



BIONETICS

5516 Nicholson Lane, Kensington, Maryland 20795 301 881-5600

March 28, 1979

Mr. J. C. Weber
Product Acceptability Manager
Monsanto Industrial Chemicals Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166

Dear Mr. Weber:

We would like to review with you the facts leading up to the Litton Bionetics, Inc. (LBI) request for an additional \$21,374 for work performed on the AROCLOR 1254 Study (Bio-77-2; LBI Project #20771).

Originally, the cost estimate for this study was provided to Monsanto in early 1976, and even though the award was not made until early 1977, we did not increase the price to Monsanto even though Monsanto asked if any increases would be necessary at that time. The award was made almost simultaneously with the appearance of the draft FDA-GLPs and no one had any idea at that time what the cost impact of these regulations would be on non-clinical laboratory studies. We believe that it is also important to note that the price we quoted for this study was determined by actual estimated costs, when in fact we realized that no other laboratory in the world could provide a similar study where animals could be obtained, each having a known history of a minimum of five pregnancies under laboratory conditions, to use as a baseline.

As you can well imagine, LBI had no idea at the time of award what the increases in our overhead rate might be in August 1978, the beginning of the LBI's new fiscal year, and four months after the planned conclusion of the study. It should also be recognized by Monsanto that LBI's annual salary reviews are effective in August, thus the pathology originally expected to be performed prior to August 1978, will now be performed in January - April 1979 at the higher labor rates.

When Monsanto requested that LBI continue the work beyond the originally estimated time period, LBI did so, acting in good faith. We think it worth noting that the formal approval for continuing the study from 1 April 1978 - 31 May 1978 was received on 5 June 1978 in a letter from Dr. Peter Berteau dated 1 June 1978. Likewise the formal approval to continue the study an additional six months - 1 June 1978 to approximately 1 December 1978 - was received 30 June 1978 in a letter from Dr. Berteau dated 18 June 1978. Clearly, our continuation of the study with the attendant accumulation of costs indicates that LBI acted in a spirit of cooperation and trust. Dr. Berteau's letter of 8 March 1979 to Mr. Giss, indicates that one of the problems in Monsanto's acceptance of costs is that "no written documentation indicating that these changes would be

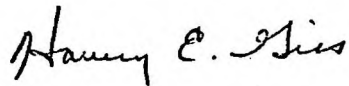
Mr. J. C. Weber
Monsanto Industrial Chemicals Company

Page Two
March 28, 1979

encountered", was provided until after the work had actually been performed. In fact, the majority of the adult animals were killed in early December 1978, while Monsanto was told of the \$21,374 request for additional funds by Dr. David Martin through Dr. Berteau by telephone on 30 June 1978, the very day that authorization for a six month extension was received. Letters indicating this amount and explaining it were sent to Dr. Berteau from Dr. Martin on 14 July 1978 and 5 October 1978 and from Mr. Harvey Giss on 7 August 1978 and 11 September 1978. Clearly, the Monsanto Company was informed in writing as early as six months prior to the completion of the bulk of the work, and even without assurance of payment, we have continued in good faith.

While we agree with Dr. Berteau that "it does not seem that the Monsanto Company could be legally responsible for this payment", Monsanto Company is responsible for, and requested, the delays in completing the work beyond the time frame originally estimated. While we fully intend to complete the required work on this program, we do request that Monsanto Company review the circumstances leading to this situation and reconsider whether or not some form of payment for the increased cost of the work performed by us in response to the Monsanto request, is in order.

Sincerely,



Harvey E. Giss
Manager
Program Development

HEG:af