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JUN 18 1985

Research Medical Center
ATTN: Morton H. Levitt
Vice President
Clinical Services
2316 E. Meyer Blvd.
Kansas City, MO 64132

License No. 24-18625-01

Gentlemen:

We have reviewed your letter dated April 3, 1985 requesting byproduct material for in vitro studies and find that we will need additional information as follows:

Currently, your license authorizes possession of byproduct material for diagnostic and therapeutic use in humans. In order for us to authorize you to perform in vitro studies beyond that which is authorized in 10 CFR 31.11, you will need to submit the information requested in Regulatory Guide 10.7 (enclosed). While some of the items covered in this guide may have already been addressed in your current licensed program, you need to restate some of this material within the context of a research and development environment. In particular, you should provide detailed responses to Items 6, 8E, 9, 10, 12, 13, 14 and 15 of the guide as well as 16 and 17 if you will need to request additional authorized users. Please note that your license already authorizes you for the use of FDA-approved INDs. Such authorization is granted along with authorization to use Groups I through V of 10 CFR 35.100 (See 10 CFR 35.100(a)(8), (b)(13), (c)(5), (d)(4), and (e)(3) enclosed).

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 78709.

Sincerely,

Original Signed By
William J. Adam, Ph.D.
Materials Licensing Section

Enclosures:
1. Regulatory Guide 10.7
2. 10 CFR Part 35

RIII
WJA
Adam/jl
6/17/85