

Appendix E

FDA Acknowledgement Letter

Food and Drug Administration
Rockville, MD 20857

IND 49,078

Date

NOV 16 1995

Hoechst-Roussel Pharmaceuticals Inc.
Route 202-206, P.O. Box 2500
Somerville, NJ 08876-1258
Attention: James L. DeMartino, Ph.D.
Assistant Director
Drug Regulatory Affairs

Dear Sir or Madam:

We acknowledge receipt of your Investigational New Drug Application (IND) submitted pursuant to Section 505(i) of the Federal Food, Drug, and Cosmetic Act. Please note the following identifying data:

IND Number Assigned: 49,078

Sponsor: Hoechst- Roussel Pharmaceuticals Inc.

Name of Drug: HOE 901 [insulin analogue (rDNA origin) injection]

Date of Submission: November 10, 1995

Date of Receipt: November 14, 1995

Studies in humans may not be initiated until 30 days after the date of receipt shown above. If, within the 30-day waiting period, we identify deficiencies in the IND that require correction before human studies begin or that require restriction of human studies until correction, we will notify you immediately that the study may not be initiated ("clinical hold") or that certain restrictions must be placed on it. In the event of such notification, you must continue to withhold, or to restrict, such studies until you have submitted material to correct the deficiencies, and we have notified you that the material you submitted is satisfactory.

It has not been our policy to object to a sponsor, upon receipt of this acknowledgement letter, either obtaining supplies of the investigational drug or shipping it to investigators listed in the IND. However, if drug is shipped to investigators, they should be reminded that studies may not begin under the IND until 30 days after the IND receipt date or later if the IND is placed on clinical hold.

You are responsible for compliance with the Federal Food, Drug, and Cosmetic Act and the regulations implementing that Act (Title 21 of the Code of Federal Regulations). Those responsibilities include reporting any adverse experience associated with use of the drug that is both serious and unexpected to the FDA as soon as possible and in no event later than 10 working days after initial receipt of the information and reporting any unexpected fatal or life-threatening experience to the FDA by telephone no later than 3 working days after receipt of the information (21 CFR 312.32), and submission of annual progress reports (21 CFR 312.33).

Please forward all future communications concerning this IND in triplicate, identified by the above IND number, and addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research (HFD-510)
Attention: Document Control Room
5600 Fishers Lane
Rockville, Maryland 20857

Should you have any questions concerning this IND, please contact Mr. John Short at 301-443-3510.

Sincerely yours,



Consumer Safety Officer
Division of Metabolism and Endocrine
Drug Products
Office of Drug Evaluation
Center for Drug Evaluation and Research

cc: Original IND - pink
HFD-510 - yellow
HFD-510/CSO - green

IND ACKNOWLEDGEMENT