

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



OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: February 27, 2012

SUBJECT: Fipronil Spot-on Products: Conditional Registration and Enhanced Reporting

PC Code: 129121, 105402

Decision No.: 455041, 455042, 455045, 455048

Petition No.: N/A

Risk Assessment Type: N/A

TXR No.: N/A

MRID No.: N/A

DP Barcode: 397793, 397794, 397796, 397797

Registration No.: 65331-2, 65331-3, 65331-4, 65331-5

Regulatory Action: N/A

Case No.: N/A

CAS No.: 120068-37-3, 65733-16-6

40 CFR: N/A

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THROUGH: Michael Metzger, Branch Chief
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TO: Richard Gebken, Risk Manager
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Merial Limited has submitted enhanced reporting of adverse events for Frontline spot-on products in a September 9, 2011 submission. This submission included enhanced incident data from 01 January 2004 through 31 December 2010. Merial proposed that the data show that the two-year conditional registration status of EPA Reg. Nos. 65331-2, -3, -4, and -5 is no longer necessary.

It is recommended that the conditional registration be lifted for the following reasons:

- The purpose of the two-year time limitation is to allow for the post-market surveillance of these pet spot-on products and to better understand their safety profile. Merial's products have been registered in the US for several years (since 1996, for 65331-2 and -3, and since 2000, for 65331-4 and -5), and are also used in the European Union
- EPA agrees that Merial's products, EPA Reg. Nos. 65331-2, -3, -4, and -5 did not appear to contribute to the spike in incidents seen in 2008 and do not appear to be disproportionate to the doses sold, considering Frontline's share of the market.
- EPA agrees that the incident trends per doses sold associated with the 4 products above have been either consistent or decreasing since 2004. EPA feels that 7 years of enhanced reporting showing such consistency is sufficient to allow the Agency to conclude that additional post-market surveillance is unnecessary.
- There is a low percentage of serious incidents.

In addition, HED recommends that Merial's reporting of enhanced incident data only be required on an annual basis, rather than a quarterly basis, because 7 years of enhanced reporting have been provided and did not demonstrate a concern.