



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

SEP 11 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP# 8F3592. Method Validation Evaluation of Avermectin in Citrus. No MRID Number. No DEB Number.

FROM: Stephanie H. Willett, Chemist *SHW*
Tolerance Petition Section 2
Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Debra F. Edwards, Ph.D., Section Head
Tolerance Petition Section 2
Dietary Exposure Branch
Health Effects Division (H7509C)

Debra Edwards

TO: George LaRocca, PM 15
Registration Division (H7505C)

A method validation was requested by DEB for avermectin in oranges, beef liver and milk (see PP#7G3468, memo of L. Cheng dated 2/19/87). It was concluded previously that the proposed methodology for animal commodities was acceptable (see PP#8F3592, memo of V. Boyd dated 9/2/88).

The method validation for citrus was also completed (see memo of Jay Wilner, ACS, dated 9/30/87). Method No. 1009, Revision 2, was found to be adequate for enforcement purposes. When whole citrus fruit was fortified with avermectin at levels of 5 and 10 ppb, recoveries ranged from 93 to 106%. No revisions were necessary in the analytical procedures. DEB later requested that the method be revised only to combine methodology for whole citrus fruit and citrus processed fractions into one method (see also PP# 8F3592, memo of S.H. Willett dated 8/8/89). Method No. 1009, revision 3, will therefore be sent to FDA for inclusion in PAM II.

Conclusions/Recommendations

DEB concludes that adequate enforcement methodology is available for quantifying avermectin in citrus fruit, pulp and oil. Merck Sharp and Dohme Method No. 1009, Revision 3, will be sent to FDA for inclusion in PAM II. In the interim a copy of the approved method with supporting information is being sent to ISB/PMSD so

that the method will be immediately available to anyone interested in enforcement.

Attachments:

- 1) PAM II Cover Sheet
- 2) Method Trial Request, DEB , dated 2/19/87
- 3) Memo of Jay Wilner, ACS, dated 9/30/87
- 4) Method No. 1009, Revision 3

cc with attachments: M. Bradley (PAM II editor) E. Eldredge (ISB/PMSD)

cc without attachments: Willett, RF, PP#8F3592, D. Marlow (COB), Corneliussen (FDA, HFF426) Circu

H7509C:DEB:SHW:shw-9/6/89:CM2:RM810:X1439

RDI: D. Edwards, 9/7/89; R. Loranger, 9/7/89