

EFFICACY REVIEW

DATE: IN 2-7-85 OUT 4-3-85

FILE OR REG. NO. 4758-144

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED January 31, 1985

DATE OF SUBMISSION January 31, 1985

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): (I,) D, H, F, N, R, S _____

DATA ACCESSION NO(S). Record No. 144829; Action Code 301

PRODUCT MGR. NO. 16 - Miller

PRODUCT NAME(S) Hill's Holiday[®] Flea & Tick Dip for Dogs, Cats, Puppies & Kittens

COMPANY NAME Pet Chemicals, Incorporated

SUBMISSION PURPOSE Amend label rate to specify 1.5 fl. oz. per gal. for light, 2.0 fl. oz./gal. for medium and 2.5 fl. oz./gal. for heavy flea infestation, no accompanying data.

CHEMICAL & FORMULATION d- Limonene 78.20%

CONCLUSIONS & RECOMMENDATIONS The label amendment is unacceptable in the absence of performance data justifying need for higher rate, which data is alluded to in registrant's 1/31/85 letter. In view of toxicity reactions with this active, especially on cats, need for higher rate must be justified. Also, registrant has never submitted additional data requested for related product 4758-141 on 4/9/82, used at same concentration of active. No data ever submitted for this product, which should be required under 40 CFR 162.18-2(d)(3), former, or 40 CFR 162.163(b)(2)(iii), current. OBJ Vern L. McFarland, IRB-TSS