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11/18/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 18 2010

Mr. Lewis Ward
Certol International, LLC
6120 E. 58th Avenue
Commerce City, CO 80022

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: Omni II/ProSpray C-60
EPA Registration No.: 46851-1
Notification Date: 10/29/2010
EPA Receipt Date: 11/01/2010

Dear Mr. Lewis Ward,

This letter acknowledges receipt of your notification submitted under the provision of FIFRA section 3(c)9 and PR Notice 98-10.

Proposed Notification

- Addition to include H₁N₂, H₃N₂, and H₅N₁ Influenza A viruses

General Comments

Based on a review of the submitted materials, your notification for the addition to include H₁N₂, H₁N₂, and H₁N₂ Influenza A viruses is unacceptable because the product's efficacy data is insufficient to support the claims against the different Influenza A strains. The Agency's guidance for Testing and Labeling Claims against Pandemic 2009 H₁N₁ Influenza A virus is specific to this strain of Influenza A. If you would like to support additional strains of Influenza A, you must submit efficacy data on each strain into the Agency for review.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacqueline Campbell-McFarlane".

Jacqueline Campbell-McFarlane
Product Manager

Regulatory Management Branch
Antimicrobials Division (7510P)

