

	Compliance Alert
15 February 2022	CARES Act Reporting Deadline Clarified

After close of business yesterday, the FDA announced that the deadline (today, 2/15) for CARES Act submissions is "Non-binding and Not a Requirement".

"FDA is considering comments to our draft guidance on Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act, including comments about the recommended timelines for submitting the required reports. The draft guidance document is not a binding document, and the recommended February 15, 2022 reporting date for 2020 data is not a requirement. We are carefully reviewing all issues raised by stakeholder comments to the docket, including regarding the recommended reporting timeframes. We will consider updating the draft guidance's recommended timeframes for reporting, as appropriate, along with other issues raised by such stakeholder feedback."

[Click here for more information from the FDA.](#)

What does this mean for you? If you are still working on your FDA Drug Listing or CARES Act submission, you may want to continue the effort as a matter of routine business and not necessarily as a rush project.

This GAWDA Compliance Alert is issued by GAWDA Consultant Tom Badstubner. Please contact him at tom@asteriskllc.com or 508-883-0927 for further information.