The next piece of information in the huge jigsaw comes from 1969, when Siefe of the FDA wrote to Lafayette to inform them that they had failed to submit any annual reports and also that they needed to make various changes in the package inserts.

Strangely enough, Lafayette saw fit within the same year to conclude that Pantopaque II had no

"real improvement over conventional Pantopaque"

and attributed this to the summaries of their three principal investigators, Taveras, Peterson and Fager.

Accordingly, on June 25, 1969, the President of Lafayette, Bucke, wrote to the FDA to request withdrawal of NDA 16-377 for marketing approval of Pantopaque II.

It appears that the FDA was not informed of the animal toxicity studies that had failed to support the safety of the original Pantopaque.

IND 1-161 also had to be amended, and a ?notice' from Lafayette was required to notify the authorities of discontinued clinical studies.

This should have included information about

"clinical studies that have or will be submitted to the NDA before its official withdrawal."

One assumes this covers the 15-week intrathecal study, but this was seemingly ?overlooked'.

The Lafayette representative, Kunz, who liased with the FDA on this matter, appears to have ?fudged the issue' by cross referencing information on clinical studies reported in the NDA to serve as a progress report for the IND.

In other words, he was ?killing two birds with one stone!'

The fact that technically Hazleton had sent the study results to Kodak, not Lafayette might excuse Kunz being unaware of them, except that one would expect him to be cognisant of the studies being undertaken, otherwise he would surely not be the right person in the company to be dealing with the NDA requirements.

Had he not been aware of the results, he should have taken the necessary steps to rectify the lack of information.

Pleading ignorance hardly seems a valid excuse, especially when the FDA representative, Dr. Grigsby documented in a memo that he has specifically indicated to Kunz that the firm was required to be forthright and honest.

One wonders why he felt it necessary to stipulate this statutory requirement so bluntly.

Perhaps (and this must be conjecture) he sensed that he was not being told the full story!