

CHILD-RESISTANT PACKAGING REVIEW

Technical Review Branch

IN 6/2/2009 OUT 6/23/2009

Reviewed by Rosalind L. Gross *Rosalind L. Gross*
6/23/2009

EPA Reg. No. or File Symbol 65331-5

DP Barcode _____

Decision No. _____

EPA Petition or EUP No. _____

Date Division Received 6/2/2009

Type Product(s) Insecticide

Data Accession No(s). _____

Product Mgr./Chemical Review Mgr./Contact Person PM 10 Division RD

Product Name(s) Frontline Plus for Dogs

Company Name(s) Merial Ltd

Submission Purpose Examine labeling to ascertain if packaging is CRP or additional testing is required

Active Ingredient(s), PC code, & % S-Methoprene 8.8%
Fipronil 9.8%

Summary of Findings

The discrepancy between the CRP use directions used in SAUE testing and the CRP use directions in this submission as well as current approved labeling (3/24/2004 per registrant's email 5/28/2009) is **unacceptable**. Any reference to CRP use directions on the retail package regardless of location (e.g. the box, inside of box, leaflet, labeling, etc.) must all be **identical to the CRP use directions used in SAUE**. According to 16 CFR 1700.20 (a)(3)(iv) the CRP use directions used in SAUE should be the same as those on the retail package. As this is not the case the registrant's **CRP certification is no longer considered valid** and they must **retest** the package with the CRP use directions that are on the retail package or **change** the CRP use directions on the retail package back to the directions used in SAUE testing.

Additionally, registrant must submit evidence regarding the appearance of the back of blister CRP used in CRP SAUE testing.

There is also a **question** as to whether the **CRP use directions used in the SAUE testing for the package involved use directions for opening the applicator/pipette** based on the comment with EPA Reg No 65331-3 and 65331-5 regarding the revision of step 2 "to be more consistent with the CR testing wording." The blister and not the applicator/pipette is the CRP. **However, if use directions for opening the applicator/pipette were a part of the CRP use directions used in SAUE testing then they must be on the retail package in the identical language used in CRP SAUE testing.** Any changes to the language (e.g. addition of a pictogram) would necessitate retesting.

Discussion and Conclusion

The registrant submitted the wording used for the CRP use directions in the Senior Adult Use Effectiveness (SAUE) testing for this package (5/28/2009 email). The label submission for with EPA Reg No 65331-4 has CRP use directions in four locations. These locations are:

- On page 3 part of the box there is a pictogram on how to open the CRP and step 1 is "Remove Applicator from Child-Resistant Package", which states the CRP use directions. **Note these are not CRP use directions used in the SAUE testing for the package.**
- On page 4 the back of the box there are CRP use directions on "Remove Applicator from Child-Resistant Package". **Note these are not CRP use directions used in the SAUE testing for the package.**
- On page 7 the back of the blister, which is the CRP, there is a dashed line, a picture of scissors, and the words "Cut here". **Note these instructions do not appear consistent with CRP use directions used in the SAUE testing for the package (per PPLS submission 3/24/2004 p12 and question whether even this was appearance of CRP in CRP SAUE testing). Registrant must submit evidence regarding the appearance of the back of blister CRP used in CRP SAUE testing.**
- On page 8 the front of a label or something there are CRP use directions on "Remove Applicator from Child-Resistant Package". **Note these are not CRP use directions used in the SAUE testing for the package.**

The discrepancy between the CRP use directions used in SAUE testing and the CRP use directions in this submission as well as current approved labeling (3/24/2004 per registrant's email 5/28/2009) is unacceptable.

Any reference to CRP use directions on the retail package regardless of location (e.g. the box, inside of box, leaflet, labeling, etc.) must all be **identical to the CRP use directions used in SAUE.** According to 16 CFR 1700.20 (a)(3)(iv) the CRP use directions used in SAUE should be the same as those on the retail package. As this is

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