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ALERT

FDA CARES a Lot About Drug Reporting: Takeaways From Draft Guidance for New Annual 510(j)(3) Reporting Requirement for Released Drug Products

November 16, 2021

Recently, the U.S. Food and Drug Administration (FDA) announced the availability of a draft guidance titled "Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act" (Draft Guidance). The Draft Guidance is intended to assist registrants of drug establishments in complying with its responsibility to annually report on the amounts of each listed drug manufactured, prepared, propagated, compounded, or processed for commercial distribution. This new reporting obligation was added by section 3112 (e) of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) in order to enhance FDA's ability to identify, prevent, and mitigate potential drug shortages.

The Draft Guidance is available for public comment until January 3, 2022. We provide a summary of the content, timing, and process for submitting the required reports, as well as key takeaways.

CONTENT: THE "WHO" AND THE "WHAT"

The "Who"

The Draft Guidance applies to each person who:

- Registers with FDA under section 510 of the FD&C Act; and
- Lists drug products. New section 501(j)(3) applies to all listed drug products, except for biologic products or categories of biologic products specifically exempt by an FDA order.

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Thus, drug products subject to this new rule include:

- Finished and unfinished drug products;
- Active pharmaceutical ingredients (API);
- Approved and unapproved drug products;
- Medical gases;
- Homeopathic products;
- Over-the-counter (OTC) monograph drugs;
- Animal drug products; and
- Biologic products not exempt by an FDA order.

The "What"

The FD&C act requires registrants to report the amount of each listed drug that it manufactured, prepared, propagated, compounded, or processed for commercial distribution. The draft guidance states that these reports should provide the amount of each listed drug that was *released* by each registered establishment during the reported year.[1]

Other important points include:

- Entries should be organized by the amount of drug released each month;
- Since a registrant's drug listing file may identify multiple business operations for each establishment registered, registrants should include the *single* business operation that is most relevant for the listed drug that is the subject of the 510(j)(3) report;
- For finished dosage form products, the amount reported should correspond to the quantity of package type associated with the assigned National Drug Code (NDC). For example, if the NDC package description is a bottle of 100 tablets, the amount reported to FDA should be measured in bottles, not tablets. For packages with multiple layers, the amount should be reported for both the outermost package type and the innermost packaging (e.g., 20,000 cases containing 960,000 cartons);
- The amount of APIs and other bulk drug products must be reported in terms of appropriate unit containers as reported in drug listing (e.g., tanks, drums, cylinders, bags) rather than by weight, mass, or volume using metric or imperial system units; and
- For drugs that were manufactured, prepared, propagated, compounded, or processed for commercial distribution by contract manufacturers under the trade name of a private label distributor, data should be submitted separately by the NDC associated with the registrant's labeler code and the NDC associated with the contract manufacturer's or private label distributor's labeler code; and
- To avoid double counting, repackers and relabelers should include in their reports both their own NDC code as well as the source NDC (the NDC assigned to the drug product as received by the repacker/

relabeler).

TIMING: MARK YOUR CALENDARS

The 510(j)(3) reports should be submitted on an annual basis for the prior calendar year's activities (January 1 – December 31). To assist registrants, we have developed the following table to track the submission due dates starting with calendar year 2020:

Calendar Year of Report	**Report Submission Due Date**
2020	February 15, 2022
2021	May 16, 2022
2022	February 15, 2023
2023 and onwards	No later than February 15 of the following calendar year

PROCESS: WHERE DOES IT ALL GO?!

FDA requires registrants to electronically submit 510(j)(3) reports via the recently launched NextGen Portal. Information to create a NextGen Portal account can be found on FDA's CDER NextGen Portal FAQ webpage. Additional technical conformance information is provided in FDA's supplementary materials to the draft guidance.

FDA QUESTIONS AND ANSWERS

Within the draft guidance, FDA also provides answers to some likely questions. Among these answers are the following:

- A drug must be reported even if no quantity of that drug was manufactured, prepared, propagated, compounded, or processed for commercial distribution during the previous year. In essence, the quantity in the report will be zero;

- In determining the total amount of drug to report, registrants must not subtract amounts that have been returned or recalled; and
- A report must still be submitted by a registrant even if they manufactured, prepared, propagated, compounded, or processed an applicable drug during only part of the calendar year.

FDA recognized the potential reporting burden for applicants that also have to submit distribution data under the applicant's annual report requirement pursuant to 21 C.F.R. § 314.81(b)(2)(ii)(a) as well as in the new 510 (j)(3) report. While both reports still need to be submitted, in an attempt to streamline the process, FDA indicated applicants do not need to regenerate the distribution data in the annual report submitted under 21 C.F.R. § 314.81(b)(2)(ii)(a) provided the following criteria is met:

- A timely and complete 510(j)(3) report is submitted;
- Information concerning the amount of listed drug product (organized by NDC number) that was distributed for foreign use during the reporting period is added to the 510(j)3) report; and
- The applicant's annual report provides: 1) the NDC number(s) and strength(s) of drug product it included in the 510(j)(3) report and 2) the submission date for the 510(j)(3) report.

If the aforementioned criteria are met, FDA will not take regulatory action against an applicant for not submitting the distribution data in the exact format prescribed in 21 C.F.R. § 314.81(b)(2)(ii)(a).

TAKEAWAYS: ANOTHER ITEM IN THE TO-DO LIST

The proposed new annual reporting requirement under section 510(j)(3) of the FD&C Act will undoubtedly be a big change for many in the industry who have not had to report distribution data to the Agency for drug products such as OTC monograph drugs, homeopathic drugs, and other unapproved drugs. As a result, these entities will now have to devote company time and resources to comply.

Even entities with a bit more annual reporting experience, such as those that already submit drug distribution data in annual reports, are not out of the woods. As discussed earlier, in an attempt to reduce reporting burden, FDA proposed a process for applicants to repurpose the information submitted in the 510(j)(3) report to meet other reporting obligations. Whether this will alleviate or contribute to the reporting burden is an open question. We expect this section in particular to generate discussion.

Companies should review their internal systems to determine if there are opportunities to leverage pre-existing data to generate the new section 510(j)(3) report and thus alleviate some of the burden. For instance, given the reported amounts concerns only each listed drug that was *released* during the reported year, companies may want to create a cross-functional working group comprised of the quality control unit, technical operations, regulatory/compliance, and finance/accounting departments. In our experience, these groups house a significant amount of relevant information that can be utilized and cross-checked to ensure the section 510(j)(3) report's accuracy.

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If you have any questions about the above-described guidance document or would like assistance submitting comments to FDA, please contact the authors listed on this alert. As stated earlier, the Draft Guidance is available for public comment until January 3, 2022 (Docket No. FDA-2021-D-1031-0001).

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1 "Released" means that the batch or lot has been determined to conform to final specifications and the production and control records have been reviewed and approved by the quality control unit.

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