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
- ADDITIONAL PRODUCT INFORMATION
- PRODUCT DESCRIPTION
- DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION
- FOR GENERIC DRUG PRODUCTS
- GTIN PRODUCT INFORMATION
- SPECIAL HANDLING AND STORAGE REQUIREMENTS
- ORDER INFORMATION
- PHARMACY ORDER/ BILL UNIT
- ITEM AND PACKING INFORMATION
- COST INFORMATION PAGE

PAGE TWO
- MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION
- SDS HAZARD CLASSIFICATION
- HAZARDOUS WASTE IDENTIFICATION
- ADDITIONAL STORAGE INFORMATION
- CLASS OF TRADE RESTRICTION
- REMS or REGISTRY RESTRICTIONS
- RETURN INSTRUCTIONS
- MISCELLANEOUS NOTES AND BARCODE IMAGE

PAGE THREE – FOR PRODUCTS DESIGNATED AS DROP-SHIP ONLY
- ORDER METHOD
- EXPEDITED FREIGHT INFORMATION
- CLASS OF TRADE RESTRICTION
- OTHER DATA REQUIRED TO PROCESS PURCHASE ORDER
- MISCELLANEOUS NOTES
- STANDARD ORDER RECEIPT AND PROCESSING
- OVERNIGHT AND PRIORITY OVERNIGHT PROCESSING
- RETURN INSTRUCTIONS
- ADDITIONAL INFORMATION

Although not all information on the form is required by each distribution trading partner, this form includes the data points a majority of HDA members most frequently request from suppliers for item set up. 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. This form is provided as a guide to new item set up for use between trading partners.

In 2017, the names of certain fields were changed to make the form more consistent with language used by FDA and in other HDA guidelines. The form was reorganized to create a more logical grouping and flow, which eliminated redundant questions in some instances. Additions and changes include:

Page One
- Separate fields for selling unit NDC and individual unit NDC, if applicable
- A write-in field for product therapeutic classification
- A write-in field for Country of Origin
- A check box to select if the product is subject to the Trade Agreements Act
- Separation of the fields for size, strength, and dosage form
- The simplification of the generic drug products section and a check box for authorized generic
- A Global Location Number (GLN) was added to the DSCSA section of the form.
- A check box was added to the GTIN product information to note which level is the saleable unit and additional blank space was added to accommodate additional levels.
- The form validates the GTIN to ensure it is correct; an error message will show if it is incorrect.
- Temperature options and corresponding ranges were modified.
- A group email box was added for temperature excursion questions.
- An automatic calculation for volume of a cube was added.
- “Box/carton” was modified to include additional options—“bundle” and “inner pack” for clarity.

Page Two
- The material handling classification and transportation section was modified to include “proper shipping name” and the order of questions was changed to be consistent with DOT’s sequence of the basic description.
- Listed chemicals were changed to a drop down and additional following questions were added to note if it is a scheduled listed chemical product.
- The options for “is this product a NIOSH hazardous drug” were modified to include groups.
- REMS or Registry information previously also on page 3 (for drop ship only) was consolidated onto page 2.

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.

Application: Indicate in drop-down menu whether product is a new item, promotion/deal, open stock, or post launch change.

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device)- Indicate which type of application authorizes product for marketing and its application number, e.g., NDA 012345; ANDA oo1234; 510(k) K12345; PMA P12345, etc.

DUNS: Provide the unique nine-digit identifier number for the company.

Proprietary Name (if applicable) and Established Name: Enter product proprietary/trade/brand name, if applicable, and established (compendial or common/usual) name.

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

Individual Unit NDC: Indicate the 10-digit National Drug Code (NDC) Number for the prescription drug product contained within the selling unit NDC, e.g. for items that sell as a box of 25 individual vials, indicate the NDC number of the vials.

Unique Device Identification (UDI) (if applicable): Indicate the UDI, if assigned.


CVX: If applicable, indicate the numeric U. S. Licensed Vaccine Administered (CVX) code that identifies the type of vaccine product used.

MVX: If applicable, indicate the alphabetic string that identifies the manufacturer of the vaccine product.

Description: Enter product description in space provided. This description should match what was included on the FDA application, license, or clearance (e.g., [Established Name] Tablets USP, 20 mg; Prosthetic Heart Valve).

Active Ingredient(s): The active ingredient (or ingredients) is any component of a drug product 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 of humans or other animals. 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.

Product Therapeutic Classification: The therapeutic category/pharmacological class to which the product belongs, e.g., Antipsychotic, Aldosterone Receptor Antagonist, or as otherwise identified on the drug's package insert.


Additional Product Information

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.”

Reverse Numbered: Unit Dose product which has each dose on a punch card numbered from largest number to lowest number.

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

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).

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, that is, in the manufacturer's original, sealed, labeled container, 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 Reverse Numbered box.

**Country of Origin:** Enter the country of origin as defined in 19 CFR 134.1, that is, the country of manufacture, production, or growth for any article of foreign origin entering the United States. Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the “country of origin.” For a good of a NAFTA country, the NAFTA Marking Rules will determine the country of origin. Reference: https://www.cbp.gov/trade/nafta/country-origin-marking

**Products Covered Under the Trade Agreements Act (TAA):** Note if the product is covered by the Trade Agreements Act ([19 USC 2501 Trade Agreements Act](https://www.cbp.gov/trade/nafta/country-origin-marking))

**Product Description**

**Size/Strength/ Dosage Form:** Size refers to total quantity in container. For example, 1000 count bottle, 100 mg, capsule; 5 vials, 400 mg/vial; lyophilized powder injection.

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

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

**Product Imprint** – List imprint, if any. For example, “dp25.”

**FOR GENERIC DRUG PRODUCTS**

**Authorized Generic:** Check the box to indicate if the product is an authorized generic. If product is an authorized generic, other section fields are not applicable.
Reference: [http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm126391.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm126391.htm)

**Orange Book Rating:** For generic products, provide the [FDA Orange Book Therapeutic Equivalence Evaluation](https://www.fda.gov/drugs/consumerinformation/consumerinformation-drugs-and-drug-products/orange-book), e.g., AB, AT, AP etc.

**Generic Equivalent to What Brand:** Enter brand name for the generic equivalent in this field.

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

This section supports implementation of the DSCSA applicable to certain prescription pharmaceuticals.

**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](http://www.law.cornell.edu/uscode/text/21/360eee) for definition of “manufacturer.”

**Is product exempt from DSCSA?** Answer Yes or No based on the exemptions listed in the DSCSA. If yes, select from the drop-down menu or write in the exemption. Exemptions include but are not limited to the following:

- 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 and OTC drugs.

See [http://www.law.cornell.edu/uscode/text/21/360eee](http://www.law.cornell.edu/uscode/text/21/360eee) for definitions of “product” and “transaction.”

**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 manufacturer (mfr)?** If product is repackaged, 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. See [http://www.law.cornell.edu/uscode/text/21/360eee](http://www.law.cornell.edu/uscode/text/21/360eee).

**Has FDA granted waiver/exception/exemption for product?** Indicate whether FDA has granted a waiver, exception, or exemption from DSCSA requirements for the product. If yes, attach relevant documentation from FDA granting the waiver, exception or exemption.

**GTIN PRODUCT INFORMATION**

**Serialized?** Indicate whether the product has been individually identified with a serial number. If so, indicated to what level (item, case or pallet). If not, write in the date product will be serialized.

**Items aggregated?** Indicate whether items are aggregated.

**Level:** For each level of packaging, provide the corresponding information.
Saleable Unit: Check the level of packaging that is the saleable unit.

2D and Linear: Check the box for the type of bar codes contained on each level of packaging

Quantity: Provide the number of units within in the corresponding level of packaging

GTIN 14: Indicate the 14-digit Global Trade Item Number (GTIN) in space provided, as appropriate. Note that GTIN validation is performed. An error message will indicate if the GTIN is invalid.

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, phone number, and, if available, a group email for questions.

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 any 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.

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).
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.

ITEM AND PACKING INFORMATION

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) – Volume will be automatically calculated based on the dimensions entered, expressed as cubic 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.

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. See 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.


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.
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 for Designated Drop Ship Product Only.
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.


**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.who.int/occupational_health/](https://www.who.int/occupational_health/) 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](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).


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.
Indicate whether the product is regulated for shipment by the US Department of Transportation (DOT) or International Air Transport Association (IATA) and if so, complete the following a – e:

a. **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:  

b. **Proper Shipping Name**: Enter Proper Shipping Name for the material as listed in DOT’s Hazardous Materials Table.
   Reference:  

c. **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:  

d. **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.

e. **Inhalation Hazard** – Indicate whether the product is an inhalation hazard.

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

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.

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 172.10.

**Storage Information**

**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)
**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).

**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 21 CFR 1308.03.


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

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**Class of Trade Restrictions**

**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.

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**SDS Hazard Classification**

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.
Is this product a NIOSH hazardous drug? Indicate if the product is a NIOSH hazardous drug and which category:

- Group 1 items (antineoplastic)
- Group 2 items (non-antineoplastic that meets a hazard criterion)
- Group 3 items (primarily adverse reproductive effects)

For Group descriptions, see page 7 of: [https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf](https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf)

**REMS or Registry Restrictions**
Indicate whether there is REMS (Risk Evaluation and Mitigation Strategy) on this product (such as iPledge for isotretinoin) and, if so, indicate if it is managed with a pharmacy registry and include a URL if appropriate. Add comments / details as needed.

**Return Instructions**
Indicate the contact phone number for damaged product; indicate whether the product is returnable for credit and include a link to the returns policy. Indicate whether there are any special returns requirements in particular states and use the comment field 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.
This page 3 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 numbers, 3PL)
- Expedited Freight Information (expedited or drop ship fee indicator and comments)
- Class of Trade Restriction (restrictions to particular customer types, if any)
- Miscellaneous Notes
- Standard Order Receipt and Processing (P.O. receipt cut off time, lead time, shipping)
- Overnight and Priority Overnight Processing (overnight PO processing details)
- Return Instructions (contact number for damages, return policy, special return regulations)
- Additional Information (physician/clinic information, patient procedure, date if applicable.