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MEMORANDUM:

SUBJECT: Reregistration of Thiabendazole. Product Chemistry {Guideline 63 Requirements}. (Case No. 2670) [CBRS No.: 10704; MRID: 424905-01; DP Barcode: D183292]

FROM: Dennis McNeilly, Chemist  
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THRU: Francis B. Suhre, Section Head  
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TO: Franklin Rubis, PMT-51  
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Thiabendazole is on List B. CBRS completed a Phase IV review for thiabendazole on 2-20-91 (C. Olinger). With regards to Guideline 63-13, the phase IV review concluded that data were required to determine the stability of thiabendazole during exposure to metal, metal ions, and sunlight.

The structure of thiabendazole is:

In response Merck, Sharp, & Dohme Research Laboratories (MRID 424905-01) provided data to demonstrate the stability of thiabendazole (TGA1) when stored at room temperature for up to 64 months, or at an elevated temperature for up to 14 months.

The registrant also states that: "... they do not feel that these requirements apply

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to their product since in the interval between manufacture and processing into end-use formulations, the dry active is stored in polyethylene bags and sealed in a kraft board drum. The active ingredient is therefore never exposed to metals, metal ions or sunlight prior to being processed into end-use formulations."

#### Conclusions and Recommendations

The data submitted in this MRID were previously submitted by Merck in MRID 410250-01. The registrant also stated in that submission, that they did not want to perform the metal, metal ions, and sunlight storage stability tests. DEB (now CBRS and CBTS) recommended against this waiver request (M. Nelson, 6/13/89).

CBRS reiterates our previous conclusions and recommendations:

1. Merck has provided data demonstrating the stability of thiabendazole (TGA) when stored at room temperature (25 C) for up to 64 months, or at an elevated temperature (40 C) for up to 19 months.
2. CBRS does not agree to a waiver for storage stability data (63-13) for thiabendazole to metal, metal ions, and sunlight. These data remain outstanding.

CC:Reviewer;Thiabendazole List B file:circulation.

RDI: FBS,10/21/92;MSM,10/21/92;EZ,10/23/92.

H7509C: DMM;dmm;CM-2;Rm 800D;X305-5934;10/21/92