Monday, March 9, 2020

On March 9, 2020, the U.S. Environmental Protection Agency (EPA) announced that due to the outbreak of SARS-CoV-2, the coronavirus that causes COVID-19, it is expediting review of submissions made by companies that are requesting to add Emerging Viral Pathogen claims to its labels of already-registered surface disinfectants.

EPA states that only claims that do not require review of new efficacy data are being expedited at this time. Companies can submit these claims as non-Pesticide Registration Improvement Extension Act (PRIA 4) fast-track amendments. Registrants are asked not to include other label changes typically covered under amendments and notifications as part of the submission to add Emerging Viral
Pathogen claims.

EPA requests that registrants include the following information in a letter to ensure the efficient processing of submissions:

- A subject line that clearly indicates “Emerging Viral Pathogen Claim for SARS-CoV-2”;
- A request to make emerging viral pathogen claims;
- A description of how the product meets the eligibility criteria for use against one or more categories of viral pathogens consistent with the guidance;
- The identification of the virus(es) from the product label that the registrant is using to support the emerging viral pathogen claims and the study ID number (MRID) that supports the claim;
  - Note: EPA recommends using the minimum number of supporting viruses needed for the emerging pathogen claim in order to expedite EPA’s review
- An up-to-date matrix (Form 8570-35); and
- A request to add the Terms of Registration outlined in Attachment I of the Emerging Viral Pathogens Guidance.

Registrants should also submit a revised master label with a separate section for emerging viral pathogen claims that includes the generic claim statements identified in Attachment I of the Emerging Viral Pathogens Guidance document.

EPA requests that applications are submitted through EPA’s CDX portal and email disinfectantlist@epa.gov with the CDX tracking number (CDX_2020_XXXXXXX) once an application was submitted to expedite the application.

If approved, the product will be added to List N: Disinfectants for Use Against SARS-CoV-2, during the next update to the list, which is scheduled to be updated in the next two weeks.

Additional information is available at Emerging Viral Pathogen Claims for SARS-CoV-2: Submission Information for Registrants and on our blog.

©2020 Bergeson & Campbell, P.C.

Source URL: https://www.natlawreview.com/article/epa-expediting-emerging-viral-pathogens-claim-submissions