JANSSEN
PHARMACEUTICA

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October 18, 1985

Mr. F. Sapienza
Drug Enforcement Agency
Drug Control Section
1405 High Street, N.W.
Washington, D.C. 20537

Dear Mr. Sapienza:

This letter is to confirm our telephone conversation of Friday, October 18, 1985. Janssen Pharmaceutica has done preclinical research and clinical development work with two Schedule I compounds, i.e. sufentanil and alfentanil. For sufentanil this work was successfully completed when the sufentanil NDA was approved by the FDA and the drug was subsequently reassigned to Schedule II by the DEA. For alfentanil, a series of clinical studies has been completed and an NDA has been submitted to the FDA. Although we expect that this drug will be approved shortly, another series of clinical investigations intended to expand our data base is currently ongoing.

The sufentanil program involved some 25 investigators. For the initial alfentanil program we worked with some 20 investigators. The current alfentanil program is expected to enroll an additional 50 investigators over the next several months.

To achieve this, Janssen Pharmaceutica, as well as each of the investigators, had to apply to the DEA for a Schedule I license and submit to the FDA and the DEA the study protocols. The DEA procedures require compliance with recordkeeping and safe guarding regulations and one has to allow time for administration processing. In these matters we always found both the DEA and the FDA extremely cooperative. In our experience the DEA Schedule I limitations did not change the IND and IRB review processes.

I trust that this answers your questions.

Most sincerely yours,

Jo Brugmans

Jo Brugmans, M.D.
Vice President, Scientific Affairs

JB:dd