



## HDMA Standard Pharmaceutical (Rx-only) Product Information Form Instructions

The information conveyed about new 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 **three-page** form contains a series of questions about the product in these sections:

### PAGE ONE

- PRODUCT INFORMATION (For branded and generic pharmaceutical products only)
- DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION
- SPECIAL HANDLING AND STORAGE REQUIREMENTS
- ITEM AND PACKING INFORMATION
- ORDER INFORMATION as well as PHARMACY ORDER/ BILL UNIT INFORMATION
- COST INFORMATION

### PAGE TWO

- HAZARDOUS MATERIAL and TRANSPORTATION
- ADDITIONAL PRODUCT INFORMATION – Serialization
- ADDITIONAL STORAGE INFORMATION
- REMS / REGISTRY INFORMATION
- RETURN INSTRUCTIONS
- CLASS OF TRADE RESTRICTION
- ADDITIONAL INFORMATION
- MISCELLANEOUS NOTES AND BARCODE IMAGE

### PAGE THREE – FOR PRODUCTS DESIGNATED AS DROP-SHIP ONLY

- ORDER METHOD
- STANDARD ORDER RECEIPT AND PROCESSING
- EXPEDITED FREIGHT INFORMATION
- PRIORITY AND OVERNIGHT PROCESSING
- CLASS OF TRADE RESTRICTION
- REMS / REGISTRY INFORMATION
- RETURN INSTRUCTIONS
- OTHER DATA REQUIRED TO PROCESS PURCHASE ORDER
- ADDITIONAL INFORMATION
- MISCELLANEOUS NOTES

Although not all information on the form is required by each distribution trading partner, it represents the most frequently requested data points by a majority of HDMA members for item set up. For questions about specific data fields, please check with your trading partners for their requirements. Please note that HDMA does not receive copies of these forms or store any product information. This form is provided as a guide to new item set up for use between trading partners.

In 2014, additional questions were added to Page One to support implementation of the Drug Supply Chain and Security Act (DSCSA). A write in field for the product's Controlled Substance Code was added to Page One. The automatic formula for cubic volume was removed. A write-in field for the "As of date" was added to the Regular Cost Per Unit of Sale and Invoice Cost (WAC) fields. Serialization information moved from Page One to Page Two. Page Three for drop-ship only product was added in 2013.

**Please review each section on Pages One and Two of the form and provide all relevant information. Include only one product or promotion per form. If your product is designated as a drop-ship only product and will not be warehoused, please also complete Page Three. Use the LEFT mouse button to select check-boxes and highlight gray areas to write in text or numbers. Blue boxes indicate drop-down menu options.**

*This form was developed for the introduction of Rx products. There may be other information relevant for the introduction of over-the-counter (OTC) drugs (e.g. other bases for marketing) not referenced on this form.*

## PAGE ONE

**Introduction Type** - Check the appropriate box to identify the purpose of the form / item introduction type.

- **New Item** – Select if this product is new to the distributor as part of the pre-launch communications.
- **Promotion/Deal** – Select if product is available as part of a promotion or deal package. [Product details have been previously communicated.]
- **Open Stock** – Select if product is to be kept in the distributor's warehoused inventory.
- **Post Launch Change** – Select if information previously communicated has changed or will change during the first year of a new product launch.

Check the **Final Version** box and enter the **Date** as a last step prior to submitting the form to your distributor.

### PRODUCT INFORMATION

**Company Name** - Enter the manufacturer's corporate or division name, or the manufacturer representative, if applicable. This should match the Company Name on the Food and Drug Administration (FDA) Application.

**New Drug Application (NDA), Abbreviated New Drug Application (ANDA) or Biologics License Application (BLA) or Med Device** - Indicate which type of application per FDA guidance.

Include **application numbers** for NDA, ANDA, BLA and Med Device

**Rx Product / Proprietary Name** - Enter complete product proprietary name,

**NDC:** Indicate the 10 digit National Drug Code (NDC) Number for the prescription drug product.

Note: this HDMA form is not meant for OTC drugs.

**UPC:** Indicate product's 12 digit Universal Product Code (UPC) Number

**CVX:** Indicate the numeric U. S. Licensed Vaccine Administered (CVX) code that identifies the type of vaccine product used.

**MVX:** Indicate the alphabetic string that identifies the manufacturer of the vaccine product.

**Description:** Enter product description in space provided. This description should match what has been included on the Food and Drug Administration (FDA) Application.

**Active Ingredients:** An active ingredient (AI), also active pharmaceutical ingredient (API) or bulk active is any component that is intended to furnish pharmacological activity. See 21 CFR 210.3(b)(7).

**URL for additional product information:** List product or company website with additional reference material.

**Address:** Manufacturer's corporate or divisional address. Include city, state and zip on the line following.

**Key Contact:** Name of key contact at headquarters level, e.g., V.P., Sales, National Account Manager, Director of Trade Relations, etc.

**E-mail:** Include e-mail address for key contact

**Phone Number(s):** Enter '800' number, if applicable. Also, include key contact's direct phone number.

**Fax:** Enter fax number for key contact.

## FOR GENERIC DRUG PRODUCTS

FDA Reference for this section: [FDA Information on Drugs](#)

**Orange Book Rating** - For generic products, provide the [FDA Orange Book Therapeutic Equivalence Evaluation](#), e.g., AB, AT, AP etc.

**Brand Name** – Enter brand name for the generic equivalent in this field.

**Generic Equivalent for the brand** – Enter the generic equivalent for the brand in this field.

### DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

This section supports implementation of the Drug Supply Chain Security Act (21 USC § 360eee).

**Does supplier meet DSCSA definition of manufacturer?** Answer Yes or No based on the definition in the Act. (Reference: <http://www.law.cornell.edu/uscode/text/21/360eee>)

**Is product exempt from DSCSA?** Answer Yes or No based on the exemptions listed in the Act. If yes, select from the drop-down menu or write in the exemption. Exemptions include but are not limited to the following (see 21 USC §360eee(13) (definition of product) 21 USC §360eee(24) (definition of transaction)):

- Blood and blood components intended for transfusion.
- Radioactive drugs and radioactive biologics.
- Imaging drugs.
- Certain intravenous products (e.g., for replenishment, irrigation, to maintain equilibrium of water and minerals in the body).
- Medical gas.
- Compounded drugs.
- Certain medical convenience kits and combination products.
- Sterile water and products intended for irrigation.
- Homeopathic drugs.

**Is product repackaged?** Indicate whether the product was repackaged or relabeled for further sale or distribution without a further transaction by selecting Yes or No.

**If yes, was original product purchased direct from mfr?** If yes, indicate whether the original product was purchased directly from the manufacturer by selecting Yes or No.

**Is product sold by manufacturer's exclusive distributor?** Indicate whether the product is sold by the manufacturer's exclusive distributor by selecting Yes or No. The term "exclusive distributor" means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

**Are any waivers granted for product ID/barcode?** Yes or No. If yes, attach documentation from FDA.

## Additional Product Information

**Shipment Information:** Indicate whether product is a Direct Ship Item, a combination of Direct and Drop Shipment or a Drop Ship Only Item (and see page 3 if so).

**Legend Device** - Indicate if this product is a device registered with the Food and Drug Administration (FDA) through the PMA or 510K process and carries a statement such as “RX only” or “Caution; Federal (USA) law restricts this device to be used or sold unless on the order of a physician.”

**State Control** - Indicate whether this product is subject to requirements to treat it as a controlled substance in particular states (that differs from its federal designation as a controlled substance). If Yes, use the Miscellaneous Notes field on Page Two to list the states and applicable state control numbers.

**ARCOS Reportable** - Indicate whether this product must be reported in the Drug Enforcement Administration’s Office of Diversion Control’s **Automation of Reports and Consolidated Orders System** (ARCOS).

**Co-Licensed** - Is the product manufactured or marketed under an official collaborative licensing agreement?

**Controlled Substance** - Indicate whether this product is a controlled substance and, if so, what **Schedule Number** (2, 2N, 3, 3N, 4 and 5) under the Controlled Substances Act (21 U.S.C. 801) (CSA). Reference:

[DEA Diversion Control Controlled Substance Schedules](#) and  
[DEA Diversion Control Controlled Substances by CSA Schedule](#)  
 (Note: N in the “Narc” column indicates non-narcotic)

**Administration Controlled Substances Code Number** - List the 4 digit Administration Controlled Substances Code Number associated with the product. The administration controlled substances code number can be found in [section 1308.03](#) of the most recent issue of [Title 21 Code of Federal Regulations \(CFR\) Part 1300 to end. \(21 CFR §1308\)](#) and the final rules which were published in the Federal Register subsequent to the issuance of the CFR.

See the Controlled Substances Column on this page - <http://www.deadiversion.usdoj.gov/schedules/> - for lists of the Code Numbers by Alphabetical Order, DEA Drug Code Number and CSA Schedule.

**HAZMAT/Cytotoxic Agent** - Indicate whether product is a Hazardous Material or Cytotoxic Agent, and provide additional information on page two of form, as appropriate.

Reference:

[HazMat Definition 49 CFR 105.5: Definitions.](#)  
 Cytotoxic Definition: [National Institutes of Health - National Library of Medicine](#)

**Unit Dose** - Indicate if product is a unit dose, drug product that is packaged for the delivery of a single dose of a drug to the patient (e.g. tablets or capsules in a blister pack or a pouch or preformed unit dose pack).

**Unit of Use** - Indicate if product is in "[Unit of Use](#)" packaging, defined as ‘a method of preparing a legend medication in an original container, sealed and labeled, pre-labeled by the manufacturer, and containing sufficient medication for one normal course of therapy.’

If Unit Dose, indicate whether item is bar coded to the unit level for hospital scanning. Also, indicate if it is Reverse Number Unit dose (e.g. controlled substances that are reverse numbered for inventory tracking) by checking the RN box.

## Wholesaler Use Only

**Vendor Number** - Most drug wholesaler/distributors assign vendor numbers to identify manufacturers. This number is typically entered by the drug wholesale buyer.

**Wholesaler Code #** - Entered by wholesaler/distributor.

**Fineline Code** - Entered by wholesaler/distributor.

## SPECIAL HANDLING AND STORAGE REQUIREMENTS

**a. Temperature** - Indicate the U.S. Pharmacopeial Convention (USP) temperature range for this product.

**b. Contact for temperature excursions** - Indicate a contact name and phone number for questions and indicate whether the product is to be shipped to customers on ice or dry ice.

**c. Additional Requirements** - Indicate whether there are special regulations for this product in certain states. Indicate whether there are special returns requirements for this product. If yes for either, provide additional information on Page Two in the comment section.

**d. Store product upright / protect from light** – indicate whether the unit of sale needs to be stored upright and/or protected from light.

**e. Shelf Life** - Indicate product's shelf life in months, and initial shelf life at launch, if it is different.

\* **Note** - Additional information can be provided on page 2.

## ITEM AND PACKING INFORMATION

### Order Information

**Unit of Sale** - Indicate the smallest selling unit by choosing from the options below or writing in if not listed.

**NDC Selling Unit** – Indicate (write-in) the order unit that will be transmitted by the distributor to the manufacturer (e.g. one box of 10 vials). (i.e., What is the selling unit indicated by the NDC field on Line 4 above?)

**Minimum Order Quantity (MOQ)** - Indicate whether there is a minimum order quantity required and, if so, how many and of which package type (**Each, Inner/Carton or Case**).

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

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

**Volume (Cube)** - Enter the calculation of cube dimensions here for case, carton, item and pallet, as appropriate. Cubic volume of item usu. expressed in inches.

**# of Pieces per level** – Enter the number of items in each packaging level.

**UPC** - Indicate product case and carton's 12 digit Universal Product Code (UPC) Number

## PHARMACY ORDER / BILL INFORMATION

**Recommended Selling Unit** – Indicate (write-in) the recommended selling unit to the customer (e.g. one vial).

**Rx Billing Unit** – Check the National Council for Prescription Drug Programs (NCPDP) billing unit standard: Each, Gram or Milliliter as appropriate.

### Other Product Information

**Size/Strength/Form** – Size and strength may be stated in milligrams or as extra, medium, etc. Also, indicate form of product as required, e.g., tab cap, gel cap, etc.

**Product Shape** - Include the shape as listed on the package insert. Example “Oval”

**Product Color** – Include the color as listed on the package insert. Example “Purple”

**Product Imprint** – List imprint, if any. Example: “dp25”

### COST INFORMATION

**Regular Cost Per Unit of Sale (\$)** – List the cost for the distributor to order the sellable unit and the “as of date.”

**Invoice Cost (\$)** – Include the invoice cost, which is also known as Wholesale Acquisition Cost. WAC represents the manufacturer’s published catalog or list price for a drug product to wholesalers as reported to First Databank by the manufacturer. WAC does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions in price. [www.fdbhealth.com/policies/drug-pricing-policy](http://www.fdbhealth.com/policies/drug-pricing-policy)

**Federal Excise Tax Per Unit of Sale** – Section 4191 of the Internal Revenue Code imposes a 2.3% excise tax on the sale of certain medical devices by the manufacturer/importer of the device. This tax applies to sales of taxable medical devices made after December 31, 2012.

Reference: [Internal Revenue Service \(IRS\) final regulations](#) and [interim guidance](#) December, 2012

**Attach copy of SAFETY DATA SHEET (MSDS) or non-hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE**

\*Provide additional information on Page 2.

See Page 3 (new in 2013) for Designated Drop Ship Product Only.

## PAGE TWO

### Material Hazard Classification and Transportation

This section of the form is intended to help pass along important product-specific information to assist all channel members in meeting hazardous material, dangerous goods shipping, and occupational health and safety regulatory requirements. **It is critical it be provided.**

**Cytotoxic** – Indicate whether the product is cytotoxic. Antineoplastic/Cytotoxic: A class of drug that is cell-killing or used to stop the spread of abnormal tissue (neoplasms). These are often used to treat cancers.

**CA Prop. 65 Carcinogen or Reproductive Toxicant** – Indicate whether the product is classified as a carcinogen under California’s proposition 65. Proposition 65 regulates substances listed by California as causing cancer or birth defects or other reproductive harm.

Reference: [California EPA - Chemicals Known to Cause Cancer or Reproductive Toxicants May 2013](#)

**Contact Hazard** – Indicate whether this contains a contact-hazard chemical, an allergen or sensitizer when it meets any of the following:

Is so identified or described in the SDS or on the label;

Is so identified or described in the medical or industrial hygiene literature; or

Is known or found to be an allergen or sensitizer.

**Special Clean-up Instructions** - Indicate whether product requires special clean-up instructions, and attach instructions on **Safety Data Sheet (SDS)**. Note: The overview of the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) - <https://www.osha.gov/dsg/hazcom/ghs.html> and the change to Safety Data Sheets (SDSs) from Material Safety Data Sheets (MSDS) is described here: <https://www.osha.gov/dsg/hazcom/ghs.html#4.9>

**Does the product contain DEHP?** Indicate whether the product contains Di (2-ethylhexyl) phthalate (DEHP), a plasticizer (softener) added to increase the flexibility of the polymer of most PVC medical devices such as IV bags or tubing.

**Hazardous Waste Identification** - Indicate the Environmental Protection Agency (EPA) waste code corresponding to the type of hazardous or characteristic waste. Fill in based on the Reference Lists of Hazardous Wastes (should include the letter F, K, P, U or D and a corresponding number).

EPA Reference: <http://www.epa.gov/osw/hazard/wastetypes/pdfs/listing-ref.pdf>

There are four different lists of hazardous wastes that are located in Title 40 of the CFR at Part 261. These four lists are:

The F list (non-specific source wastes) is found in the regulations at 40 CFR 261.31.

The K list (source-specific wastes) is found in the regulations at 40 CFR 261.32.

The P list and the U list (discarded commercial chemical products) can be found in the regulations at 40 CFR 261.33.

EPA Characteristic Waste (D-list): Indicate which of the D list (characteristic wastes) (D004-D0043).

<http://www.epa.gov/osw/hazard/wastetypes/characteristic.htm>

**Indicate whether the product is regulated for shipment by the US Department of Transportation (DOT) and if so, complete the following a – d:**

- a) **Hazard Class:** DOT classifies material into nine internationally recognized classes and two domestic-only classes. The classes are defined in 49 CFR 171.8 and are needed for storage and transport of the material. Class may be found in column 3 of the DOT Hazardous Substance Table 49 CFR 172.101.

Reference:

[http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/Hazmat/Alpha\\_Hazmat\\_Table.pdf](http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/Hazmat/Alpha_Hazmat_Table.pdf)

- b) UN/ID Number:** This is the United Nations of North American identification number for a hazardous substance which is required for transporting the material. It may be found in column 4 of the DOT Hazardous Materials Table 49 CFR 172.101.  
Reference:  
[http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/Hazmat/Alpha\\_Hazmat\\_Table.pdf](http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/Hazmat/Alpha_Hazmat_Table.pdf)
- c.) Packing Group:** The packing group (designated in Roman numerals) prescribed for the material in column 5 in 49 CFR, Part 172.101 Table, indicating the degree of danger presented by the material. The shipper is responsible for determining the appropriate packing group.
- d.) Inhalation Hazard** – Indicate whether the product is an inhalation hazard.

**Indicate whether it is a reportable quantity (RQ) and include the RQ Threshold if so.**

Reference: 49 CFR. 171.8 and 49 CFR. 172.101 [Appendix A](#).

**Indicate whether it is a marine pollutant.**

Reference: [Guidance on the Transportation of Marine Pollutants](#)

**Indicate whether the product is shipped utilizing an authorized DOT exception or Special Permit.** If yes, identify the method in the space provided. Select from the options listed as appropriate. [Limited Quantity; Consumer Commodity, ORM-D; Small Quantity (49 CFR 173.4); Special Permit; DOT-SP; Special Provision (listed in Column 7 of 49 CFR 172.101)]

**Indicate whether the product is restricted for air shipment, and check “Passenger,” “Cargo,” or “Passenger & Cargo” as appropriate.**

### Additional Product Information - Serialization

**Serialized?** Indicate whether the product has been individually identified with a serial number.

If so, indicated to what level (**item, case or pallet**) and how (via **2D or linear barcode or RFID** tag). If not, write in the date product will be serialized. Also indicate the 14 digit Global Trade Item Number (GTIN) in space provided, as appropriate. Indicate whether items are **aggregated to the case**.

### Storage Information

**Indicate as appropriate the classifications that impact product storage.**

**Organic/Inorganic** - OSHA requires only compatible chemicals be stored, packaged and shipped together. Organic and inorganic substances must be separated. Organic substances contain carbon compounds. Inorganic substances do not involve organic life and are not products thereof, i.e., carbon.

**Antineoplastic** - A class of drug that is cell-killing or used to stop the spread of abnormal tissue (neoplasms). These are often used to treat cancers.

**Corrosive** - A product that contains chemicals that have the potential to react with or migrate from other hazardous materials. The reaction tends to dissolve or wear away gradually by a chemical action (e.g., rust).

**Steroid/Androgen** - A class of drug now regulated as controlled substances by federal and state governments. They are fat-soluble, organic compounds and hormones.

**Oxidizer** - A substance that combines with oxygen to form an oxide or induces another substance to oxidize.

**Aerosol** - Indicate whether product is packaged under pressure with gaseous propellant for release as an aerosol and requires special storage.



**Aerosol Class** - Aerosols are classed by the National Fire Protection Association as level one, two or three depending on the flammability and mix of the propellant. Level one is the least flammable, level three the most. Automotive products are typically level three.

**Listed Chemical** – Is this a chemical classified by the DEA in 21 CFR 1310.02(a) that may be used in illegally manufacturing controlled substances? Note: All listed chemicals are precursor chemicals. (Identify which listed chemical type below).

**REMS or Registry Restrictions**

Indicate whether there is REMS (Risk Evaluation and Mitigation Strategy) on this product and if so, indicate if it is managed with a pharmacy registry and include a URL if appropriate. Add comments / details as needed. For example, write in if this product is in the iPledge program (for isotretinoin), if applicable.

**Return Instructions**

Indicate the contact phone number for damaged product; indicate whether the product is returnable for credit and including a link to the returns policy.

Indicate whether there are any special returns requirements in particular states and use the comment field as needed.

**Class of Trade Restrictions**

Indicate whether there are any restrictions to the types of customers who can receive the product and include comments as needed.

**Additional Information**

If the product is barcoded to the unit level (unit dose), indicate the NDC.

**Miscellaneous Notes**

Include any other information here and an image of the product barcode if it is available. If you were unable to provide complete information in a fill-in box, indicate (See Notes) and then place the information in this field.

**PAGE 3 INSTRUCTIONS**

This page 3 (new in 2013) is provided for products designated as “drop ship only,” and contains information that will be required for the order to be processed. Complete sections as appropriate. Sections include:

- Order Method (EDI, autofax, fax, phone, website, minimum order quantity, contact #s, 3PL)
- Standard Order Receipt and Processing (P.O. receipt cut off time, lead time, shipping)
- Expedited Freight Information (Expedited or drop ship fee indicator and comments)
- Overnight and Priority Overnight Processing (Overnight PO processing details)
- Class of Trade Restriction (Restrictions to particular customer types, if any)
- REMS or Registry Restrictions (REMS or registry program details)
- Return Instructions (Contact # for damages, return policy, special return regulations)
- Additional Information (Physician/ clinic information, patient procedure date if applicable)
- Miscellaneous Notes