Posting an FDMS Docket Without a Federal Register Notice

MEMORANDUM

SUBJECT: Posting EPA-HQ-OPP-2020-0529 to Regulations.gov for Public Access

FROM: Michele Cottrill 10/26/2020
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This memorandum authorizes the posting of EPA-HQ-OPP-2020-0529 to Regulations.gov for public access.

Background:

EPA is announcing the expedited review of certain applications for registration and amended registration for products intended for use against the SARS-CoV-2, the novel human coronavirus that causes COVID-19. Pursuant to Title VII of the CARES Act passed on March 27, 2020, EPA is providing notice of its intention to expedite (at least one to two months faster than the normal PRIA timeframe) reviews for addition of residual (i.e., extended or long-lasting) efficacy claims for currently registered or new product registrations that are on EPA's Disinfectant List N, that would qualify for List N, or products that can be used as a residual supplement to disinfectants on List N. Recently, there has been increased interest in obtaining residual efficacy claims (i.e., claims that a product provides an ongoing antimicrobial effect beyond the initial time of application, ranging from days to weeks to months). There is significant desire from stakeholders and the public for products that are continuously active and can provide efficacy in between regular cleaning and disinfection.

Products with residual effect claims that qualify for this expedited review fall into two major categories; (1) disinfectants that also provide residual efficacy, and (2) supplemental residual antimicrobial products (e.g., coatings, paints, solid surfaces) that do not meet EPA's standards for disinfectants but are intended to be used as a supplement to standard List N disinfectants.

Information contained in the docket will provide a full description of these types of claims as well as efficacy testing standards and associated methods to support these claims. The methods contained in the docket are intended to provide interim guidance on the study design elements necessary to support these types of claims. Note that EPA may consider other methods or studies to support residual efficacy claims, provided they are scientifically sound.

EPA encourages the user community to provide feedback on the expedited process, design elements for evaluating residual product claims, and the test methods associated with this initiative.

This document will be open for public comment from 10/26/2020 to 01/04/2021.

Submit your comments, identified by Docket ID No. EPA-HQ-EPA-HQ-OPP-2020-0529, to www.regulations.gov.

Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit: http://www.epa.gov/dockets/commenting-epa-dockets.

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