Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act

Guidance for Industry

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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)

February 2024
Procedural

Contains Nonbinding Recommendations

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Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act 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

The Food and Drug Administration (FDA) is issuing this guidance to assist registrants of drug establishments[2] in submitting reports to FDA on the amount of each listed drug manufactured,[3] 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) (21 U.S.C. 360(j)(3)), as added by section 3112(e) of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).

This guidance describes the process that should be used for reporting information under section 510(j)(3) by each person who registers with FDA under section 510 of the FD&C Act with regard to a listed drug (including a drug product that is in finished package form, a drug product that is not in finished package form, an active pharmaceutical ingredient (API), and other types of listed drugs, except for biological products or categories thereof exempted by an order under section 510(j)(3)(B)).[4] Listed drugs subject to reporting include human drug products (including non-exempt biological products) marketed under an approved application, animal drug products marketed under an approved application, medical gases,[5] homeopathic products, products

[1] This guidance has been prepared by the Office of Regulatory Policy and the Office of Pharmaceutical Quality in 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.

[2] For the purposes of this guidance, the terms "establishment" and "facility" are used interchangeably.

[3] For the purposes of this guidance, "manufacture" means the manufacture, preparation, propagation, compounding, and processing of a drug. "Manufacture, preparation, propagation, compounding, or processing" also includes repackaging and relabeling. See section 510(a) of the FD&C Act; § 207.1 (21 CFR 207.1) (definitions of *manufacture* and *manufacturer*).

[4] 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 an order that exempts 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. See 88 FR 22454 (Apr. 13, 2023). See also Question & Answer IV.J.

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

marketed in accordance with requirements under section 505G of the FD&C Act (21 U.S.C. 355h),[6] often referred to as over-the-counter monograph drugs, and animal drug products that are not approved, conditionally approved, or indexed under sections 512, 571, and 572 of the FD&C Act.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and 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

An establishment engaged in the manufacture of a drug in the United States is required to be registered with FDA.[7] Likewise, any establishment within a foreign country engaged in the manufacture of a drug that is imported or offered for import into the United States is also required to be registered with the FDA.[8, 9] Further, domestic and foreign registrants are required to list with FDA all the drugs being manufactured by their registered establishments for commercial distribution.[10] Each registrant must provide certain information[11] for each listed drug it manufactures for commercial distribution,[12] including unfinished drugs[13] and APIs. These obligations pertain to the registrant (e.g., manufacturers, including contract manufacturers[14]).[15] Unless the application holder is also the registrant, these obligations do not pertain to the application holder of an approved drug.

On March 27, 2020, the CARES Act[16] was enacted to aid response efforts and ease the economic impact of the Coronavirus Disease 2019 (COVID-19). In addition, the CARES Act included authorities to enhance FDA's ability to assess, prevent, and mitigate possible drug shortages by,

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[6] 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. Other listed unapproved drugs are also subject to reporting under section 510(j)(3) of the FD&C Act.
[7] Section 510(b), (c) and (d) of the FD&C Act; § 207.17 (21 CFR 207.17).
[8] Section 510(i) of the FD&C Act; § 207.17.
[9] Registration and listing information helps the FDA maintain a catalog of all drugs in commercial distribution in the United States.
[10] Section 510(j)(1) of the FD&C Act; § 207.41 (21 CFR 207.41). Manufacturers, repackers, relabelers or salvagers of Type B or Type C medicated feed are exempt from drug listing (section 510(g)(5) of the FD&C Act; 21 CFR 207.13(g)).
[11] Section 510(j) of the FD&C Act; 21 CFR 207.49(a) (e.g., § 207.49(a)(4); § 207.49(a)(8)); 21 CFR 207.53.
[12] See §207.1 (21 CFR 207.1) (defining "manufacture" and "commercial distribution"). Donated drugs and drug samples are considered to be in commercial distribution.
[13] *Unfinished drug* means an active pharmaceutical ingredient either alone or together with one or more other ingredients but does not include finished drug products (§ 207.1).
[14] See § 207.41(a) and (c). While contract manufacturer registrants are included in the scope of registrants for which a report is required, note that a person (e.g., holder of a drug application) that has been authorized as an agent on behalf of a contract manufacturer registrant may submit the section 510(j)(3) report. See Question and Answer IV.D for further information.
[15] See footnote 10.
[16] Public Law 116-136.

among other things, improving FDA's visibility into drug supply chains. Section 3112(e) of the CARES Act added section 510(j)(3) of the FD&C Act, which requires that each person (including repackers and relabelers) who registers with FDA under section 510 of the FD&C Act with regard to a drug must report to FDA annually on the amount of each listed drug that was manufactured by such person for commercial distribution.

Section 510(j)(3) of the FD&C Act applies to each registrant of listed drugs in the drug supply chain (e.g., registrants that manufacture for commercial distribution a package form suitable for distribution to pharmacies, hospitals, or other dispensers or sellers of the drug product to patients or consumers, as well as registrants that manufacture drugs for commercial distribution that are not in such package forms). Data reported from registrants along the supply chain on the amount of listed drugs[17] that they manufacture (including data from registrants that manufacture a drug before it is in finished package form) provide FDA with a more comprehensive picture of the drug supply chain, which can inform operational decisions.[18,19]

These data support the Agency's efforts to reduce drug shortage risk. When FDA is notified of an impending interruption in manufacturing that is likely to lead to a supply disruption,[20] these data can provide insight into how much manufacturing typically occurs at the affected establishment and whether the interruption may lead to a drug shortage. Furthermore, these data can help the Agency identify and assess supply chain vulnerabilities that could be long term risk factors for drug shortages. With earlier awareness of persistent or emerging supply chain challenges, FDA is better informed and able to take more targeted and timely actions to promote stronger supply chains and reduce drug shortage risks.

In addition to supporting FDA's response to drug shortages, section 510(j)(3) of the FD&C Act also facilitates FDA's access to information useful in making decisions regarding the appropriate level of drug facility surveillance. FDA can use reported drug amount information in concert with other information about a particular facility (e.g., inspection history, hazard signals, inherent product risk) as part of FDA's quality surveillance oversight and risk-based approach to surveillance actions. Because drug amount data assist in the Agency's understanding of how much of a drug is typically manufactured at each facility, it may allow for a better estimate of potential public exposure to a particular drug manufactured at a particular facility. Additionally, information reported from repackers and relabelers on the amount of listed drugs they process[21] for commercial distribution provides FDA with information useful in making surveillance decisions. For example, assuming all other factors are the same, a facility that has a higher

[17] Listed drugs include drug product in finished package form, drug product not in finished package form, APIs, and other types of listed drugs, except for biological products or categories thereof exempted by an order under section 510(j)(3)(B) of the FD&C Act.

[18] Accordingly, data reported from different registrants along the supply chain for a particular drug are not considered duplicative.

[19] In assessing data received in section 510(j)(3) reports, the Agency intends to review for general trends, and does not intend to focus on minor data discrepancies.

[20] See, e.g., section 506C(a) of the FD&C Act (notifications of discontinuance or interruption in the production of life-saving drugs). See also 21 CFR 310.306, 314.81(b)(3)(iii), and 600.82.

[21] As noted above, repackagers and relabelers are considered drug manufacturers under the definitions of "manufacture" and "manufacturer" in 21 CFR § 207.1. See footnote 3.

production volume may have a higher risk than one that has a lower production volume due to the relative levels of potential public exposure. Amount reporting data submitted by repackers and relabelers under section 510(j)(3) of the FD&C Act helps FDA to gain visibility to make such an assessment.

Regarding confidentiality of data, information submitted to the Agency in a section 510(j)(3) report with respect to the amount of each listed drug manufactured at a specific establishment is generally considered confidential commercial information (CCI) under FDA regulations.[22] CCI is valuable data or information which is used in one's business and is of a type that is customarily held in confidence and not disclosed to the public by the person to whom it belongs.[23] When a firm submits confidential business or financial information to FDA, the Agency is required to follow applicable federal disclosure laws and regulations that generally prohibit public disclosure of that information. CCI is exempt from disclosure under FDA's disclosure regulations and the Freedom of Information Act.[24]

III. DISCUSSION

A. Who Must Report

Each registrant that lists a drug must report to FDA annually on the amount of such drug that it manufactured for commercial distribution.[25] While contract manufacturer registrants are included in the scope of registrants for which a report is required,[26] note that a person, including an application holder, that has been authorized as an agent on behalf of a contract manufacturer may submit the section 510(j)(3) report. See Question and Answer IV.D for further information.

B. What To Report

The section 510(j)(3) report should provide the amount of each listed drug, identified by the National Drug Code (NDC), that was manufactured by each registered establishment during the reported calendar year, organized by the amount of drug manufactured for commercial distribution in each month. Having data organized by month facilitates the Agency's ability to review for trends (e.g., trends associated with hurricane or typhoon seasons, or seasonal drug manufacturing campaigns), and assess whether such trends may be associated with drug supply disruptions.

When reporting, registrants should first consider (1) when their drugs were manufactured,[27] and (2) whether they were manufactured for commercial distribution. When reporting the amount of listed drugs, registrants should identify the drug by its NDC and the single business operation that best describes the activities that the registrant performs at the establishment with respect to

[22] See § 20.61 (21 CFR 20.61).
[23] See § 20.61.
[24] 5 U.S.C § 552(b)(4).
[25] See section 510(j)(3)(A) of the FD&C Act.
[26] See id. Additionally, as described in II. Background, reporting from contract manufacturers provides FDA with information useful in FDA's understanding of potential vulnerabilities for supply disruptions in registered drug establishments.
[27] See footnote 3.

such drug (see part III.B.4 below). In structuring the report, registrants should take into account the type of drug and its packaging (see part III.B.5 below). Further, a report from a contract manufacturer registrant should provide the amount of drug that the contract manufacturer registrant themselves manufactured, rather than what other registrants further downstream in that drug supply chain manufactured. Further details on reporting recommendations are below.

1. Determining When a Drug Is Manufactured

To determine which month a drug is manufactured, it is suggested that registrants (or their authorized agents) use the month in which the drug is released. For the purposes of this guidance, *released* means that the batch or lot has been determined to conform to final specifications.[28, 29]

2. Manufactured for Commercial Distribution

Registrants are required to *list* with FDA each drug they manufacture for commercial distribution.[30] Under section 510(j)(3) of the FD&C Act, each registrant must report to FDA annually on the *amount* of each such listed drug that it manufactured for commercial distribution.

The term "commercial distribution" is defined in 21 CFR 207.1 to mean "any distribution" of a drug, subject to certain limited exceptions.[31] The reference in this guidance to *commercial distribution* is intended to capture the concept described in § 207.1.

For purposes of section 510(j)(3) reports by domestic registrants, the annual amount of each listed drug manufactured for commercial distribution includes any amount manufactured for commercial distribution within the U.S. and any amount manufactured for commercial distribution outside the U.S. If all of the drug manufactured by the domestic establishment is intended to be exported, that amount should be reported, unless it is being exported for investigational use under 21 CFR part 312 or part 511, or if the exporting of the drug is an interplant transfer as described in the definition of "commercial distribution" in § 207.1.

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[28] See 21 CFR 211.165 regarding testing and release for distribution; see also the FDA guidance for industry *ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* (ICH Q7 (September 2016), section 11.2). In addition, the production and control records have been reviewed and approved by the quality control unit (see 21 CFR 211.192; see also ICH Q7 section 6.7). We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[29] Additional information regarding how to report the amount of each listed drug under section 510(j)(3) is available in FDA's guidance for industry *Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide* (PLACEHOLDER FOR DATE OF REVISED TECHNICAL CONFORMANCE GUIDE).

[30] Section 510(j)(1) of the FD&C Act; 21 C.F.R. 207.41(a).

[31] Under § 207.1, *commercial distribution* "means any distribution of a human drug, except for investigational use under [21 C.F.R part 312]…and any distribution of an animal drug or an animal feed bearing or containing an animal drug, except for investigational use under [21 C.F.R. part 511]...The term does not include internal or interplant transfer between registered establishments under common ownership and control, including a parent, subsidiary, or affiliate company. For foreign establishments that manufacture, repack, relabel, or salvage, or for foreign private label distributors, the term 'commercial distribution' has the same meaning except the term does not include distribution of any drug that is neither imported nor offered for import into the United States".

For foreign establishments, the annual amount of each listed drug manufactured for commercial distribution should be determined based on the amount that was manufactured for importation (or to be offered for importation) into the U.S. This determination does not always solely rely on whether the drug was actually imported into the U.S. For example, if a registrant manufactures an amount of a drug based on compliance with multiple different countries' standards (including U.S. standards) and some or all of that amount of the drug will be available to be imported into the U.S., then the foreign registrant should report the amount of that listed drug that will be offered to be imported into the U.S., even if it is not ultimately distributed to the U.S. market.

The determination of commercial distribution also does not depend on whether the registrant is manufacturing a drug that is in finished package form. Registrants of a listed drug[32] (including but not limited to API and contract manufacturers) that is not in finished package form are not excluded from being considered engaged in manufacture of a drug for commercial distribution.[33] Even if such registrants are unsure of which market(s) a drug may move into further down the supply chain, registrants should still apply the above principles to their own activities and information available to them to determine whether, and what amount, they are manufacturing for commercial distribution.

3. National Drug Codes

The section 510(j)(3) report should provide the amount of each listed drug, identified by the NDC, that was manufactured by each registered establishment during the reported calendar year, organized by the amount of drug manufactured for commercial distribution in each month. Reports from contract manufacturer registrants should provide the amount of drug that the contract manufacturer registrant themselves manufactured, rather than the amount that other registrants further downstream in the drug supply chain manufactured.

Registrants of human and animal drugs should report using the NDC assigned to the drug that they manufactured, even if the drug they manufactured is not in finished package form. Repackers and relabelers should also include in their reports the source NDC (i.e., the full three-segment NDC assigned to the drug received by the repacker/relabeler for repacking or relabeling), if available.

For human drugs that are manufactured by a registrant for commercial distribution under the trade name or label of a private label distributor, the drug must be listed under an NDC associated with the registrant's labeler code and listed under an NDC associated with the private

[32] Drugs not required to be listed are not required to be included in a section 510(j)(3) report. For example, if the same establishment manufactures both API and the finished dosage form that includes that API, and no remaining portion of the API is commercially distributed, the API is not required to be listed. Because in this example the API itself is not required to be listed, the API is not required to be included in a section 510(j)(3) report. See § 207.41 ("Who must list drugs and what drugs must they list?") and § 207.1 (definition of *commercial distribution*).

[33] See § 207.1 (the definition of "commercial distribution" does not exclude drug distribution by a registrant that is not the last registrant in the drug supply chain).

label distributor's labeler code.[34] Accordingly, the drug amounts should be reported separately under each NDC.[35]

For animal drugs that are manufactured by a registrant for commercial distribution under the trade name or label of a private label distributor, the drug must be listed only under an NDC associated with the private label distributor's labeler code.[36] Accordingly, the data should be organized by the NDC associated with the private label distributor's labeler code. Registrants manufacturing animal drugs who only perform early manufacturing steps and who are unaware of the volume ultimately associated with each private label NDC should attempt to obtain that information from their customers and report accordingly. If a registrant manufacturing an animal drug is unable to obtain NDC-specific volume for each package size and type distributed of any individual drug, they should allocate the known total volume for which it does not have NDC-specific volume information and divide equally across all applicable NDCs to provide an NDC-specific volume.[37]

While each registrant is ultimately responsible for ensuring that an accurate and timely report under section 510(j)(3) is submitted, note that a person, including a private label distributor that has been authorized as an agent on behalf of a registrant, may submit the section 510(j)(3) report. See Question and Answer IV.D for further information.

4. Business Operations

Registrants should also identify in their section 510(j)(3) reports the business operation that best describes the manufacturing activity performed at the establishment for the listed drug. This business operation should generally match the business operation for that establishment that was included in the drug listing. If the drug listing includes only a single business operation for that establishment, the registrant should identify that business operation in its section 510(j)(3) report. If the drug listing includes multiple business operations for that establishment, the registrant should identify the single business operation from the drug listing that best describes the activities performed at the registered establishment in that year for the listed drug.[38] Note that if the business operation from the drug listing file that best describes the activities performed for

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[34] § 207.41(c)(1)-(2).

[35] Additionally, we are requesting that this information be reported under both NDCs to facilitate the Agency's reconciliation of data. Reconciliation of data is important due to inconsistencies in drug listing data and section 510(j)(3) reports received by the Agency for drugs that are manufactured by a registrant for commercial distribution under the trade name or label of a private label distributor.

[36] § 207.41(c)(1).

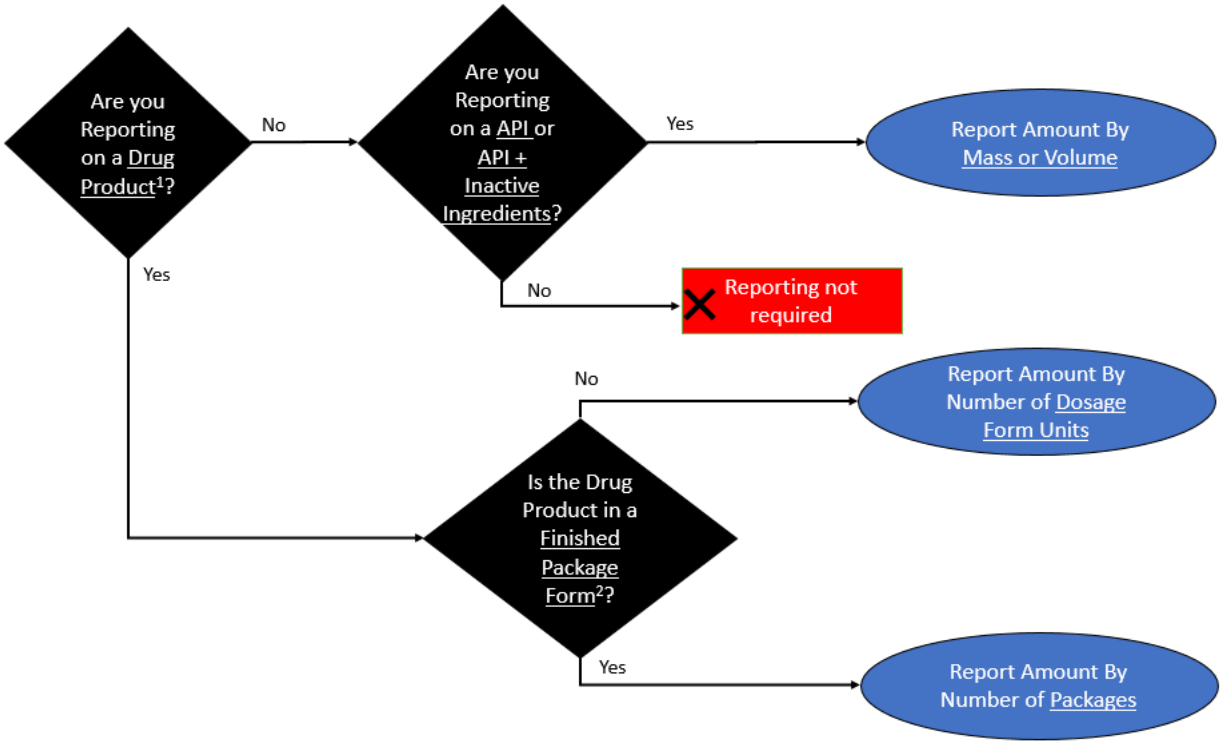
[37] For example, an animal drug registrant releases 100 identical units in a reporting period and distributes 90 of those units to 3 customers. Ten reportable units remain in inventory. Customer A receives 10 units and has a single applicable NDC (NDC1), customer B receives 30 units and has two applicable NDCs (NDC2 and NDC3), and customer C receives 50 units and has two applicable NDCs (NDC4 and NDC5). The registrant requests NDC-specific volume information from all three customers. Only customer B responds and tells the registrant customer B's volume was 30 units for NDC2. The registrant, taking into account the amount shipped to each customer and the possible applicable NDCs for each customer should therefore report: 12 units NDC1, 32 units NDC2, 2 units NDC3, 27 units NDC4, 27 units NDC5. (The 10 units remaining in inventory were divided among all 5 NDCs equally, adding 2 to each.)

[38] Additional information regarding the business operation to include in a section 510(j)(3) report is available in FDA's *Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide*.

the listed drug, or the single business operation for the listed drug, for that establishment is "pack" or "label," then the registrant should, for the purposes of a section 510(j)(3) report, identify "manufacture" as the single business operation that best describes the activities performed for the listed drug.

5. Content of Report Based on Type of Drug and its Packaging

In structuring a section 510(j)(3) report, registrants should consider the type of drug[39] and its packaging. Below is a summary diagram, followed by the details of the recommended reporting structures.



[1] For the purposes of this guidance, drug product means a finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients (see 21 CFR 210.3(b)(4)).

[2] For the purposes of this guidance, finished package form means a form suitable for distribution to pharmacies, hospitals, or other dispensers or sellers of the drug product to patients or consumers.

[39] For the purposes of this guidance, "type of drug" refers to the following categories: (i) drug that consists of API alone; (ii) drug that consists of API with other ingredient(s) but that is not in finished dosage form; (iii) drug product that is not in finished package form; and (iv) drug product that is in finished package form.

a. Drug Products

Each registrant that lists a drug, including a drug that is a *drug product*, must annually report to FDA the amount of such drug that it manufactured for commercial distribution.[40] For the purposes of this guidance, *drug product* means a finished dosage form, for example, tablet, capsule, solution, etc., that contains an API, generally, but not necessarily, in association with inactive ingredients.[41] A drug product may, but not necessarily, be in *finished package form*. For the purposes of this guidance, *finished package form* means a form suitable for distribution to pharmacies, hospitals, or other dispensers or sellers of the drug product to patients or consumers.

i. Drug Products in Finished Package Form

If the *drug product* is in *finished package form* and is listed with FDA as having a single level of packaging, the amount reported should correspond only to the quantity of that package type associated with the NDC assigned to the manufactured product. For example, if the NDC is for a drug packaged in a bottle containing 500 film-coated tablets, the registrant should report the number of bottles, not the number of tablets. Table 1 provides an illustration of the relationship between the NDC, the package description, and the quantity reported for a drug product with a single level of packaging.[42]

Table 1: Relationship Between the NDC, Package Description, and Quantity Reported for Products with a Single Level of Packaging

NDC	Package Description	Quantity of Bottles	Package Type Quantity To be Reported
00000-000-00	500 TABLET, FILM COATED in 1 BOTTLE	10,000	10,000

If the *drug product* is in *finished package form*, and listed with FDA as having multiple levels of packaging, and the product is not listed as a kit, then the product should be reported using the NDC assigned to the outermost layer of packaging, and the amounts reported should correspond to the package types associated with both the outermost layer of packaging and the innermost layer of packaging. The outermost layer of packaging is the package type associated with the NDC assigned to the manufactured drug. The innermost layer of packaging is the package type directly enclosing the product. For example, a case (outermost layer of packaging) of 48 cartons, each carton containing one bottle (innermost layer of packaging) of 30 tablets, should be reported by the NDC assigned to the case, with the amounts reported using both the number of

[40] See section 510(j)(3)(A) of the FD&C Act.
[41] See 21 CFR 210.3(b)(4).
[42] For information about how to submit the amount of each listed drug in a section 510(j)(3) report, refer to FDA's *Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide*.

cases and the number of bottles.[43] Table 2 provides an illustration of the relationship between the NDC, the package description, and the quantity reported for a drug product with multiple levels of packaging.[44]

Table 2: Relationship Between the NDC, Package Description, and Quantity Reported for Products With Multiple Levels of Packaging

NDC	Package Description (Inclusive of all levels)	Quantity of Cases	Quantity of Bottles	Outermost Package Type Quantity To be Reported	Innermost Package Type Quantity To be Reported
11111-1111-1	48 CARTONS in 1 CASE (11111-1111-1); 1 BOTTLE in 1 CARTON; 30 TABLETS in 1 BOTTLE	20,000	960,000	20,000	960,000

If the product is listed as a kit,[45] the amount reported should be based on the outermost layer of packaging associated with the NDC assigned to the manufactured kit.

In some instances, a product that has been assigned an NDC (NDC #1) may be both commercially distributed on its own and commercially distributed (and listed) as a part of a kit or as an inner packaging layer for another product that is assigned a separate NDC (NDC #2). Reports submitted under NDC #1 should only include amounts intended to be commercially distributed on their own and should not include amounts of the product that are a part of the kit or an inner packaging layer for the other product assigned NDC #2, as those would be accounted for in the amount reported for NDC #2.

[43] We are requesting that this information be reported at both of these packaging levels for multiple reasons. First, having this information, combined with the information in the self-reported drug listing files, will help us validate the data submitted and identify certain possible reporting errors. Second, having this volume information at multiple reporting levels will increase the utility of the data. Although the Agency may have the capability to use some of the data from the drug listing files to convert from one packaging level to the other, the Agency has identified discrepancies between the package descriptions included in self-reported drug listing files and packaging descriptions included in product labeling. These discrepancies could impact the validity of the data if the Agency were to try to convert amounts from one packaging level to the other. Accordingly, the Agency currently believes that, with respect to drug products listed as having multi-level packaging, reporting of drug amount information by both the outermost layer of packaging and the innermost layer of packaging would ensure the data is provided in the most useful way to the Agency.

[44] For information about how to submit the amount of each listed drug in a section 510(j)(3) report, including drugs in partially-filled packages, refer to FDA's *Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide*.

[45] For purposes of this guidance, a kit is a co-packaged product that includes at least one or more drug items.

For *drug products* that are in *finished package form*, registrants should not submit section 510(j)(3) reports to FDA based on the number of tablets, volume, or mass of the product.[46]

ii. Drug Products Not in Finished Package Form

If the drug is a *drug product* (as defined in part III.B.5.a) but is not in *finished package form* (e.g., not in a package form suitable for distribution to pharmacies, hospitals, or other dispensers or sellers of the drug product to patients or consumers), the amount reported should correspond only to the dosage form associated with the NDC assigned to the manufactured product.[47] For example, if the NDC is for a drug packaged in a drum containing 50,000 film-coated tablets, the registrant should report the number of tablets manufactured per drum (adjusting for any partially-filled drums, as appropriate). Table 3 provides an illustration of the relationship between the NDC, the dosage form, and the quantity reported.[48]

[46] Medical gas manufacturers should report to the Agency each year the number of units (e.g., cylinder, dewar, tank) of each medical gas manufactured at each registered establishment. FDA recognizes that, during normal manufacturing, storage, and filling operations for medical gases, venting may result in some product loss, and that manufacturers reuse containers that may contain residual gas from previous use. Registrants that list a medical gas need not, in preparing a report under section 510(j)(3), determine what amount has vented during normal operations or what amount of manufactured gas consisted of residual gas from previous use.
Additionally, FDA recognizes that some designated medical gas manufacturers produce and distribute the same gas for both medical and non-medical (e.g., industrial) purposes and may not be able to determine how much of the gas will be used for medical purposes. Registrants that list a designated medical gas need not, in preparing a report under section 510(j)(3), determine whether the gas will be ultimately used for a medical or non-medical purpose; rather, they should report to the Agency each year the number of units of each designated medical gas manufactured at each registered establishment, regardless of its ultimate use.

[47] The amount reported should correspond only to the dosage form associated with the NDC assigned to the manufactured product, regardless of whether the product is in single or multi-level packaging.

[48] For information about how to submit the amount of each listed drug in a section 510(j)(3) report, refer to FDA's *Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide*.

Table 3: Relationship Between the NDC, Dosage Form, and Quantity Reported for Products With a Single Level of Packaging

NDC	Package Description	Quantity of Drums	Quantity of Drug Product per Drum	Dosage Form Type Quantity To be Reported
22222-222-22	50,000 TABLET, FILM COATED in 1 DRUM	25	50,000 tablets in each drum	1,250,000
33333-333-33	50,000 TABLET, FILM COATED in 1 DRUM	25	50,000 tablets in 23 drums 25,245 tablets in 1 drum 24,942 tablets in 1 drum	1,200,187

b. Drugs That Are Not Drug Products

Each registrant that lists a drug, including a drug that is not a *drug product*, must report to FDA annually the amount of such drug that it manufactured for commercial distribution.[49] Drugs that are not *drug products* include:

- Drugs that consist of API alone; and
- Drugs that consist of API with other ingredient(s) but that are not in finished dosage form.

For the purposes of this guidance*, active pharmaceutical ingredient* (API) means any substance that is intended for incorporation into a finished drug product and is 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.[50]

If the drug is not a *drug product* (as defined in part III.B.5.a), the amount should be reported in terms of the mass or volume of the contents of the drug container, using the appropriate unit as reported in the drug listing (e.g., kilograms, liters).[51]

[49] See section 510(j)(3)(A) of the FD&C Act.

[50] API does not include intermediates used in the synthesis of the substance (§ 207.1). Additionally, for the purposes of this guidance, API includes *drug substance* as defined by FDA's guidance for industry: Q6B, Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (ICH Q6B) (August 1999).

[51] The amount reported should correspond only to the mass or volume of the listed drug within the container, regardless of whether the product is in single or multi-level packaging.

For drugs that are formulated by activity (e.g., heparin), API registrants should also provide the activity. API amounts are typically measured by mass or volume. However, for certain APIs such as hormones or antibiotics, dosing may be expressed in terms of biological effect or activity. The biological effect of a drug may be expressed in Units (U) or International Units (IU), which are standard units that define the amount of API that causes a certain biological effect. The volume or mass of API that corresponds to one unit may vary from drug to drug and from batch to batch. Therefore, it is recommended that registrants of drugs formulated by activity report how a unit is defined in terms of biological effect and how it corresponds to a mass or volume.[52]

C. Timing of Reports

Reports on the amount of each registrant's listed drugs must be submitted annually.[53] Such reports should include information regarding the amount of drug manufactured[54] for the respective calendar year (January 1 – December 31).

Reports for calendar year 2023 should be submitted no later than [*insert date six months after final guidance issuance*]. Reports for subsequent calendar years should be submitted no later than March 31 of the following calendar year. For instance, registrants that manufactured listed drugs for commercial distribution at any time in calendar year 2024 should submit reports to FDA reporting the drug amounts for calendar year 2024 no later than March 31, 2025.[55]

Reports for calendar years 2020, 2021, and 2022 that have yet to be submitted as of the date of issuance of this final guidance are still required under the statute and should be submitted to the Agency as soon as possible.[56] The Agency uses historical data from prior year reports under FD&C Act section 510(j)(3) to better understand the patterns that preceded specific supply chain issues, such as shifts in manufacturing for products involved, alongside changes in other potential risk factors such as market and product characteristics.

D. Process for Report Submission

Registrants should submit reports via the NextGen Portal, available at edm.fda.gov.[57] Additional information regarding technical specifications for submissions is available on FDA's website.[58]

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[52] Additional information regarding the activity information to include in a section 510(j)(3) report is available in FDA's *Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide*.
[53] Section 510(j)(3)(A) of the FD&C Act.
[54] See part III.B.1.
[55] In addition to annual reporting requirements, FDA is authorized under section 510(j)(3)(A) of the FD&C Act to require registrants to submit reports on the amount of listed drugs manufactured for commercial distribution at the time a public health emergency is declared by the Secretary under section 319 of the Public Health Service Act. Report submissions related to a public health emergency under section 510(j)(3)(A) of the FD&C Act do not satisfy the requirement to submit a separate annual report under such section.
[56] The effective date of section 510(j)(3) of the FD&C Act, as added by section 3112(e) of the CARES Act, was September 23, 2020.
[57] Under section 510(j)(3)(A) of the FD&C Act, FDA is authorized to require submission of section 510(j)(3) reports in an electronic format as determined by the Agency. Use of the NextGen Portal facilitates accurate submission of report data.
[58] See FDA's *Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide*.

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) DrugAmountReporting@fda.hhs.gov, (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010, or (CVM) Office of Surveillance and Compliance, 240-402-7002 or AskOSC@fda.hhs.gov, as applicable).

IV. QUESTIONS AND ANSWERS

A. What type of drug reporting is the subject of this guidance?

This guidance describes the process that registrants should use for annually reporting the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed for commercial distribution. Under section 510(j)(3) of the FD&C Act, such information must be reported by each person who registers with FDA under section 510 of the FD&C Act with regard to a listed drug (including a drug product in finished package form, a drug product not in finished package form, an API, and other listed drugs, except for biological products or categories thereof exempted by an order under section 510(j)(3)(B)).[59] Listed drugs subject to reporting include human drug products (including non-exempt biological products) marketed under an approved application, animal drug products marketed under an approved application, medical gases, homeopathic products, products marketed in accordance with requirements under section 505G of the FD&C Act (21 U.S.C. 355h),[60] often referred to as over-the-counter monograph drugs, and animal drug products that are not approved, conditionally approved, or indexed under sections 512, 571, and 572 of the FD&C Act.

B. If an applicant submits a report containing distribution data under 21 CFR 314.81(b)(2)(ii)(*a*) or 21 CFR 600.81(a) for human drugs or biological products, respectively, does the registrant of an establishment(s) identified in the application also need to annually submit a separate report under section 510(j)(3) of the FD&C Act containing the amount of the listed drug that was manufactured, prepared, propagated, compounded, or processed at the establishment for commercial distribution?

In this situation, a registrant[61] of a listed drug still must submit a report as required under section 510(j)(3) of the FD&C Act.[62] FDA acknowledges that

[59] See footnote 4 and Question & Answer IV.J.
[60] 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. Other listed unapproved drugs are also subject to reporting under section 510(j)(3) of the FD&C Act.
[61] *Registrant* means any person that owns or operates an establishment that manufactures, repacks, relabels, or salvages a drug, and is not otherwise exempt from establishment registration requirements under section 510 of the FD&C Act or 21 CFR part 207. See § 207.1.
[62] See section 510(j)(3)(A) of the FD&C Act.

applicants with approved applications[63] provide to FDA certain drug product distribution data in reports under § 314.81 (21 CFR 314.81) and § 600.81 (21 CFR 600.81); however, such data is aggregated and reflects the total amount distributed by an applicant, and does not include reporting specific to each establishment for the listed drug. If an application includes multiple establishments, the information reported under § 314.81 and § 600.81 would not be specific to each establishment, which can introduce challenges for the Agency in accessing information that could be used to make drug facility surveillance decisions and for assessing or mitigating drug shortages. In contrast, reports submitted under section 510(j)(3) of the FD&C Act should be submitted for each establishment. Additionally, reports that the Agency receives under § 314.81(b)(2)(ii)(*a*) and § 600.81(a) are limited to the finished drug product and do not include information about the API, drug substance, or unfinished drug product. Moreover, these reports arrive at the Agency at different times throughout the year and cover different time periods, which makes it challenging for the Agency to assess data received across different approved applications. In contrast, under FDA's recommendations for reports submitted under section 510(j)(3) of the FD&C Act, the data from all applicable registrants should arrive at the Agency during the same timeframe and cover the previous calendar year (see section III.B). This will enhance the Agency's ability to combine the data across establishments and drugs to provide a more comprehensive picture of the drug supply chain during a specific time period.

FDA does not intend to take action against an applicant regarding the requirement to submit distribution data in annual reports[64,65] submitted under §314.81(b)(2)(ii)(*a*), if:

(1) Each registrant of establishments identified in the application submits a timely and complete report under section 510(j)(3) of the FD&C Act;

[63] For the purposes of this Question & Answer IV.B, *applicant* includes (i) any person who submits a new drug application (NDA) under section 505(b) of the FD&C Act, abbreviated new drug application (ANDA) under section 505(j) of the FD&C Act, or a biologics license application (BLA) under section 351 of the PHS Act (or an amendment or supplement to any such NDA, ANDA, or BLA), and (ii) any person who owns an approved NDA, ANDA, or BLA. See 21 CFR 314.3, 21 CFR 601.2(a).

[64] For the purposes of this enforcement policy, the § 314.81(b)(2) annual report would be submitted no later than 1 year after the submission of the section 510(j)(3) report(s) by each registrant of establishments identified in the application. To the extent that the reporting periods for the § 314.81(b)(2) annual report and the section 510(j)(3) report are not aligned, 510(j)(3) report data covering the reporting period of a single § 314.81(b)(2) annual report may be submitted over the course of two consecutive section 510(j)(3) reports. For instance, if the reporting period for a § 314.81(b)(2) annual report is July – June, the corresponding section 510(j)(3) report data would include July-December of one calendar year and January-June of the following calendar year.

[65] Additionally, annual reports submitted under § 314.81(b)(2) are required to provide as applicable, among other information, a brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product; labeling information; chemistry, manufacturing, and control change information, nonclinical laboratory studies, clinical data; and status reports of postmarketing study commitments.

(2) Each registrant of establishments identified in the application adds to its section 510(j)(3) report the amount of listed drug product (organized by NDC number) that was distributed for foreign use during the reporting period;[66] and
(3) The applicant's annual report submitted under § 314.81(b)(2) provides:
    - The NDC number(s) and strength(s) of drug product for which each registrant submitted or will submit its report(s) under section 510(j)(3) of the FD&C Act;[67] and
    - The date(s) of the report(s) submitted under section 510(j)(3) of the FD&C Act.

FDA believes that this enforcement policy would maintain the Agency's access to information that would be useful in making drug surveillance decisions, would enhance the Agency's ability to reduce drug shortage risks, and would also address the potential reporting burden for applicants that are subject to both § 314.81(b)(2)(ii)(*a*) and section 510(j)(3) of the FD&C Act.[68]

C. If an applicant submits a report containing distribution data for animal drugs under 21 CFR 514.80(b)(4)(i), and/or 21 CFR 514.87(b)(4)-(5), does the registrant of an establishment(s) in the application also need to submit a separate report under section 510(j)(3) of the FD&C Act containing the amount of the listed drug that was manufactured, prepared, propagated, compounded, or processed at the establishment for commercial distribution?

Yes, a registrant of a listed animal drug must submit a separate report under section 510(j)(3) of the FD&C Act containing the amount of the listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution. This is in addition to the reporting requirements of applicants[69] under § 514.80(b)(4)(i) (21 CFR 514.80(b)(4)(i)) and § 514.87(b)(4)-(5) (21 CFR 514.87(b)(4)-(5)).[70]

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[66] § 314.81(b)(2)(ii)(*a*) requires applicants to provide to the Agency information about the quantities of drug product distributed for foreign use.

[67] See also footnote 64.

[68] The Agency does not intend to extend this enforcement policy to the submission of distribution reports under § 600.81. Distribution reports submitted under § 600.81 contain certain information relating to the quantity of biological product distributed by the applicant by lot, which is not required for reports submitted under section 510(j)(3) of the FD&C Act. For example, distribution reports submitted under § 600.81 include the fill lot numbers for the total number of dosage units of each strength or potency distributed, the label lot number (if different from fill lot number), the number of doses in fill lot/label lot, and the date of release of fill lot/label lot for distribution. See § 600.81(a). Additionally, distribution reports under § 600.81 are generally submitted once every 6 months, while reports under section 510(j)(3) of the FD&C Act are submitted annually.

[69] For the purposes of this Question & Answer IV.C, *applicant* is a person or entity who owns or holds on behalf of the owner the approval for a new animal drug application (NADA) or an abbreviated new animal drug application (ANADA), and is responsible for compliance with the applicable provisions of the FD&C Act and regulations. See 21 CFR 514.3.

[70] The Agency does not intend to extend a policy similar to that described for § 314.81(b)(2)(ii)(*a*) (see Question & Answer IV.B), with respect to reports containing distribution data submitted under § 514.80(b)(4)(i) or § 514.87(b)(4)-(5). In contrast to annual reports submitted under § 314.81, distribution reports submitted under § 514.80(b)(4)(i) are generally submitted once every 6 months for the first 2 years following approval of an NADA or

FDA understands that applicants provide to FDA certain distribution data in reports under § 514.80(b)(4)(i) and § 514.87(b)(4)-(5); however, such data is limited to the applicants, and it does not include reporting specific to each establishment of the listed drug. If an application includes multiple establishments, the information reported under § 514.80(b)(4)(i) and § 514.87(b)(4)-(5) would not be specific to each establishment, which can introduce challenges for the Agency in accessing information that could be used to make drug facility surveillance decisions and assessing and mitigating drug shortages. In contrast, for reports submitted under section 510(j)(3) of the FD&C Act, reports should be submitted for each establishment, which would enhance the Agency's access to information used to make drug surveillance decisions, as well as the Agency's ability to assess and mitigate possible drug shortages.[71]

D. Can an authorized agent of a registrant submit a report under section 510(j)(3) of the FD&C Act on behalf of a registrant (including a contract manufacturer registrant)?

An agent that has knowledge regarding the amount of drug manufactured for commercial distribution and who has been authorized by the registrant to submit the registrant's report under section 510(j)(3) of the FD&C Act may submit such a report on the registrant's behalf to the Agency. Accordingly, a private label distributor with knowledge of the amount of drug released and who has been authorized as an agent[72] to submit a report under section 510(j)(3) on the registrant's behalf may do so. Additionally, an application holder (e.g., holder of an NDA, ANDA, BLA, NADA, or ANADA) that has been authorized as an agent on behalf of a contract manufacturer (registrant) to submit a report under section 510(j)(3) on the contract manufacturer's behalf may do so.[73] However, each registrant is ultimately responsible for ensuring that an accurate and timely report under section 510(j)(3) is submitted on its behalf.

ANADA. Further, FDA is required to publish annual summary reports of data and information it receives under § 514.87, and these published reports are required to include a summary of distribution data received under § 514.87. See § 514.87(f); see also section 512(l)(3)(E) of the FD&C Act.).

[71] Additionally, reports that the Agency receives under § 514.80(b)(4)(i) and § 514.87(b)(4)-(5) are limited to the finished drug product and do not include information about the API or unfinished drug product. Moreover, these reports arrive at the Agency from numerous applicants at different times throughout the year, which makes it challenging for the Agency to assess, and mitigate drug shortages at any particular point in time. In contrast, under FDA's recommendations for reports submitted under section 510(j)(3) of the FD&C Act, the data from all applicable registrants would arrive at the Agency during the same time frame, which would enhance the Agency's ability to assess and mitigate possible drug shortages.

[72] The reference in this guidance to authorized agent is intended to capture the concept described in § 207.17(b) with respect to an authorized agent. Note that the authorized agent for the purposes of submitting a registrant's report under section 510(j)(3) of the FD&C Act need not be the same agent that is authorized to submit information to FDA that is outside the scope of a section 510(j)(3) report. For example, the agent that is authorized to submit a section 510(j)(3) report does not necessarily have to be the same agent that submitted registration information on behalf of a registrant.

[73] Contract facilities should consider outlining the reporting arrangements in a written quality agreement or other written contract.

E. Should the registrant report the amount of listed drug manufactured based on theoretical yield?

Registrants should report the actual amount of drug that is manufactured during the reporting period (This value would equate to the actual yield, if calculated). Percent yield is the percent ratio of actual yield to theoretical or predicted yield and can only be 100% if there are no losses or errors during actual production. Registrants should not report the amount of listed drug available for commercial distribution based on a theoretical assumption of 100% yield.

F. In determining the amount of drug to report in a section 510(j)(3) report, should a registrant include amounts of drug that were returned and/or recalled?

Registrants are required to report "on the amount" of listed drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution.[74] There is no exemption for drugs that have been returned or recalled. For that reason, the report must not subtract amounts that have been returned[75] or recalled.[76]

G. If a registrant manufactured, prepared, propagated, compounded, or processed an applicable drug for commercial distribution during only part of the calendar year, does the registrant still need to submit an annual drug amount report under section 510(j)(3) of the FD&C Act?

Yes, the registrant should submit a report to FDA no later than the recommended date each year (see section III.C). The registrant is responsible for reporting annually the amount of listed drug that was manufactured by the registrant for commercial distribution.

If there is an ownership change with respect to a registered establishment during the reporting period, the new owner should ensure the submission of data for the entire reporting period.

H. If a registrant had a drug listed with FDA during the calendar year, but did not ultimately manufacture, prepare, propagate, compound, or process any of the drug for commercial distribution during that calendar year, does the registrant need to submit a report under section 510(j)(3) of the FD&C Act?

Registrants are required to report "on the amount" of listed drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution.[77]

[74] Section 510(j)(3)(A) of the FD&C Act.
[75] See 21 CFR 211.204.
[76] See 21 CFR part 7, subpart C.
[77] See section 510(j)(3)(A) of the FD&C Act.

If such amount for an individual registrant is zero, the registrant still must submit a report under section 510(j)(3) of the FD&C Act. The drug listing data submitted to FDA must also be updated accordingly.[78]

I. What amount should a registrant of a foreign establishment report if some, but not all, of the listed drug it manufactures is imported or offered for import into the United States?

In the case of a listed drug manufactured, prepared, propagated, compounded, or processed in a foreign establishment for commercial distribution and the registrant of the foreign establishment knows how much of the listed drug was imported or offered for import into the United States, then the registrant should report that amount. However, if the registrant does not know how much of the listed drug was imported or offered for import into the United States, then the registrant should report the total amount of the listed drug that it manufactured, prepared, propagated, compounded, or processed (including repacked or relabeled) during the reporting period.[79]

J. Should a registrant of a listed biological product submit a section 510(j)(3) report to FDA, if the biological product falls within a category of biological products identified in FDA's order as exempt from section 510(j)(3)(A) reporting requirements?

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 an order that exempts 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.[80] Therefore, registrants of such biological products need not submit section 510(j)(3) reports to FDA for these products.

[78] See 21 CFR 207.57(b)(1).

[79] The amount reported should be for drugs that comply with applicable U.S. standards (e.g., the approved application, final order issued under section 505G of the FD&C Act). Even in instances where the registrant of a foreign facility does not know how much of the listed drug was imported or offered for import into the U.S., the reported data still will be of value to the Agency in carrying out its public health mission (see part II, *supra*). In such instances, the Agency will interpret these amounts as an upper estimate of how much was intended for the U.S. market.

[80] See 88 FR 22454 (Apr. 13, 2023). Such cell and gene therapy products, where one lot treats a single patient, are a subset of all cell and gene therapy products.

K. Should a registrant of a listed drug submit a section 510(j)(3) report to FDA, if the registrant's only business operation in the drug listing file is "sterilize," "analysis," "particle size reduction," and/or "salvage"?

FDA does not intend to take action if registrants whose only business operation in the drug listing file is "sterilize," "analysis," "particle size reduction," and/or "salvage" do not submit reports under section 510(j)(3) of the FD&C Act. FDA believes the data reported by other registrants (e.g., registrants with business operations of manufacture, repack, or relabel in the drug listing file) will be sufficient.