DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
550 W Jackson Blvd. (312) 353-5863
Suite 1500
Chicago IL 60661

DATE(S) OF INSPECTION
01/29,30,31/2003

FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Matthew B. Wheeler Investigator

FIRM NAME
University of Illinois @ Urbana-Champaign

STREET ADDRESS
1207 W. Gregory Drive Rm 366

CITY, STATE AND ZIP CODE
Urbana, Illinois 61801

TYPE OF ESTABLISHMENT INSPECTED
Clinical Investigator

DURING AN INSPECTION OF YOUR FIRM I/WE OBSERVED:

1. from April 2001 until the present time, 386 "Black and Gold" tagged hogs from INAD [redacted] were sold for slaughter as human food. This sale was not authorized by FDA.

2. On 9-27-2002 hog # [redacted] was euthanized for poor performance. This animal, involved in INAD [redacted], was subsequently offered to [redacted] and rendered into animal feed components. This disposition was not authorized by FDA.

3. The above incident was not investigated until 10-16-2002. FDA was not notified of the problem until 11-4-2002.

4. Instructions in the revised protocol in effect at the time of the 9-27-2002 incident specifically prohibited rendering of suspect animals involved in the study as follows:

(a) Page 1 [redacted] Revised 7/7/00 States. "If There is any question about disposition of an animal then the animal should be INCINERATED. This is the default.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	[signature]	Mark A. Peterson Investigator Amey L. Adams Biologist Michele C. Mc Guinness	1-31-2003

EF

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Clinical Investigator

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4. (continued)

(b) [redacted] prepared 4/1/01 " states:

"If there is any doubt with regard to the disposition of a particular animal from the transgenic pig program the animal MUST BE INCINERATED."

"Finally no animals in the Transgenic Pig Program may be moved or removed without [redacted] approval!

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	[signature]	Mark G. Robinson Investigator Amey L. Adams Biologist Michele C. McGuinness Bio	1-31-2003

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