indicates an exemption expires or is being terminated on a particular date — be it the result of a new exemption being granted, a biennial review of an existing exemption, or limited duration request — indicate the date the expiration or termination is effective.** Specify the date the exemption expires.

**Enter a phone number and/or e-mail address, per FDA final guidance recommendations, for trading partners to contact regarding questions and status pertaining to this exemption.**

**Indicate any brief notes/comments/status update regarding the DSCSA exemption FDA has granted for the product if appropriate.** (Optional) Enter notes as appropriate.

**GTIN AND HIBCC PRODUCT INFORMATION**

**This section is intended for any updates to product packaging and resulting GTIN changes.**

**Saleable Unit of Measure:** Starting with the lowest selling unit of measure at the item/each row, place an X next to all applicable packaging levels.

**Saleable Quantity:** Provide the number of saleable units within the corresponding level of packaging. For the first row, the **Saleable Quantity** should always be 1 since Item/Each is the smallest package configuration available for sale. Example: Smallest saleable unit is a package of qty 10 vials, the saleable Quantity for that GTIN should = 1. Note the **Box/Carton/Bundle/Inner Pack** row is reserved for intermediate packaging larger than an each but smaller than a case. GTIN rows going down the table with higher levels of packaging beyond **Item/Each** should contain the **number of saleable units** contained in that level of packaging’s **Saleable Quantity**. For example, if a case GTIN contains 45 saleable units for the product, specify 45 in the case GTIN row for **Saleable Quantity.**

**HIBCC:** If your product uses the HIBCC barcode/product assignment numbering system in place of GTINs, specify that number.

**GTIN-14:** If your product uses the Gs1 system, specify the GTIN-14 assigned to this level of packaging.

**Is this a new GTIN? (Y/N):** This will signal to the distributor the new GTIN introduced for this product.

**ITEM AND PACKING INFORMATION**

**Weight Lbs.:** Enter weight in pounds for item, box/carton, case and pallet, as appropriate.

**Dimensions:** Enter dimensions by depth, width and height for each packaging level.

**Volume (Cube):** Volume will be automatically calculated based on the dimensions entered, expressed as cubic inches.

**Saleable # of Pieces Per Level:** Enter the number of saleable unit items in each packaging level.

Example:
Item/Each = 1
Box/carton/bundle = 8
Case = 96
Pallet = 1,152

And NOT:
Item/Each = 1
Box/carton/bundle = 12/case
Case = 91/pallet
Pallet = 1 pallet