Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)

October 2021
Procedural

Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs
and/or
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Room 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010
Email: ocod@fda.hhs.gov
https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances
and/or
Policy and Regulations Staff, HFV-6
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place, Rockville, MD 20855
https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
October 2021
Procedural

Contains Nonbinding Recommendations

TABLE OF CONTENTS

Contains Nonbinding Recommendations

Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

FDA is issuing this Technical Conformance Guide (guide) to assist registrants of drug establishments (or their authorized agents) in submitting reports on the amount of each listed drug manufactured, prepared, propagated, compounded, or processed for commercial distribution, as required by section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act),[2] as added by section 3112(e) of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).[3] This guide supplements the draft guidance for industry *Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act* (October 2021).[4] The guide describes 1) how first-time users can access FDA's CDER NextGen Portal[5] (the portal) to submit these reports, 2) the different methods for submitting the reports through the portal, and 3) the data elements to be included in the reports.

The data elements described in this guide apply to reports for listed drugs including medical gases;[6] homeopathic products; products marketed in accordance with requirements under section 505G of the FD&C Act,[7] often referred to as over-the-counter monograph drugs; and animal

[1] This guidance has been prepared by the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research and the Center for Veterinary Medicine at the Food and Drug Administration. You may submit comments on this guidance at any time. Submit comments to Docket No. FDA-2017-D-6821 (available at https://www.regulations.gov/docket?D=FDA-2017-D-6821). See the instructions in that docket for submitting comments on this and other Level 2 guidances.

[2] 21 U.S.C. 360(j)(3)

[3] Public Law 166-136

[4] When final, this guidance will represent the FDA's current thinking on this topic. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[5] All registrants (not just registrants of CDER-regulated drug establishments) should use the CDER NextGen Portal to submit reports as required under section 510(j)(3) of the FD&C Act.

[6] For purposes of this guidance, *medical gas* and *designated medical gas* have the meanings set forth in section 575 of the FD&C Act.

[7] Under section 505G of the FD&C Act, certain nonprescription drug products may be lawfully marketed without an approved application under section 505 of the FD&C Act if applicable requirements are met.

drug products that are not approved, conditionally approved, or indexed under sections 512, 571, and 572 of the FD&C Act.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

On March 27, 2020, the CARES Act was enacted to aid response efforts and ease the economic impact of the Coronavirus Disease 2019 (COVID-19). The CARES Act includes authorities to enhance FDA's ability to identify, prevent, and mitigate possible drug shortages by, among other things, improving FDA's visibility into drug supply chains. Section 3112(e) of the CARES Act added new section 510(j)(3) to the FD&C Act. Under section 510(j)(3), each person (including repackers and relabelers) who registers under section 510 of the FD&C Act with regard to a drug must report to FDA annually the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution.[8]

III. USING THE CDER NEXTGEN PORTAL

All registrants or their authorized agents should use the portal to submit reports on the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed for commercial distribution. If you are a first-time user, you will need to register and create an account.[9] You may submit reports through the portal by 1) uploading a comma-separated values (CSV) file,[10] or 2) manually entering information.

To upload data to the portal as a CSV file, you should use the template provided in the portal. The CSV template file will display in a Microsoft Excel format; you can paste or type your data into it and then upload the file to the portal. If you create your own CSV file instead of using the provided template, formatting must match the CSV template to ensure that it uploads successfully. A user guide with step-by-step instructions for downloading the template file, entering the data, and submitting the report using this method is available via the portal.

---

[8] Under section 510(j)(3)(B) of the FD&C Act, FDA may issue an order to exempt certain biological products or categories of biological products regulated under section 351 of the Public Health Service Act from some or all of the reporting requirements under section 510(j)(3)(A) of the FD&C Act, if FDA determines that applying such reporting requirements is not necessary to protect the public health. FDA has issued a Proposed Order that, if finalized, would exempt from section 510(j)(3)(A) reporting requirements the following categories of biological products: (i) blood and blood components for transfusion; and (ii) cell and gene therapy products, where one lot treats a single patient.

[9] For further instruction, see the reference guide available at https://edm.fda.gov/customThemeStatic/themes/customTheme/docs/CDERDirectNextGen_ReferenceGuide_SF.pdf

[10] The CSV template showing the data elements is available at https://www.fda.gov/drugs/drug-shortages/cders-coronavirus-aid-relief-and-economic-security-act-cares-act-drug-shortage-mitigation-efforts.

To enter data into the portal manually, you will use the portal's interface to provide the appropriate information by following a series of prompts, using drop-down boxes, and entering free text. A user guide with step-by-step instructions for entering the data manually and submitting reports is available via the portal.

Technical questions regarding the submission process should be sent to EDMSupport@fda.hhs.gov. For questions regarding the content to be submitted in a section 510(j)(3) report, please contact (CDER) DrugVolumeReporting@fda.hhs.gov; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CVM) Office of Surveillance and Compliance, 240-402-7082 or CVMSurveillance@fda.hhs.gov, as applicable.

IV. DATA ELEMENT SPECIFICATIONS

In general, the submission process includes three steps:

1. Verifying the submitter information: The submitter's information is displayed. This information automatically populates based on information you submitted when registering for your CDER NextGen account.
2. Describing the submission: The system will prompt you to provide information about the submission. Specifically, you will be asked to identify your role with respect to the submission, which calendar year the submission will cover, and how you will complete the report (i.e., by submitting manually or by uploading data from a CSV file).
3. Completing the report: The system will prompt you to either complete the report by using manual entry or by uploading data from an appropriately formatted CSV file.

We describe the data elements relevant to each of these steps in more detail below. These descriptions will help you complete the process and understand what information to include for the various data elements at each step. For additional information, illustrative examples are also included in the Appendix to facilitate reporting amounts of listed drugs.

A. Submitter Information

The following data elements come directly from your CDER NextGen account profile and are displayed for identity verification purposes. These data elements are read-only on this display; you can change them by updating your CDER NextGen account profile.[11]

1. First Name and Last Name

This is the first and last name you provided during portal registration.

2. Email

This is the email address you provided during portal registration.

[11] If you are submitting as an authorized agent, see section IV.B.1 for further detail.

3. Phone Number and Extension

This is the phone number and optional extension you provided during portal registration.

4. Organization Name

This is the organization name you provided during portal registration.

5. Organization Address

This is the address you provided during portal registration. This data element is separated as Address Line 1, Address Line 2, City, State/Province, Zip/Postal Code, and Country.

B. Submission Description Elements

You will enter the following data elements into the portal interface regardless of whether you plan to submit the report manually or by uploading data from a CSV file.

A separate submission is needed for each report, but each report may include multiple establishments and multiple national drug codes (NDCs). The elements selected for the following fields will apply to every establishment and NDC included in the submission.

1. Submitter Type

The system will prompt you to indicate whether you are submitting the information as the registrant of the reporting establishment or as an authorized agent on behalf of the registrant of the reporting establishment.

- If you are an employee of the reporting establishment or of another organization with or under common control or ownership of the reporting establishment (e.g., parent, subsidiary, affiliate), you should indicate that you are submitting this information as a registrant.
- If you are not an employee of the reporting establishment or of another organization under or with common control or ownership of the reporting establishment, you should indicate that you are reporting as an authorized agent.
- If your role differs based on the establishment for which you are reporting (i.e., you will be submitting as a registrant for some and as an authorized agent for others), you need to submit these reports separately because the submitter type will apply to every establishment and NDC included in the report. For example, if you are an employee of a registrant that manufactures its own drugs but also relies on contract manufacturers to manufacture drugs that your organization distributes as a private-label distributor, and you plan to submit a report for the drugs your establishment manufactures and on behalf of your contract manufacturer for the drugs your organization distributes as a private-label distributor, you need to submit one report in which you identify your role as registrant and another report in which you identify your role as authorized agent.

2. Reporting Year

The system will prompt you to select which calendar year the submission covers.

3. Data Submission Method

The system will prompt you to indicate whether you will submit the report manually or by uploading data from a CSV file.

C. Data Elements for Reporting the Amount of Listed Drug

The data elements described in this section comprise the specific information for reporting (whether manually or by uploading data from a CSV file) the amount of listed drug manufactured, prepared, propagated, compounded, or processed for commercial distribution.

A report will not be considered ready for submission unless, at a minimum, it:

- Identifies at least one establishment by Data Universal Numbering System (DUNS) number
- Identifies at least one drug by NDC at that establishment
- Identifies the business operation performed at that establishment with respect to that drug

The portal will automatically check the entered DUNS number and NDC against FDA's internal database. If an entered DUNS number or NDC is not found in the internal FDA database, that entry will be flagged and a message will display on the screen. If the entry is flagged, you can change the entry,[12] or you can proceed with your submission if you know the number is valid and accurate even though it was not found in the internal FDA database.

The submission format allows you to provide a single report for multiple establishments. Recognizing that each establishment may perform different business operations with respect to different drugs, instead of identifying the business operations for each NDC, the report is designed to allow establishments to identify the different business operations performed and then identify the specific drugs, by NDC, for which they perform that business operation. However, as explained in more detail below, you should generally associate an NDC with only a single business operation at each establishment.

1. Establishment Identity

You will include the DUNS number for each establishment covered by the submission.

[12] For a manual submission, you can change the number manually in the portal. To change the number for a CSV submission, you need to update the CSV file and resubmit it.

2. Business Operation

For each establishment you identify, the drugs for which you are reporting for that establishment will be grouped by business operation performed. To simplify the reporting, we have limited the types of business operations to:

- MANUFACTURE
- API MANUFACTURE
- REPACK
- RELABEL
- TRANSFILL
- POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION

You should select the single business operation that best describes the activities the establishment performs for each NDC for which you reported for that establishment.

- MANUFACTURE is the default selection. You should select this option unless one of the other business operations applies to the NDC for which you are reporting.
- API MANUFACTURE applies only if the NDC for which you are reporting identifies an API (active pharmaceutical ingredient) and the establishment performed operations besides repackaging or relabeling the API.
- REPACK applies only if the establishment repackaged[13] the drug and that drug was manufactured at a different establishment.
- RELABEL applies only if the establishment relabeled[14] the drug and that drug was manufactured at a different establishment.
- TRANSFILL applies only if the NDC for which you are reporting is a medical gas and the establishment transfills that medical gas.
- POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION applies only if the NDC for which you are reporting identifies a positron emission tomography drug.

Generally, you should not enter an NDC in association with more than one business operation at a specific establishment. For example, if you manufacture both the API and the finished dosage form at a single establishment, you should not enter the NDC for the finished dosage form under

[13] For purposes of selecting the appropriate business operation, *repackaging* involves removing the drug from the container in which it was received by the establishment and placing the drug into a different container without manipulating, changing, or affecting the composition or formulation of the drug (see 21 CFR 207.1). Although the establishment may have placed a different label on the repackaged drug, this operation is included within the activities associated with repackaging a drug.

[14] For purposes of selecting the appropriate business operation, *relabeling* involves changing the existing label or labels on the drug's package, or changing or altering the drug's existing label, without repackaging or manipulating, changing, or affecting the drug's composition or formulation (see 21 CFR 207.1).

both MANUFACTURE and API MANUFACTURE; you should just enter the NDC under MANUFACTURE.[15]

In some circumstances, it may be appropriate to enter the same NDC under separate business operations at a single establishment. For example, if you are a repackager and a relabeler for a specific drug, and sometimes you repackage the drug and sometimes you just relabel the drug, then you should include the NDC under both REPACK and RELABEL and include the appropriate amounts with respect to each business operation.

3. NDC

To identify each drug for which you are reporting, you will use the 10-digit NDC for the drug as listed with FDA. You will need to format the NDC using hyphens between the labeler code, the product code, and the package code. Appropriately formatted NDCs should have one of the following configurations: 4-4-2 (e.g.,1234-5678-90), 5-4-1 (e.g., 12345-6789-1), 5-3-2 (e.g., 12345-678-90).[16]

4. Outermost Package — Quantity Released

You should enter the quantity of the drug that the establishment manufactured, prepared, propagated, compounded, or processed for commercial distribution[17] during the relevant time period. This quantity should be based on the number of units measured by the drug's outermost packaging. We request that you provide this amount based on the month in which the drug was released.[18] For months in which a drug was released, you should include a positive (non-zero) integer; for months in which no drug was released, you can leave the field blank or enter a zero. Based on the monthly data provided, the system will calculate the annual sum.

5. Outermost Package — Quantity Distributed (Non-U.S.)

If you are including this information in the report as an alternate reporting process to the annual report as required by 21 CFR 314.81 as discussed in the draft guidance for industry *Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act*, you should enter only the amount of a listed drug that the establishment manufactured, prepared, propagated, compounded, processed for commercial distribution and distributed for foreign use during the reporting period that would have been included in an annual report as required by 21 CFR 314.81. We request that you provide this amount based on the month that the drug was distributed. For months in which a drug was distributed, you should include a positive (non-zero)

[15] However, if you manufacture both the API and the finished dosage form at a single establishment, and you separately list the API with its own NDC, then you should include the NDC for the finished dosage form under MANUFACTURE and the NDC for the API under API MANUFACTURE.

[16] For certain minimally manipulated human cell and tissue products, you may use an alternatively formatted NDC approved for use by the relevant center director.

[17] See 21 CFR 207.1 (defining *commercial distribution*).

[18] For the purposes of this guidance, *released* means that the batch or lot has been determined to conform to final specifications (see 21 CFR 211.165 and the ICH guidance for industry *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* (September 2016) (ICH Q7)), and the production and control records have been reviewed and approved by the quality control unit (see 21 CFR 211.192 and ICH Q7).

integer; for months in which no drug was distributed, you can leave the field blank or enter a zero. Based on the monthly data provided, the system will calculate the annual sum.

The draft guidance for industry *Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act* allows application holders to report through the portal as an alternate reporting process to the annual report as required by 21 CFR 314.81. If the drug's application holder is not seeking to use the alternate reporting process for the distribution data required in an annual report under 21 CFR 314.81, you should leave this field blank. If a listed drug is not subject to an approved application for which an annual report is required under 21 CFR 314.81, then you should leave this field blank.

6. Outermost Package — Package Type

You should enter the package type associated with the NDC for which you are submitting data. Values entered here should adhere to the FDA package types as outlined in the portal or the CSV template file.

7. Source NDC

For drugs listed under REPACK or RELABEL, you should provide the source NDC in the appropriate format (i.e., using hyphens between the labeler code, the product code, and the package code) using the 10-digit NDC assigned to the drug received by the repacker or relabeler for repacking or relabeling. Appropriately formatted NDCs should have one of the following configurations: 4-4-2 (e.g.,1234-5678-90), 5-4-1 (e.g., 12345-6789-1), 5-3-2 (e.g., 12345-678-90). This configuration is used to identify the drug that was repacked or relabeled, so that FDA can avoid double counting this drug when analyzing the data.

8. Innermost Package — Quantity Released

You should use this field for multi-level packaged drugs only. You should enter the quantity of the drug that the establishment manufactured, prepared, propagated, compounded, or processed for commercial distribution during the relevant time period. This quantity should be based on the number of units measured by the drug's innermost packaging. We request that you provide this amount based on the month in which the drug was released. For months in which a drug was released, you should include a positive (non-zero) integer; for months in which no drug was released, you can leave the field blank or enter a zero. Based on the monthly data provided, the system will calculate the annual sum.

9. Innermost Package — Quantity Distributed (Non-U.S.)

You should use this field for multi-level packaged drugs only. If you are including this information in the report as an alternate reporting process to the annual report as required by 21 CFR 314.81 as discussed in the draft guidance for industry *Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act*, you should enter only the amount of a listed drug that the establishment manufactured, prepared, propagated, compounded, processed for commercial distribution, and distributed for foreign use during the reporting period

that would have been included in an annual report as required by 21 CFR 314.81. We request that you provide this amount based on the month in which the drug was distributed. For months in which a drug was distributed, you should include a positive (non-zero) integer; for months in which no drug was distributed, you can leave the field blank or enter a zero. Based on the monthly data provided, the system will calculate the annual sum.

The draft guidance for industry *Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act* allows application holders to report through the portal as an alternate reporting process to the annual report as required by 21 CFR 314.81. If the drug's application holder is not seeking to use the alternate reporting process for the distribution data required in an annual report under 21 CFR 314.81, you should leave this field blank. If a listed drug is not subject to an approved application for which an annual report is required under 21 CFR 314.81, then you should leave this field blank.

10. Innermost Package — Package Type

You should use this field for multi-level packaged drugs only. If you are submitting information for a listed drug that has multiple levels of packaging, this field should reflect the package type directly enclosing the drug for which you are reporting data. Values entered here should adhere to the FDA package types as outlined in the portal or the CSV template file.

11. Market Unknown

You should use this field only when reporting for foreign establishments. If a listed drug was manufactured, prepared, propagated, compounded, or processed in a foreign establishment for commercial distribution (i.e., in the United States[19]) and the foreign establishment knows how much of the listed drug was imported or offered for import into the United States, then you must report that amount.[20] However, if a listed drug was manufactured, prepared, propagated, compounded, or processed for commercial distribution in a foreign establishment but you do not know how much of the listed drug was imported or offered for import into the United States, then you should report the total amount of the listed drug that was manufactured, prepared, propagated, compounded, or processed (including repacked or relabeled) during the reporting period, and indicate *market unknown.*

[19] See 21 CFR 207.1 (defining *commercial distribution*).
[20] See section 510(j)(3)(A) of the FD&C Act.

V. RESOURCES

- Draft guidance for industry *Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act* (October 2021)
- CDER NextGen Portal[21]
  - Frequently Asked Questions web page
  - Technical Support
  - Reference Guide: Account Registration and Multi-Factor Authentication (MFA) Enrollment Process
- CARES Act Amount Information Reporting Reference Guide[22]

[21] Available at https://edm.fda.gov/.
[22] https://www.fda.gov/drugs/drug-shortages/cders-coronavirus-aid-relief-and-economic-security-act-cares-act-drug-shortage-mitigation-efforts#Reporting%20the%20Amount%20of%20Drugs%20Manufactured

APPENDIX

The following examples illustrate how to submit amounts of listed drugs based on packaging configuration in different scenarios.

Example 1 — Finished Dosage Form With Single-Level Packaging

Drug A is listed under national drug code (NDC) 12340-567-89 with the package description shown in Table 1.

Table 1. Drug A Package Description

Item code	Package description
12340-567-89	100 TABLETS in 1 BOTTLE

Scenario 1 — Drug Manufactured for Commercial Distribution

An establishment (in a particular month) manufactured for commercial distribution and released 2,000 bottles of Drug A. The amount should be entered using the fields shown in Table 2 (corresponding to the month the drug was released). In this scenario, there is no innermost packaging, so those fields should be left blank.

Table 2. Amounts Entered if Drug A Is Manufactured for Commercial Distribution

	Outermost package			Innermost package			
NDC	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Market unknown**
12340-567-89	2000		BOTTLE				

Scenario 2 — Drug Manufactured for Commercial Distribution, Some Distributed to Non-U.S. Markets

An establishment (in a particular month) manufactured for commercial distribution and released 1,700 bottles of Drug A. Of those 1,700 bottles, 200 were distributed for foreign use. If Drug A is subject to an approved application for which an annual report is required under 21 CFR 314.81, and the application holder is seeking to use the alternate reporting process for the distribution data required for the annual report under 21 CFR 314.81, then the amount should be entered using the fields shown in Table 3

(corresponding to the month the drug was released or distributed). The 200 bottles of Drug A that were distributed for foreign use should be included in the *Quantity distributed (non-U.S.)* field. In this scenario, there is no innermost packaging, so those fields should be left blank.

Table 3. Amounts Entered if Drug A Is Manufactured for Commercial Distribution with Some Distributed to Non-U.S. Markets

	Outermost package			**Innermost package**			
NDC	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Market unknown**
12340-567-89	1700	200	BOTTLE				

Scenario 3 — Drug Manufactured for Commercial Distribution, Market Unknown

A foreign establishment (in a particular month) manufactured for commercial distribution and released 1,700 bottles of Drug A, but the establishment does not know how many bottles were imported or offered for import into the United States. The amount should be entered using the fields shown in Table 4 (corresponding to the month the drug was released). Because the establishment does not know exactly how many of the 1,700 bottles were imported or offered for import into the United States, they all should be entered in the *Released* column and the entry should indicate *market unknown.*[1] In this scenario, there is no innermost packaging, so those fields should be left blank.

Table 4. Amounts Entered if Drug A Is Manufactured for Commercial Distribution and Market Is Unknown

	Outermost package			**Innermost package**			
NDC	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Market unknown**
12340-567-89	1700		BOTTLE				YES

[1] How *market unknown* is indicated depends on the method used to provide the data. The example shown in Table 4 reflects using the comma-separated values (CSV) file. For manual entry, the portal prompts the user to check a box for this field.

Example 2 — Finished Dosage Form With Multi-Level Packaging and a Single NDC

Drug B is listed under NDC 12340-567-01 with the package description shown in Table 5. In this example, the case is the outermost packaging because it is the packaging referred to by the NDC. The innermost packaging is the bottle, since it directly encloses the drug (in this case, the capsules). Note that in this example, only the outermost packaging has been assigned an NDC.

Table 5. Drug B Package Description

Item code	Package description
12340-567-01	96 CARTONS in 1 CASE
	5 BOTTLES in 1 CARTON
	60 CAPSULES in 1 BOTTLE

An establishment (in a particular month) manufactured for commercial distribution and released 20 cases of Drug B. The amount should be entered using the fields shown in Table 6 (corresponding to the month the drug was released). In this scenario, the innermost packaging amount should be entered based on the quantities in the package description.

Table 6. Amounts Entered if Drug B Has a Single NDC

	Outermost package			Innermost package			
NDC	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Market unknown**
12340-567-01	20		CASE	9600		BOTTLE	

Example 3 — Finished Dosage Form With Multi-Level Packaging and Multiple NDCs

Drug C is listed under NDC 12340-999-02 with the package description shown in Table 7. In this example, the outermost packaging should be the carton, and the innermost packaging should be blister packs because they directly enclose the drug (i.e., the tablets). The pouches also have been assigned an NDC since they are sometimes commercially distributed on their own outside of the carton.

Table 7. Drug C Package Description

Item code	Package description
12340-999-02	3 POUCHES in 1 CARTON
12340-999-01	5 BLISTER PACKS in 1 POUCH
	21 TABLETS in 1 BLISTER PACK

Scenario 1 — Single Innermost Package Presentation

An establishment (in a particular month) manufactured for commercial distribution and released 20 cartons of Drug C (NDC 12340-999-02). The amount should be entered using the fields shown in Table 8 (corresponding to the month the drug was released). In this scenario, the innermost packaging amount should be entered based on the package description.

Table 8. Amounts Entered if Drug C Has a Single Innermost Package Presentation

	Outermost package			Innermost package			
NDC	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Market unknown**
12340-999-02	20		CARTON	300		BLISTER PACK	

Scenario 2 — Multiple Innermost Package Presentations

An establishment (in a particular month) manufactured for commercial distribution and released 20 cartons of Drug C (NDC 12340-999-02) and separately manufactured for commercial distribution and released 500 pouches of Drug C (NDC 12340-999-01) on their own (not in cartons). The amount should be entered using the fields shown in Table 9 (corresponding to the month the drug was released). In this scenario, the innermost packaging amount should be entered based on the package description.

Table 9. Amounts Entered if Drug C Has Multiple Innermost Package Presentations

	Outermost package			Innermost package			
NDC	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Market unknown**
12340-999-02	20		CARTON	300		BLISTER PACK	
12340-999-01	500		POUCH	2500		BLISTER PACK	

Example 4 — Active Pharmaceutical Ingredient With Single-Level Packaging

Drug D is listed under NDC 23450-567-01 with the package description shown in Table 10.

Table 10. Drug D Package Description

Item code	Package description
23450-567-01	200 kg in 1 DRUM

An establishment (in a particular month) manufactured for commercial distribution and released 50 drums of Drug D. The amount should be entered using the fields show in Table 11 (corresponding to the month the drug was released). In this scenario, there is no innermost packaging, so those fields should be left blank.

Table 11. Amounts Entered if Drug D Has No Innermost Package

	Outermost package			Innermost package			
NDC	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Market unknown**
23450-567-01	50		DRUM				

Example 5 — Active Pharmaceutical Ingredient With Multi-Level Packaging

Drug E is listed under NDC 23450-000-01 with the package description shown in Table 12. In this example, the drum is the outermost packaging because it is the packaging referred to by the NDC. The innermost packaging is the bag, because it directly encloses the substance (i.e., the powder). Note that in this example, only the outermost packaging has been assigned an NDC.

Table 12. Drug E Package Description

Item code	Package description
23450-000-01	2 BAGS in 1 DRUM
	50 kg in 1 BAG

An establishment (in a particular month) manufactured for commercial distribution and released 10 drums. The amount should be entered using the fields shown in Table 13 (corresponding to the month the drug was released). In this scenario, the innermost packaging amount should be entered based on the quantities in the package description.

Table 13. Amounts Entered if Drug E Has Multi-Level Packaging

	Outermost package			Innermost package			
NDC	Quantity released	Quantity distributed (non-U.S.)	Package type	Quantity released	Quantity distributed (non-U.S.)	Package type	Market unknown
23450-000-01	10		DRUM	20		BAG	

Example 6 — Kit With Multiple Components

Kit X is listed under NDC 23451-999-11 with the package description shown in Table 14 and the parts quantities shown in Table 15.

Table 14. Kit X Package Description

Item code	Package description
23451-999-11	1 in 1 CARTON

Table 15. Kit X Parts Quantities

Part number	Package quantity
1	Drug 1 (1 VIAL, MULTI-DOSE)
2	Drug 2 (1 VIAL, SINGLE-DOSE)
3	Drug 3 (1 PACKET)

An establishment (in a particular month) manufactured for commercial distribution and released 200 cartons. The amount should be entered using the fields shown in Table 16 (corresponding to the month the drug was released). For kits, the fields for innermost package should be left blank.

Table 16. Amounts Entered for a Kit With Multiple Components

	Outermost package			Innermost package			
NDC	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Quantity released**	**Quantity distributed (non-U.S.)**	**Package type**	**Market unknown**
23451-999-11	200		CARTON				