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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Note:

Subject: EPA Id# 069001. Pyrethrins: Minutes of a meeting with the registrant and their consultant to discuss the Carcinogenicity Peer Review Report.

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and

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Pyrethrins Meeting.

On Thursday July 27, 1995, representatives of the registrants of pyrethrins, Drs. Gerald Schoenig and Thomas Osimitz met with HED staff Drs. Karl Baetcke, John Doherty and Marion Copley (later part of the meeting) to discuss the Carcinogenicity Peer Review report for pyrethrins which was completed by HED in June, 1995. The HED Carcinogenicity Peer Review requested that a complete internal (at the laboratory) pathology peer review be conducted for both the rat and mouse studies. Topics raised by the visitors included the need for a complete peer review. They claim that the thyroid was already internally peer reviewed and the skin does not require additional pathology review or reading because the type of tumors noted are readily visible at necropsy. They also claim that the mouse lung tissue was already serially sectioned and this led to data not comparable to historical controls and that this also constitutes an internal peer review.

The registrant expressed their willingness to do a partial pathology peer review. The registrants presented several tables



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of comparing the statistical methods used by HED where the concurrent control groups were combined and their own method in which the treated animals were compared against each concurrent control group. They demonstrated that differences in the degree of statistical significance result when these methods are used and that their method is more appropriate.

The registrant expressed their interest in doing some special studies to try to determine the mechanism for induction of thyroid tumors. Dr. Baetcke agreed to obtain the latest version of the Agency's recommendations for assessing the mechanism of thyroid tumors for them.

The registrant was advised that the Agency is also very concerned with the presence of ovary theca cell tumors and that these tumors are still important even though a mechanism for the thyroid tumors is demonstrated.

It was concluded that the registrant would submit their plans for the pathology peer review including which tissues they were willing to reread as well as their inquiries regarding statistical analysis in writing to the Agency for further review.