

**Building Effective Partnerships
FDA and Stakeholders Public Meeting
Duke University Medical Center**

April 12, 2000

Agenda

Rec'd
APR 14 2000
JK

- I. Welcome** Mark Barnett, Moderator
- II. Opening Remarks** Jane Henney, M.D.
Linda Suydam, D.P.A.
- III. Presentations of Leveraging Models**
- Tobias Massa, Ph.D.
Eli Lilly and Company
 - Victoria Durant-Gonzales, Ph.D.
Spelman College
 - David R. Lineback, Ph.D.
Joint Institute for Food Safety and Applied Nutrition
- IV. Discussion of Proposed Leveraging Initiatives**
- Safety Review for New Products
Safety Assurance in Clinical Trials
 - Assuring Industry Compliance with Safety Regulations
Gene Therapy, Human Cellular and Tissue Based Products
 - Patient/Consumer Education on the Safe Use of Products
Risk Management
 - Monitoring the Internet
 - Safety-related Research
 - *NCTR Chip Technology*
 - *Other Proposed Initiatives*
- V. Leveraging Overview/ Q&A** Linda Suydam, D.P.A.

00N-0001

LST-3



CUSTOMER SURVEY

NAME OF EVENT: Leveraging-Collaborating With Stakeholders

DATE _____

DID YOU GIVE/RECEIVE THE INFORMATION YOU WANTED/NEEDED/EXPECTED? YES ___ NO ___

IS THE DIALOGUE USEFUL TO YOU? YES ___ NO ___

WERE MATERIALS USEFUL TO YOU? YES ___ NO ___

WERE THE LISTENERS PROFESSIONAL, KNOWLEDGEABLE AND ABLE TO ANSWER YOUR QUESTIONS?

YES ___ NO ___

WOULD YOU PARTICIPATE IN ANOTHER SIMILAR EVENT? YES ___ NO ___

HOW CAN WE IMPROVE? COMMENTS/SUGGESTIONS:

AN AGENCY MAY NOT CONDUCT OR SPONSOR, AND A PERSON IS NOT REQUIRED TO RESPOND TO, A COLLECTION OF INFORMATION UNLESS IT DISPLAYS A CURRENTLY VALID OMB CONTROL NUMBER" OMB # (0910-0360) EXPIRES 7/31/01