

This report is required by [redacted] report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

[redacted] for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

42-V-003

FORM APPROVED  
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, Include Zip Code)

VA Central Iowa Health Care System  
3600 30<sup>th</sup> St.  
Des Moines, IA 50310-5774

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

*Copy*  
*Previous Report*

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

555 - Surgical Teaching Lab (STL)

October 2003 - September 2004

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	0		51		51
5. Cats	0		24		24
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Rats	0		0		0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTER RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer or Legally Responsible Institutional Official)

DEC 8 2006

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

2004

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 93-R-0018  
CUSTOMER NUMBER: 1188

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Bayer Corporation  
P. O. Box 1986  
Berkeley, CA 94701

Telephone: (510) -705-4648

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquillizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			57		57
9. Non-human Primates			94		94
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese: teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

10/8/04

*[Handwritten Signature]*



OCT 13 2004

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 93-R-0020  
CUSTOMER NUMBER: 1185

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

University Of Southern California  
University Park  
Los Angeles, CA 90089

Telephone: (323) -442-1689

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report )	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	0	67	0	67
5. Cats	0	0	9	0	9
6. Guinea Pigs	0	0	2	0	2
7. Hamsters	0	1	126	0	127
8. Rabbits	0	136	827	0	963
9. Non-human Primates	0	0	16	0	16
10. Sheep	0	0	0	0	0
11. Pigs	0	5	282	0	287
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

10/18/04

( AUG 91 )  
Andreas

OCT 25 2004

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1143

1 REGISTRATION NO. **93-R-0189**  
FORM APPROVED OMB NO 0579-0036 **SD**

**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA include Zip Code)  
**NORTHVIEW PACIFIC LABORATORIES  
2800 SEVENTH STREET  
BERKELEY, CA 94710**

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

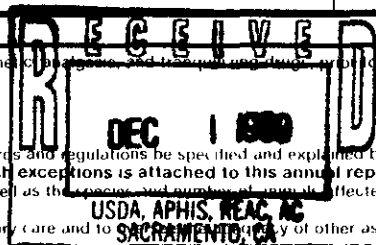
**NVP, BERKELEY, CA 94710**  
(same as #2)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4 Dogs					
5 Cats					
6 Guinea Pigs	192	4652	0	2678	7330
7 Hamsters					
8 Rabbits	176	3741	518	0	4259
9. Non-human Primates					
10. Sheep					
11 Pigs					
12 Other Farm Animals					
13 Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthesia and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility
- 2) Each principal investigator has considered alternatives to painful procedures
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to the quality of other aspects of animal care and use.



**CERTIFICATION BY HEADQUARTER RESEARCH FACILITY OFFICIAL**  
(Chief Executive Officer or Legally Responsible Institutional Official)

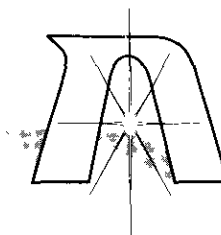
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

DATE SIGNED

11/29/99

# Northview Pacific Laboratories, Inc.

2800 Seventh Street ✧ Berkeley, CA 94710 ✧ 510/548-8440 ✧ Fax 510/548-5425



USDA Registration Number: 93-R-0189

Robert M. Gibbens, D.V.M.  
Director, Animal Care  
USDA, Western Region  
9580 Micron Avenue, Suite J  
Sacramento, CA 95827

November 29, 1999

Dear Dr. Gibbens:

Northview Pacific Laboratories, Inc. is an AAALAC accredited animal facility dedicated to the humane care and use of laboratory animals.

Northview's Institutional Animal Care and Use Committee (IACUC) meets two-to-four times per year in order to review ongoing experimental procedures involving animals and to vote on any new proposals for procedures involving animals. Twice a year, at six month intervals, the IACUC audits the company's animal care program for compliance with the Animal Welfare Act, and conducts an inspection of the company's animal facility. The IACUC submits a report to the company's Institutional Official noting any changes to the company's animal care program, any areas of noncompliance with AWA regulations, any problems or deficiencies that require corrective action, as well as any suggestions for future consideration.

Northview's IACUC assures that our program is in compliance both with the AWA and the NIH Guide for the Care and Use of Laboratory Animals.

In submitting the attached Annual Report for your review, we would like to explain the nature of all procedures conducted on the animals placed in category E.

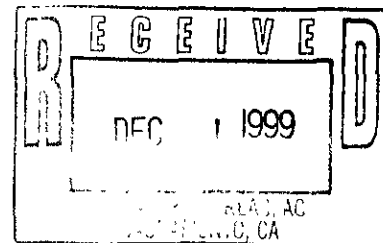
The 2678 guinea pigs placed in category E were used for the following procedure:

Test Procedure

Maximization Sensitization Test

References

ODE Memo #G95-1  
ISO 10993-6



The large number of guinea pigs used for maximization sensitization testing are automatically placed in category E of our report because this procedure involves intradermal injections of emulsions containing Freund's Complete Adjuvant (FCA) as a necessary part of the initial immune induction procedure. These injections of FCA typically cause the animals to develop inflammatory lesions. Drugs are not used to treat these sites because this would interfere with the purpose of the test, which is to evaluate the sensitization potential of a given material. Whether

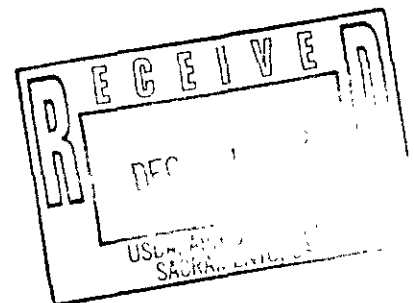


the animals are in fact suffering pain and distress as a result of the FCA injections is open to debate. Our approach here, based on the concerns raised by our IACUC is a conservative one. We automatically place all guinea pigs used on sensitization tests in category E (although, based on national statistics, it is apparent that other laboratories which perform the maximization sensitization test do not consider the animals used to be in pain or distress). We will continue to use this approach until our IACUC is assured that an adequate mechanism exists to allow study directors to unequivocally decide whether an animal administered FCA injections is in pain or distress or not.

Thank you for your attention to our Annual Report.

Sincerely,

Encl.



UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 93-R-0189  
CUSTOMER NUMBER: 1143

FORM APPROVED  
Largo MB NO. 0579-0036 *SD*

ANNUAL REPORT OF RESEARCH FACILITY  
( TYPE OR PRINT )

Northview Pacific Laboratories, Inc.  
551 Linus Pauling Drive

Telephone:  
(510)964-9000

Hercules, CA 94547

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not y	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	322	<del>474</del> <sup>2657</sup> <sub>2657</sub>	0	<del>3584</del> <sup>5668</sup>	8325
7. Hamsters	0	18	0	0	18
8. Rabbits	119	2425	483	4	2912
9. Non-human Primate	0	0	0	0	0
0. Sheep	0	0	0	0	0
1. Pigs	0	4	0	0	4
2. Other Farm Animals	0	0	0	0	0
3. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and follow actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal ca

DEC - 1 2000

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

11/30/00

**Annual Report Site Listing:**

Customer ID and Site Address:

Cust ID: 1143

2800 Seventh Street  
Old Address - No  
Longer In Use.  
Berkeley, CA 94710  
County: Alameda

Telephone  
(510)548-8440



**Annual Report Site Listing:**

Customer ID and Site Address:

Cust ID: 1143

551 Linus Pauling Drive  
Hercules, CA 94547  
County: Contra Costa

Telephone  
(510)964-9000

## Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

- 
1. Registration Number: 93-R-0189
  2. Number 5667 of animals used in this study.
  3. Species (common name) GUINEA PIG of animals used in this study.
  4. Explain the procedure producing pain and/or distress.

MAXIMIZATION SENSITIZATION TEST (ISO). PROCEDURE INVOLVES USE OF FREUND'S COMPLETE ADJUVANT, WHICH CAUSES SKIN LESIONS THAT MAY BE A SOURCE OF PAIN AND DISTRESS.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

METHOD IS FEDERALLY MANDATED.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA CFR           

- 1) ISO 10993-10, PART 10 (1995).
- 2) FDA ODE MEMORANDUM #G95-1

## Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 93-R-0189
2. Number 1 of animals used in this study.
3. Species (common name) GUINEA PIG of animals used in this study.
4. Explain the procedure producing pain and/or distress.

SAFETY TEST FOR BIOLOGICAL PRODUCTS.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

FEDERALLY MANDATED TEST.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA CFR 21 CFR PART 610.11

## Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 93-R-0189
2. Number 4 of animals used in this study.
3. Species (common name) RABBIT of animals used in this study.
4. Explain the procedure producing pain and/or distress.

USP/ISO INTRACUTANEOUS TEST

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

FEDERALLY MANDATED TEST.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA CFR           

- 1) FDA ODE MEMORANDUM #G95-1
- 2) ISO 10993-10
- 3) USP 24 (887)

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 93-R-0189	CUSTOMER NO. 1143	FORM APPROVED OMB NO. 0579-0036
2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)		
NORTHVIEW PACIFIC LABORATORIES, INC. 551 LINUS PAULING DRIVE HERCULES, CA 94547 (510) 964-9000		

**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS/sites

See Attached Listing

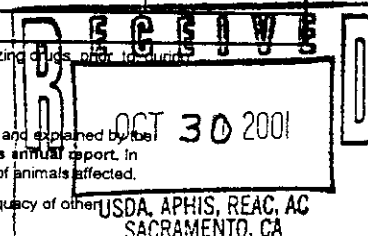
551 Linus Pauling Drive  
Hercules, CA 94547

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	—	—	—	—	—
5. Cats	—	—	—	—	—
6. Guinea Pigs	193	4032	0	2918	6950
7. Hamsters	0	0	6	0	6
8. Rabbits	191	5339	497	0	5838
9. Non-Human Primates	—	—	—	—	—
10. Sheep	—	—	—	—	—
11. Pigs	0	2	0	0	2
12. Other Farm Animals	—	—	—	—	—
13. Other Animals	—	—	—	—	—

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, other to surgery, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.



**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL**  
(Chief Executive Officer or Legally Responsible Institutional official)  
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

DATE SIGNED  
10/22/01

PART 1 - HEADQUARTERS

### Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 93-R-0189

2. Number 2918 of animals used in this study.

3. Species (common name) Guinea Pig of animals used in the study.

4. Explain the procedure producing pain and/or distress.

The guinea pig maximization test and patch test procedures involve the use of Freund's Complete Adjuvant, which causes skin lesions that may be a source of pain and distress.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Method is federally mandated.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA CFR —

1. ISO 10993-10, Part 10 (1995)
2. FDA ODE Memorandum #695-1

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 93-R-0189  
CUSTOMER NUMBER: 1143

FORM APPROVED  
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

*Northview Pacific Laboratories*

Northview Pacific Laboratories, Inc.  
551 Linus Pauling Drive  
Hercules, CA 94547  
Telephone: (510)-964-9000

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

*551 Linus Pauling Drive* FACILITY LOCATIONS ( Sites ) - See Attached Listing *Hercules, CA*

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	<i>0</i>	<i>8</i>	<i>0</i>	<i>0</i>	<i>8</i>
5. Cats	<i>—</i>	<i>—</i>	<i>—</i>	<i>—</i>	<i>—</i>
6. Guinea Pigs	<i>120</i>	<i>2769</i>	<i>0</i>	<i>2655*</i>	<i>5424</i>
7. Hamsters	<i>0</i>	<i>12</i>	<i>0</i>	<i>0</i>	<i>12</i>
8. Rabbits	<i>95</i>	<i>6368</i>	<i>163</i>	<i>0</i>	<i>6531</i>
9. Non-human Primates	<i>—</i>	<i>—</i>	<i>—</i>	<i>—</i>	<i>—</i>
10. Sheep	<i>—</i>	<i>—</i>	<i>—</i>	<i>—</i>	<i>—</i>
11. Pigs	<i>0</i>	<i>8</i>	<i>0</i>	<i>0</i>	<i>8</i>
12. Other Farm Animals	<i>—</i>	<i>—</i>	<i>—</i>	<i>—</i>	<i>—</i>
3. Other Animals	<i>—</i>	<i>—</i>	<i>—</i>	<i>—</i>	<i>—</i>

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese- teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

DATE SIGNED

*10/31/02*

NOV - 4 2002 ✓

### Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 93-R-0189

2. Species (common name) and number of animals used in this study Guinea Pig - 2655  
(list all that apply for this explanation). If you used the same species in more than one procedure, list each procedure and the number of animals used in that procedure in Item 3.

3. Explain the procedure producing pain and/or distress.

The guinea pig maximization and patch tests procedures involve the use of Freund's Complete Adjuvant (CFA), which cause skin lesions that may be a source of pain and distress.

4. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 5 below)

Method is federally mandated.

Note: Starting approx July 1, 2002, Northview now performs the mouse local lymph node assay (LLNA) which uses mice rather than guinea pig and reduces the number of test animals needed from a minimum of ten to five. This test will also reduce the likelihood of pain and distress. We anticipate a great reduction in the number of animals that fall in this category in the future.

5. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA CFR —

ISO 10993-10, Part 10 (1995)  
FDA ODE memorandum #1695-1



Customer ID and Site Address.

ID: 1143

2800 Seventh Street  
Old Address - No  
Longer In Use.  
Berkeley, CA 94710  
County: Alameda

Telephone  
(510)548-8440