



Brian R. Leahy
Director

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Governor

California Notice 2017-09

TO: Pesticide Registrants and Stakeholders

SUBJECT: CONDITIONAL REGISTRATION OF PESTICIDE PRODUCTS

To register a new pesticide product (product) or amend the label of a currently registered product in California, the registrant/authorized agent is required to submit scientific data to the Department of Pesticide Regulation (DPR) for evaluation. Title 3 of the California Code of Regulations (3 CCR) section 6200 allows the DPR, under specified conditions, to conditionally register a pesticide product. 3 CCR section 6200 states, “the Director may waive specific data requirements in this subchapter for a period reasonably sufficient, not to exceed three years, for the generation and submission of such required data.”

ACCEPTANCE OF PROPOSED CONDITIONS

When DPR proposes to conditionally register a product (new product or amendment), the regulatory scientist (RS) will inform the applicant/authorized representative of the conditions and timeframe(s) for submission of the data. In addition to mailing a hard copy of the proposed conditions, the RS will send an electronic copy (PDF) of the letter by e-mail to the registrant/authorized representative. The registrant/authorized representative must agree to all conditions in writing within thirty (30) days of the date of DPR’s letter. If more time is needed to determine whether the company can agree to the conditions, the registrant/authorized representative may, within the 30-day time-period, submit a written request to the RS requesting an extension of time to respond. The request must include a justification for the extension of time and a proposed response date. In both cases, the written request may be submitted as either a hard copy letter by mail or as an electronic copy (PDF) of the written letter(s) by e-mail to the RS.

The agreement letter must include the following:

- 1) Product brand name
- 2) Registration number
- 3) DPR Tracking identification number
- 4) Statement agreeing to the condition(s)

If the registrant/authorized representative does not submit a written letter accepting the conditions or resolve the conditions in some manner, DPR will return or deny the submission (whichever is applicable).



COMPANY CHANGES

When a conditionally registered product is subject to a change in company name and ownership or product transfer, the product's conditions will be transferred to the new company. The RS will send a letter to the new registrant/authorized representative informing them of the conditions and timeframes. The original conditions and timeframes assigned to the product remain the same regardless of the ownership change/product transfer. The new registrant/authorized representative must submit to DPR a written agreement (as described above) to the condition(s) within thirty (30) days of DPR's letter. If the new registrant/authorized representative does not submit a written letter agreeing to the proposed conditions, DPR will return the submission.

SECONDARY PRODUCTS

Secondary products (i.e., additional or alternate product brand names, substantially similar products, and distributor registrations) are subject to the same conditions and timeframes as the primary (basic) or referenced conditional registered product. The RS will inform the registrant/authorized representative of the conditions and timeframes. Registrants/authorized representatives will be given thirty (30) days to accept the conditions. If DPR does not receive a letter from the registrant accepting the conditions, the RS will return the submission. The original conditions and timeframes assigned to the product remain the same.

REQUEST TO EXTEND CONDITIONS

If a registrant needs additional time to satisfy agreed upon condition(s), the registrant/authorized representative must submit a written letter to DPR, prior to the conditional due date that includes the following:

- 1) Product brand name
- 2) Registration number
- 3) DPR Tracking identification number
- 4) Justification as to why the extension of time is needed
- 5) Study start date(s) (if applicable)
- 6) Status of data generation (if applicable)
- 7) Estimated date of completion

As with the acceptance of proposed conditions, the registrant/authorized representative has the option of submitting a request to extend conditions to the RS as an electronic copy (PDF) of the written letter by e-mail or as a hard copy by mail

DPR will respond in writing either accepting or denying the extension of time. In addition to mailing a hard copy of DPR's response, the RS will send an electronic copy (PDF) of the letter by e-mail to the registrant/authorized representative. If DPR denies the extension request and the conditional timeframe(s) have expired, DPR will consider this as a failure to meet the conditions and will proceed as described in the "Failure To Meet Condition(s)" section.

AMENDMENT OF PRODUCT LABEL TO ADDRESS CONDITIONS

A registrant may choose to address conditions by amending the product label (e.g., to remove an unsupported use site/pest or add a qualifier such as, “Not for Use in California”). When a registrant chooses to add the qualifier, “Not for Use in California” or similar phrase, the registrant must provide DPR with a copy of its notification to U. S. EPA of the label change. The qualifier phrase should be easily identifiable to the user and consistent throughout the label (e.g., wherever the unsupported use site/pest appears throughout the label). If later the registrant decides to add the unsupported use site/pest back to the product label, the application to amend the product label must be accompanied by the required data or reference data currently on file with DPR supporting the use.

ANNUAL PROGRESS REPORT

3 CCR section 6200(h) requires registrants of conditionally registered products to submit a written progress report for each conditionally registered product with their application for renewal to DPR’s Registration Licensing Unit. In addition to submitting the progress report with the application for renewal, the registrant/authorized representative is encouraged to submit a copy of the progress report to the RS either by e-mail or mailing a hard copy. The annual progress report should include the following:

- 1) Product brand name
- 2) Registration number
- 3) DPR Tracking identification number
- 4) Study start date(s) (if applicable)
- 5) Status of data generation (if applicable)
- 6) Estimated date of completion

If DPR does not receive an annual progress report for each conditionally registered product, DPR may inactivate the product’s registration. If data or information have been submitted to DPR to fulfill the condition(s), the annual progress report is not required for the specific product.

FAILURE TO MEET CONDITION(S)

If a registrant fails to meet the conditions by the agreed upon timeframe, DPR will send the registrant/authorized agent a warning letter. The registrant will have 30 days from the date of DPR’s letter to respond. If more time is needed, the registrant/authorized representative may, within the 30-day time-period, submit a written request to the RS requesting an extension of time to respond. The request must include a justification for the extension of time and a proposed response date. The RS will notify the applicant or authorized representative in writing of the action taken by DPR.

If the registrant does not respond to the warning letter within the 30-day period or submits an incomplete or unacceptable response that does not fulfill the conditions, DPR may inactivate the product’s registration. If the condition(s) were imposed on a label amendment, DPR may rescind

its acceptance of the amendment to the product label and the previously accepted version of the product label will become the latest accepted label on file with DPR. If DPR finds the submission is incomplete or unacceptable, DPR will inform the registrant before inactivating the registration.

If you have questions regarding the conditional registration process, please contact the Pesticide Registration Branch Ombudsman, Ms. Jolynn Mahmoudi-Haeri, by e-mail at <Registration.Ombudsman@cdpr.ca.gov> or by telephone at 916-324-3545.

Original Signed By Ann M. Prichard

July 5, 2017

Ann M. Prichard, Chief
Pesticide Registration Branch
916-324-3931

Date

cc: Ms. Jolynn Mahmoudi-Haeri, DPR Senior Environmental Scientist (Specialist)