December 29th, 2021

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2021-D-1031: Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry

Dear Sir/Madam:

The Biotechnology Innovation Organization (BIO) thanks the Food and Drug Administration (FDA or Agency) for the opportunity to submit comments regarding the Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry (Draft Guidance or Guidance).

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place.

BIO appreciates this opportunity to submit comments regarding the Draft Guidance Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act. Specific, detailed comments are included in the following chart. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/s/
Katherine Donigan, Ph.D.
Senior Director, Science and Regulatory Affairs
Biotechnology Innovation Organization

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202-962-9200

SPECIFIC COMMENTS

SECTION	ISSUE	PROPOSED CHANGE
1. INTRODUCTION		
Line 27	Does this exemption include all biologics reported under 21 CFR 600.81a? The current exemptions appear very narrow.	BIO recommends that the Agency exempt biologics already subject to the similar reporting requirement.
Line 40	How will FDA enforce the reporting requirement? Will there be any penalties if an establishment does not report on the quantity of a drug intended for commercial distribution? For example, what happens if a CMO is out of compliance?	We request that the Agency clarify its proposed actions and the potential impact.
Entire Section	Are viral vectors used to manufacture cell therapy treatments where one lot treats one patient in scope of this reporting requirement?	BIO recommends that the Agency address this point in the final guidance.
2. BACKGROUND		
3. DISCUSSION		
A. Content of Reports		
Line 75	If an establishment produces the API and the finished package product for a drug, is the establishment required to report on both the quantity of API and finished packaged product?	We request that the Agency clarify.
Lines 81-82	"Registrants should also report the single business operation that is most relevant to the overall business operations performed for the listed drug at the registered establishment in that year."	BIO recommends that the Agency provide criteria for determining what constitutes a "single business operation that is most relevant" (e.g., volumes, multiple SKU's, size of operation, financial).
1. Finished Dosage Form Products		
Line 95	How do we account for product manufactured and labeled for the US market that is distributed	We request that the Agency clarify.

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	internationally (e.g., for shortages or parallel import)? Should this be included in the volume reported? If not, how do we account for the fact that distribution may not be in the year of manufacture?	
2. *API*		
Line 142	Not all API manufactured is ultimately distributed to the US market. Further, distribution or use for a specific market may not occur in the year manufactured. Should reporting be of the amount manufactured at a site, or of the amount used to manufacture drugs for distribution in the US market?	We request that the Agency clarify.
3. *Other Listed Drugs*		
Line 156	The last sentence of "Other Listed Drugs" states that the reported amount should be in the unit of containers as reported in the drug listed.	BIO would prefer that there be flexibility to report the quantity in either the number of containers OR in the number of units. The Category of "Other Listed Drugs" is quite broad and depending on the type of material, a unit container or a quantity of product (e.g., quantity of vials or tablets) may be more relevant.
4. *Private Label Distribution*		
B. Timing of Reports		
Entire Section	FDA is requesting this reporting starting in February of 2022. As the draft guidance comments are not due until early January, the final guidance will not issue until after that point and will not be final when the initial reporting is requested. Further, gathering this information can be complicated and will take significant time to gather, particularly the first time. Until the guidance is finalized details of what needs to be reported and how to report it may change, creating a duplicative burden.	BIO suggests that FDA delay reporting until at least 3 months after a final guidance is issued.
Entire Section	Creating two new reports, in a new and not yet-finalized format, in such a short timeframe creates an	Please consider beginning this collection with the 2021 data.

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	unnecessary burden that does not reflect the expected annual cadence of this requirement.	
Lines 171-181	2021 Reporting	Due to the allowed delayed submission of the 2020 required reporting until Feb 2022, would the Agency consider delaying 2021 reporting until Q-3 2022?
4. QUESTIONS AND ANSWERS		
B. Question B		
Footnote #40	"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.	BIO suggests that the applicant, i.e., the owner of the NDA, BLA, etc., be accountable for the reporting of data regardless of whether the data concerns an establishment they own or not. This seems like it would enable the FDA to have a consolidated view of quantity of released drug as well as the quantity of distributed drug and eliminate the gap of having the "Market Unknown". Also, BIO believes that BLA/NDA owners want the accountability and responsibility of reporting our product volumes, and it seems odd that BLA owners would become an 'authorized agent' of an establishment (likely a CMO) represented by a 'registrant' that is manufacturing the product on their behalf. BIO believes FDA would want to hold the BLA/NDA owner accountable for volume data reporting, rather than make this accountability for the BLA/NDA holder optional.