EPA Submission Support for Pesticides

Challenges in today's job market are not limited to the private sector. In response to staffing shortages the United States Environmental Protection Agency has made some changes. To better meet Pesticide Registration Improvement Act (PRIA) dates, EPA has modified the 75-day deficiency letter for new registration submissions. Battelle can help registrants ensure a successful submission by either taking the lead to verify completeness or using our keen understanding of data requirements to provide a secondary review.

The volume of new data, data waivers and rebuttals received in response to 75-day deficiency notices had compromised EPA's ability to keep PRIA dates. The modifications by EPA now make it harder to submit new data or to have data waivers and rebuttals considered. As a result, submissions now need to be as bullet-proof as possible. This has placed more emphasis on preparation and defining requirements via pre-submission meetings.

Within 21 days of receiving a PRIA application, a completeness check is conducted. This is an administrative screen to ensure that the correct documents have been submitted and that they are complete. This screen does not address the content of the submission and is not conducted by people with knowledge about pesticides.

After the initial 21 days have passed, the Preliminary Technical Screen begins for a period of 45 or 90 days. The time for the technical screen is dependent on the type of action petitioned. The application is checked to identify deficiencies that would prevent completion of the review. If deficiencies are found, a preliminary screening letter (i.e., 10-day letter) is sent to the applicant outlining the findings. In the Registration Division (RD), these screens have not typically included a complete technical screen due to resource constraints.

Once the Preliminary Technical Screening process is complete, any further deficiencies identified during the EPA review results in a 75-day deficiency notice. EPA does not specifically track the number of 75-day letters issued, but the number has increased in recent years. In response to the uptick in deficiencies, EPA adopted a new 75-day deficiency letter template. As stated in 40 CFR § 152.105, if the identified deficiencies cannot be corrected within 75 days, the applicant must renegotiate when the deficiencies can be addressed or can decide to withdraw the petition. The agency does not routinely grant renegotiated timelines for a response and an extension is only granted in specific instances. Increasingly, submission of new studies in response to a 75-day letter will likely result in a Do Not Grant decision from EPA.

BATTELLE

There are, however, some exceptions. Under 40 CFR § 158.75, the data routinely required under Part 158 may not be sufficient to evaluate a product application. In cases where additional data or studies are required that are outside of the standard data requirements, EPA may issue a 75-day letter to alert the applicant of the data need. In these cases, EPA will typically allow time for the applicant to conduct the studies and submit data. As a general rule, the Biopesticide and Pollution Prevention Division (BPPD) is more likely to accept new data. This stems from a consideration of the nature of certain active ingredients they review.

Data waivers are under the same scrutiny when in response to a 75-day notice. Data waivers are more likely to be accepted under a pre-application study waiver conditional ruling (PRIA codes A535, B614, or R124), rather than in response to a 75-day notice.

When registrants are providing a new active submission, the requirement for completeness is now higher than ever. A successful submission is one where a concise data gap analysis (DGA) has been conducted and thoroughly addressed not just in terms of the guideline studies, but also with consideration of tier two requirements and potential gaps outside of the guideline studies. A well-conducted and documented pre-submission meeting(s) can help to resolve any questions regarding completeness. Battelle can help from early-stage development to separate completeness checks before submission. Battelle experts can take the lead or act as an extension of your organization to work with your registration experts for discipline-specific requirements. We are unique in that we have expert regulatory professionals to assist with modeling, data-gap assessment, study placement and monitoring, in addition to generating data at Battelle's laboratories.

Contact us today to let us know how we can help.

800.201.2011 | solutions@battelle.org | www.battelle.org

ID 833 11/22

BATTELLE
It can be done