

Considerations for applicants deciding when to submit elemental impurity data to FDA

In general, FDA recommends that any applicant who has not fully addressed [elemental impurities](#) in their applications in their current form submit the information as soon as possible.

If the application is currently under review, this submission would be considered an unsolicited amendment, and could impact the review clock; however, waiting for an official communication could potentially prolong approval to a greater extent.

Consider the following example:

An applicant has a Generic Drug User Fee Amendments (GDUFA) goal date in February and the elemental impurity issue is the **ONLY** outstanding deficiency. If the applicant chooses to not submit information to address the elemental impurity issue today, they would receive a CR on or before the GDUFA goal date. This CR could potentially only contain this one deficiency.

In this example, the applicant would still receive a minor amendment goal date of 3 months upon the FDA receiving their post-CR amendment. However, if the applicant submits an amendment during the current clock, the goal date would be extended 3 months from the date of the amendment. If the amendment sufficiently addresses the elemental impurity issue, FDA would be able to take action faster than waiting for a CR response and may be able to approve the application.

Consider a second example:

If the official goal date is not for several months down the road (e.g., April and beyond) the review of this information could be subsumed under the current review clock.

If an applicant is anticipating a quality discipline review letter (DRL) in March for an application due in August 2018, submitting this information immediately may not be needed, as a request for this information will likely be listed as a deficiency. However, for applications with user fee goal dates from now until the March/April time frame, it is in the applicants' best interest to submit the necessary information as soon as possible.

In most cases, submitting the elemental impurity information as soon as possible will be the least impactful on approval time.