MEMORANDUM

Subject: PP#9F03787. Abamectin (Avermectin B₁) for Use in/on Pears. Initiation of Petition Method Validation Request. (MRID#: 426922-01. No DP Barcode#. No CBTS#.)

From: G. Jeffrey Herndon, Chemist
Tolerance Petition Section II
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

Through: Richard A. Loranger, Ph.D., Acting Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

To: Donald A. Marlow, Chief
Analytical Chemistry Branch
Biological and Economic Analysis Division (H7503C)

The registrant, Merck and Company, Inc., is requesting that permanent tolerances be established for the residues of abamectin (avermectin B₁) insecticide/miticide and its delta-8,9-isomer in/on pears at 0.020 ppm based on a rate of 0.025 lbs.ai./A. and a 28 day PHI. Previously, Merck had requested a 0.035 ppm tolerance based on the same rate of 0.025 lbs.ai./A. and initially a 14 day and later a 21 day PHI.

A tolerance method validation on pears was successfully completed by the Beltsville Analytical Chemistry Laboratory based on a 0.035 ppm tolerance (see memo of M.W. Law and B.J. Puma dated 2/29/92). The Beltsville lab had recommended various changes in the method they validated which have been incorporated into the current method ("HPLC-Fluorescence Determination for Avermectin B₁ and 8,9-Z-Avermectin B₁ in Pears and Apples", M.B. Hicks, Merck Method# 8000, Rev. 4, 12/14/92, MRID# 426922-01).

A petition method validation (PMV) is requested for recovering Avermectin B₁a from pear samples at lower levels than tested previously. No further validation for recovering Avermectin B₁b
should be necessary, since the compound was previously validated down to 2.4 ppb on pears. All samples (including the controls) should be run in duplicate at the requested fortification levels (see attached table). A copy of the method is supplied as Attachment II. This includes the structures (pg. 6), method recoveries (pgs. 8-11), typical chromatograms (pgs. 15-17), suggestions to the analyst (pgs. 29-39), and the revision histories (pgs. 42-48).

Please return the requested information on the attached forms and all other information concerning the PMV that are generated according to your SOP on PMVs, including fortified samples, standard curves, and examples of sample calculations. If any communication with the registrant is necessary to clarify minor points, a description of such communication should also be returned to CBTS with your final report. The results of this PMV should be directed to E. Haeberer, Section Head, TSP-2.

Attachment I - Method Report Form (2 pages)

Attachment II - "HPLC-Fluorescence Determination for Avermectin B₁ and 8,9-β-Avermectin B₁ in Pears and Apples", M.B. Hicks, Merck Method # 8000, Rev. 4, 12/14/92, MRID # 426922-01.

cc (with Attachment I only): circu., PP # 9F03787, G.J. Herndon, E. Haeberer (section head), RF, M. Bradley (PAM II Editor), George LaRocca/Rame Cromwell (P.M. Team 13).

cc (with all attachments): D. Marlow (H7503W).

RDI: Section Head: E. Haeberer: 10/20/94,
Acting Branch Senior Scientist: M. Flood: 10/20/94,
Acting Branch Chief: R.A. Loranger: 10/20/94.

H7509C: CBTS: G.J. Herndon: 305-5079: CM #2, Rm. 804T: 10/20/94.
Method: "HPLC-Fluorescence Determination for Avermectin B₁ and 8,9-Z-Avermectin B₁ in Pears and Apples", M.B. Hicks, Merck Method# 8000, Rev.4, 12/14/92, MRID# 426922-01.

Please do not use control values for recovery corrections. Please do not report control values as 0.0 ppm; accurately state your limit of detection and note any commodity coextractives that could change the recovery values reported.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Chemical Added</th>
<th>ppm Added</th>
<th>ppm Found</th>
<th>% Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pears</td>
<td>Avermectin B₁a</td>
<td>0.0</td>
<td>0.01</td>
<td>0.02</td>
</tr>
</tbody>
</table>
Modifications to Method (major or minor):

Special Precautions to be Taken:

Sources of Analytical Standards:

Instruments Used:

Instrument Parameters (if different):

Commercial Source for any Special Reagents of Equipment:

Comments:

Chromatograms: