April 8, 1970

Herbert Blumenthal, Ph.D.
Chief, Petitions Review Branch
Bureau of Foods, Pesticides and
Product Safety
U. S. Food and Drug Administration
200 C Street, Southwest
Washington, D. C. 20204

Dear Herb:

Confirming our telephone conversation I have enclosed Xerox copies of the status reports for the chronic toxicity studies for our Aroclors at Industrial Bio-Test, Inc.

Specifically, three of our polychlorinated biphenyls are under investigation. These are Aroclors 1242 (biphenyl chlorinated to the extent of 42%), 1254 (biphenyl chlorinated to the extent of 54%), and 1260 (biphenyl chlorinated to the extent of 60%). Studies include two year oral administration to rats, two year oral feeding to dogs and a three generation rat reproduction study.

As indicated in the enclosures, the levels of administration are 1, 10 and 100 ppm for each of the compounds. Further, the status reports for the chronic dog studies represent data at the end of nine months.

The enclosed copies on the rat studies show data at the end of six months administration. As we mentioned on the telephone, we added 300 rats to the chronic studies after the original two year project had gotten underway to allow a sufficient number of animals for sacrifices at three, six and twelve months. Histopathology has been completed on the sacrificed animals and Dr. Calandra has reported verbally that there are no positive pathological findings.

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The rat reproduction studies are into the second generation. At this point Dr. Calandra has indicated that there definitely has been no effect with any of the compounds at the 10 ppm dietary level. There is some equivocal possible effect in the animals at the 100 ppm level with Aroclor 1254.

If you have any specific questions after reviewing the enclosed status summaries, please feel free to call Dr. Calandra or Dr. Fancher directly.

Best personal regards.

Sincerely,

R. Emmet Kelly, M. D.
Medical Director

REK:ju

c.c. Dr. Joseph C. Calandra
Dr. Otis E. Fancher
b.c. W. B. Papageorge, G. W. Ingle
Enclosures

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