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

4/4/88

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCESMEMORANDUM

SUBJECT: Maneb (014505)
Special Review Branch Questions
Maneb Comprehensive Data Call In of 4/1/87
Special Review (Storage Stability) Data Call In of
3/31/87
Pennwalt Letter of 12/2/87
[No MRID No., No RCB No.]

FROM: Susan V. Hummel, Chemist
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THRU: Edward Zager, Section Head
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TO: Valerie Bael
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Registration Division (TS-767C)

This memo is in response to your request for comments on the Pennwalt letter of 12/2/87, regarding the Storage Stability Data Call In Notice of 3/31/87. (See V. Bael memo of 12/22/87). Pennwalt, the registrant of Maneb Technical, pointed out that the Storage Stability Data Call In Notice of 3/31/87 was issued after the usual treatments are made for maneb on apples, almonds, green onions, and peaches; and requested a time extension until 12/1/88. You questioned the timing of the data call in notice, and asked if the Pennwalt request for a time extension was reasonable. We will respond to both the registrant's comments and the questions from SRB.

Registrant Comment 1.

The Agency did not respond to the registrant's waiver request and time extension request of 7/6/87. (The registrant's 90 day responses to both DCI's were included in two registrant letters dated 7/6/87.)

RCB Comment

1. RCB reviewed the registrant 90 day response to each of the DCIs (Registrant letters of 7/6/87).

a. M. Kovacs (memo of 8/5/87) reviewed the registrant response to the 3/31/87 Storage Stability DCI. The registrant had requested a time extension for almonds and peaches. (There was no mention of a time extension for apricots.) A time extension for residue data on almonds was considered scientifically justified. The requested time extension for residue data on peaches was not considered scientifically justified. However, RCB noted that time extensions are an administrative decision.

b. W. Hazel (memo of 8/7/87) reviewed the registrant response to the 4/1/87 Comprehensive DCI. He stated that a waiver of plant metabolism data was not justified and included a discussion of the importance of plant metabolism for maneb. He stated that a time extension was justified for residue data on metabolites/degradates of maneb other than ETU.

2. On 5/29/87, the registrant met with RCB, SRB. At this meeting, the registrant was informed that the Agency would take a hard line on time extensions for the 3/31/87 Storage Stability DCI. The registrant was also informed that no time extensions would be granted by letter on 7/24/87 (SRB to registrant).

3. The registrant's 10/1/87 progress reports (for each DCI) states that all studies are "on schedule," and presumably would be expected by the due dates in the DCIs.

4. RCB is not aware of any other communications to the registrant regarding these DCIs.

Registrant Comment 2.

The Storage Stability DCI (3/31/87) was issued after initial treatments are made for apples, almonds, green onions, and peaches. The April 1, 1988 deadline will not be met. The registrant requests a time extension until 12/1/88. The registrant will begin treatments in 2/88.

SRB Question

Why was the DCI not issued earlier. Are time extensions justified?

RCB Comment

1. The Storage Stability DCI was issued 2 months after RCB determined that the submitted storage stability data showed severe degradation in stored samples. (See M. Kovacs 1/21/87 review). The DCI was based on a registrant proposal for storage stability data on weathered residues (discussed in M. Kovacs 1/21/87 review). The registrant submitted storage stability data (and their proposal for further storage stability data) in late Nov., 1986 or early Dec., 1986. RCB received the storage stability data for review on 12/5/86.

2. The registrant was aware of the need for storage stability data long ago. The need for storage stability data was expressed in the 4/1/85 review of M. Bradley and the 1/17/86 review of M. Bradley.

3. The registrant's 10/1/87 progress report for the 3/31/87 DCI states that all studies are "on schedule," and presumably would be submitted by the due date. We do note that the registrant's 10/1/87 progress report did state that almonds, peaches, and bulb onions will be treated in 1988. The progress report also stated that apples will be dropped from the label.

We note that almonds are still on the label. Peaches, and onions were removed from the label (M. Bradley memo of 5/2/86). Apples are not on the current Pennwalt label. (Apples were on the Griffin label.) As long as apples, peaches, and onions remain off the label until adequate data are provided, RCB has no objection to a time extension.

A time extension for storage stability data would not be appropriate. We cannot evaluate any residue data without supporting storage stability data unless the samples were analyzed very shortly after harvest in every case.

General Comment

The registrant has been confusing the two DCI's. The Storage Stability DCI was issued by SRB to support the Special Review. The major issue in the special review is the presence of ETU and conversion of maneb to ETU. Thus residue data were needed for maneb and ETU. The Comprehensive data call in was issued to obtain full data on maneb so that a registration standard could be prepared. Full data on metabolism are needed to determine the total toxic residue. Then, residue data for all components of the total toxic residue as determined in the metabolism study are needed.

Earlier, the registrant stated that residue data will not be available from every location required in the 4/1/88 DCI. A few minor differences in the geographical representation or number of

samples needed can be handled as a minor deficiency in the submitted data. However, major differences, such as, no data from the number 1 growing area for a crop, very few samples per crop, no storage stability data, lack of sample storage information, etc., will result in the data being unacceptable for review.

cc: R.F., circu, S. Hummel, Maneb S.F., Maneb S.R.F. (Hummel),
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