

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

550 W. Jackson Blvd.
Suite 1500
Chicago, Illinois 60661

DATE(S) OF INSPECTION

01/29, 30 + 31/2003

FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Melanie J. Loots Associate Vice Chancellor

FIRM NAME

University of Illinois @ Urbana-Champaign

STREET ADDRESS

601 E. John St. 400 Swenland Hc. 204

CITY, STATE AND ZIP CODE

Champaign Illinois 61820

TYPE OF ESTABLISHMENT INSPECTED

Sponsor

DURING AN INSPECTION OF YOUR FIRM, I (WE) OBSERVED:

Failure to adequately monitor INADs Submitted to FDA/CVM as follows:

1. In the role of sponsor submitting INAD [redacted] to the US Food and Drug Administration, the university has not reviewed the protocol used by their Investigator in this study.
2. In the role of sponsor submitting INAD [redacted] to the U.S. Food and Drug Administration, the university has repeatedly failed to adequately monitor related research to assure the investigator complied with government regulations and the study protocol. This deficiency has resulted in the following:
 - (a) Sale of 386 investigational hogs for slaughter for food since April 2001 without prior authorization from FDA.
 - (b) Unauthorized rendering of a pig subject to INAD [redacted], on or about 9-27-2002

SEE REVERSE OF THIS PAGE

[Signature]
Michael M. [unclear]

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Mark E. Peterson Investigator
Amy L. Adams Biologist
Michelle McInnis Biologist

DATE ISSUED

1-31-2003