K872844

DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 25

Mr. Albert E. May
Continental Avenue
Ridgewood, New Jersey

Dear Mr. May:

We have reviewed your Section 513(f)(2) petition requesting classification of the device identified above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may also, subject to the provisions of the Act, implement the annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval), it may be subject to additional controls. Existing major regulations affecting your device are in Title 21, Parts 800 to 895, of the Federal Regulations. FDA may publish further announcements concerning your device in the Federal Register. Please note that this notification does not affect any requirements of any other Federal, State or local laws.

The determination that your device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, is based on the fact that no changes or modifications in the design, materials, chemical composition, energy source, manufacturing process, or intended use have been reported in your petition. A change or modification in any of these characteristics may require the submission of a new premarket notification or premarket approval application.

1.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-3040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for Lillian Yin, Ph.D.
Director, Division of OB-GYN, ENT, and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

SEP 28 87

Pharmacia, Inc.
Attn: Albert P. Mayo
800 Centennial Avenue
Piscataway, New Jersey 08854

Re: K872849
Sperm-Select Additional Indication
Regulatory Class: II 21 CFR§ 864.5250
Dated: July 13, 1987
Received: July 20, 1987

Dear Mr. Mayo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

Please be advised that the determination above is based on the fact that no medical device has been demonstrated to be safe and effective for in vitro fertilization (IVF) or gamete intrafallopian transfer (GIFT) nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Performance Standards). The Food and Drug Administration (FDA) considers devices specifically intended for IVF or GIFT to be investigational, and subject to the provisions of the Investigational Device Exemption (IDE) regulation, 21, CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use. You may submit for review your final labeling, including clinical instructions for use and promotional materials, to the Office of Compliance (HFR-340), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

1

Pharmacia, Inc.
Attn: Albert P. Mayo
[illegible] Centennial Avenue
Piscataway, New Jersey 08854

Re: [illegible]
Spermo-Select Additional Indication
Regulatory Class: II 21 CFR [illegible]
Dated: July 13, 1987
Received: July 20, 19[illegible]

Dear Mr. Mayo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for *in vitro* fertilization (IVF) or gamete intrafallopian transfer (GIFT) nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Performance Standards). The Food and Drug Administration (FDA) considers devices specifically intended for IVF or GIFT to be investigational, and subject to the provisions of the Investigational Device Exemption (IDE) regulation, 21, CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this issue. You must submit for review your final labeling, including clinical instructions for use and promotional materials, to the Office of Compliance (HFZ-[illegible]), [illegible] Georgia Avenue, Silver Spring, Maryland [illegible].

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of [illegible], ENT, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

cc: HFZ-401
HFZ-470
draft:09/17/87:kaz
Final: [illegible]
Disk 3/7(MK)
CFR: 884.5250 Class II

470	Kuchinski	9/21	[illegible]	Segreto for Gin	9/25		

U.S. GPO: 1984 458 836

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From — REVIEWER(S) - NAME(S) Kuchinski

Subject — 510(k) NOTIFICATION K872849

To — THE RECORD

It is my recommendation that the subject 510(k) Notification:

✓ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

_____ (C) Requires more data.

_____ (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

special letter

The submitter requests:

✓ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Class Code w/Panel:

85 HDR Class II
$884.5250

REVIEW: _____ (BRANCH CHIEF) (DATE)

FINAL REVIEW: David C. Segerson for Dr. Yin (DIVISION DIRECTOR) 9/25/87 (DATE)

DOED (HFZ-470)

OB-GYN BRANCH 510(k) REVIEW FORM

DMC Dated: 7/20/87 Date received by reviewer: 7/27/87

Control #: K87 2849

✓ original 30 day limit: 8/19/87

amendment 90 day limit: 10/18/87

Device Name: Sperm-Select

Manufacturer: Pharmacia, Inc.

Device Description:

Review Summary:

Sperm-Select is 0.75 ml sodium hyaluronate at 2 mg/ml and is intended for sperm separation from seminal plasma. The product is use in the technique of "swim up" separation and washing. This procedure selects for high concentration of healthy motile sperm.

Hyaluronate is a natural mucopolysaccharide of high viscosity. Na Hyaluronate is to be mixed with media of choice/recommended Earle's balanced salts (1:1) to perform sperm capacitation and wash. The sperm-select is labeled "FOR IN VITRO USE" and is identified for insemination procedures. The Pharmacia Na hyaluronate has been found substantially equivalent to bovine cervical mucus under FDA pathology DCLD panel in sperm penetration assay and has undergone PMA approval by DOD under trade name "HEALON" for vitreous humor supplement during IOL surgery (P810031).

As in the past DOED has found other products i.e. Irvine Scientific - sperm capacitation Medium equivalent to the generic class cervical cap accessories for insemination (AI) sperm penetration assays, hamster egg penetration assays.

This product should not be identified for in vitro fertilization or GIFT. Recommendation:

Product Code:

Classification: 85 HDR II §884.5250

Substantially equivalent with special letter

J. Michael Kuchinski
Reviewer

9/15/87
Date

Branch Chief / / concur / / do not concur

6/4

6

DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

JULY 22, 1987

PHARMACIA, INC.
ATTN: ALBERT P. MAYO
800 CENTENNIAL AVENUE
PISCATAWAY, NJ 08854

D.C. Number : K872849
Received : 07-20-87
Product : SPERM-SELECT ADDITIONAL INDICATION

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the above referenced device has been received and assigned a unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing your device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-8162.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

IN

K872849

Pharmacia

JUL 1987

July 13, 1987

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
(HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Re: 510(k) Notification - Sperm-Select
Additional Indication

Dear Sir/Madam:

In accordance with 21 CFR 807.81 we are submitting a 510(k) Notification for an additional indication for Sperm-Select. This new indication will be for use as a medium to prepare sperm for in-vitro fertilization.

Please note Sperm-Select was previously granted marketing clearance via 510(k) #K864524 for use in evaluating sperm penetration ability.

Please contact me at 201-457-8144 with any questions you may have.

Sincerely,

PHARMACIA INC.

Albert P. Mayo
Manager
Regulatory Affairs

Pharmacia Inc.
800 Centennial Avenue
Piscataway, N.J. 08854

Telephone 201-457-8000
Telex 6858125 Pharfcuw
Telecopier 201-457-9002

Pharmacia

Pharmacia Inc.
Piscataway, New Jersey 08854

510(k) NOTIFICATION

a. **Trade Name:** Sperm-Select

Common Name: Sperm Capacitation Medium for In-Vitro Fertilization

Classification Name: None.

b. **Establishment Registration Number:** 2215942

c. **Classification:** None. A similar device, "Sperm Capacitation Medium" by Irvine Scientific was given the classification No. 21 CFR 884.5250 (Class II) by FDA.

d. **Performance Standards:** None.

e. **Labeling:** Draft labeling is attached as Appendix A.

f. **Substantial Equivalence Statement:** The new indication for Sperm-Select is substanially equivalent to current in-vitro fertilization (IVF) procedures using Hams F-10 Medium and Earles Media and to Sperm Capacitation Medium by Irvine Scientific which was given marketing clearance via 510(k) Notification No. 861188/A (see attached FDA letter). Both the Sperm Capacitation Medium and Sperm-Select are used to prepare sperm for in vitro fertilization techniques and both are enhancements of current techniques. The Sperm Capacitation Medium is described by Irvine Scientific as "Hams F-10 Media Modified for Sperm Capacitation Procedures". Sperm-Select may also be used to enhance the Hams F-10 Media to improve chances for successful IVF procedures.

The major difference is that Sperm-Select will also be used with Earles Medium for IVF procedures.

Attached as Appendix B is a paper describing studies performed with Sperm-Select. One study involved 211 sperm samples tested with and without sperm select, using Hams F-10 Medium or Earles Medium and utilizing different test procedures.

Pharmacia

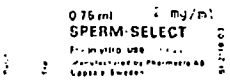
Pharmacia Inc.
Piscataway, New Jersey 08854

Another study was conducted with 80 random sperm samples. Some sperm samples (44) were prepared with sperm select and 36 were not. These studies clearly demonstrate that Sperm-Select fits well into current IVF procedures and may enhance the success rate.

Attached as Appendix C is the labeling for the Sperm Capacitation Medium and your letter granting that product substantial equivalence.

Appendix A

DRAFT LABELLING



BEST AVAILABLE COPY

10×0.75 ml Sterile

SPERM-SELECT 2 mg/ml

Medium for sperm preparation

FOR IN VITRO USE ONLY

Pharmacia

Distributed in the USA by Pharmacia Inc
Piscataway, New Jersey 08855

Each vial contains:
Sodium hyaluronate 1.5 mg
Buffer solution to 0.75 ml

Store at 2–8°C.
Protect from freezing.
Protect from light.

Manufactured by:
Pharmacia AB
Uppsala, Sweden

51-2179-03

Batch:

Exp.

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DRAFT

Directions for Use

Intended use
Sperm Select is intended to be used for separation of sperm from seminal plasma

Principle of the procedure
Sperm from fresh ejaculate are allowed to migrate into a column of a medium with increased viscosity due to the addition of Sperm Select. The increased viscosity of the medium will cause a high proportion of motile sperm to reach the upper portion of the fluid column. These washed sperm can be used for insemination procedures

Contents Sperm Select
Each vial of Sperm Select contains 0.75 ml sodium hyaluronate at a concentration of 2 mg/ml, dissolved in a phosphate buffer and sterilized.

Specimen collection and handling
Samples containing ejaculate obtained by masturbation are to be used. The ejaculate should be fresh (not more than 1 hour old) and allowed to liquify at room temperature (20–25°C) The sample should thereafter be thoroughly mixed by pipetting the ejaculate up and down several times in a Pasteur pipette (use a container of glass or other acceptable, non-toxic material). No further preparation of the sample is necessary.

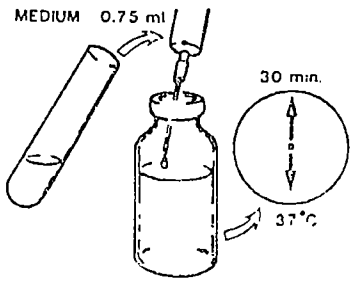
Materials required
- Vial containing 0.75 ml Sperm Select
- 0.75 ml "medium of choice" e.g. Earle's balanced salt solution I (+Na HCO_3 2 mg/ml, Na Pyruvate 0.11 mg/ml, human serum albumin to a final concentration of 1 %, Penicilline 100 IE/ml) or other media suitable for sperm preparation
- Incubator for CO_2 in air
- 8 Pasteur pipettes (sterile)
- A pipette stand
- Sterile plastic test tubes
- Syringe with needle
- Haemocytometer e.g. Bürker chamber or Makler chamber

Preparation procedure

1. Add 0.75 ml of the medium of choice e.g. Earle's balanced salt solution I (+Na HCO_3 2 mg/ml, Na Pyruvate 0.11 mg/ml, human serum albumin to a final concentration of 1 %, Penicilline 100 IE/ml) to a vial of Sperm Select

   Mix the substances by inverting the vial several times.

   The vial with contents can then be stored in a refrigerator (+4°C) up to 14 days before use. The content of the prepared vial should always be incubated at 37°C in 5 % CO_2 in air (in the open vial) for 30 minutes before use.



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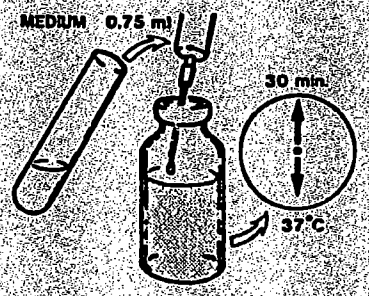
Materials required
- Vial containing 0.75 ml Sperm Select
- 0.75 ml "medium of choice" e.g. Earle's balanced salt solution 1 (+Na HCO_3 2 mg/ml, Na Pyruvate 0.11 mg/ml, human serum albumin to a final concentration of 1%, Penicilline 100 IE/ml) or other media suitable for sperm preparation
- Incubator for CO_2 in air
- 8 Pasteur pipettes (sterile)
- A pipette stand
- Sterile plastic test tubes
- Syringe with needle
- Hemocytometer e.g. Bürker chamber or Makler chamber

Preparation procedure

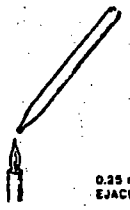
1. Add 0.75 ml of the medium of choice e.g. Earle's balanced salt solution 1 (+Na HCO_3 2 mg/ml, Na Pyruvate 0.11 mg/ml, human serum albumin to a final concentration of 1%, Penicilline 100 IE/ml) to a vial of Sperm Select.

   Mix the substances by inverting the vial several times.

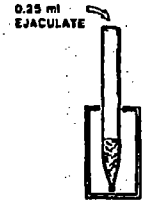
   The vial with contents can then be stored in a refrigerator (+4°C) up to 14 days before use. The content of the prepared vial should always be incubated at 37°C in 5 % CO_2 in air (in the open vial) for 30 minutes before use.



2. Close the ends of three-four short Pasteur pipettes by melting the tips in a flame.

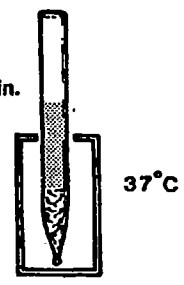


3. Use an intact, short Pasteur pipette to transfer approximately 0.25 ml of thoroughly mixed ejaculate to each of the closed pipettes.



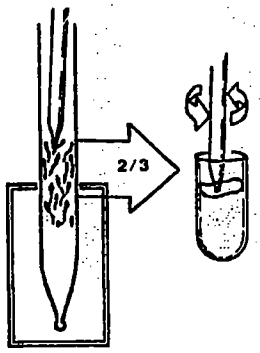
4. Carefully transfer 0.4–0.5 ml of the mixture of medium and Sperm Select to each of the pipettes containing ejaculate. Two separate layers will be maintained.

5. Place the three-four filled pipettes in a tube rack and incubate them at 37°C for 60 min. If a bicarbonate buffer is used incubate in 5 % CO_2 in air.



6. Use a long Pasteur pipette to carefully transfer approximately 2/3 of the fluid from the upper layer of each of the pipettes which have just been incubated. This fluid contains the selected, washed sperm samples.

   Transfer the sperm obtained in the previous step to a sterile, plastic test tube. Mix the substance carefully, but thoroughly by stirring with the Pasteur pipette.



7. Calculate the concentration of sperm in the medium. E.g. when using a Bürker chamber (count the number of sperm present in B-quadrant).

   15 sperm counted gives the following count/ml:

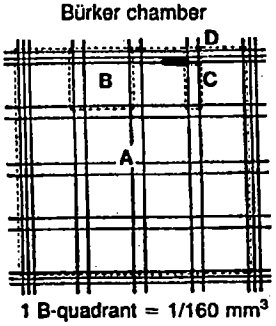
   15 × 16 × 10 × 1000 sperm/1000 µl

   2,400,000/1000 µl

   240,000/100 µl

   24,000/10 µl

   The sperm have now been selected and washed.



References:

1. Wikland M., Wik O., Steen Y., Qvist K., Soderlund B., Janson P.O.: A self migration method for preparation of sperm for IVF/ET. *Human Reproduction*, in press, 1987.
2. Steen Y. et al: A new method for the treatment of sperm in an IVF/ER program. *Fourth World Conference on In Vitro Fertilization, Melbourne, Australia, Abstract*, 1985.
3. Wikland M. et al: A new method for selection of motile spermatozoa for IVF. *12th World Congress on Fertility and Sterility, Singapore, Abstract* p. 505, 1986.

Appendix B

Human Reproduction In press

A SELF-MIGRATION METHOD FOR PREPARATION OF SPERM FOR IVF/ET

Wikland M, Wik O*, Steen Y, Qvist K, Söderlund B and Janson PO

Department of Obstetrics and Gynaecology, University of Göteborg
Göteborg, Sweden and *Pharmacia AB, Uppsala, Sweden

Running title: Sperm preparation for IVF/ET

Correspondence to: Dr. Matts Wikland
Department of Obstetrics and Gynecology
University of Göteborg
S-413 45 Göteborg
Sweden

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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
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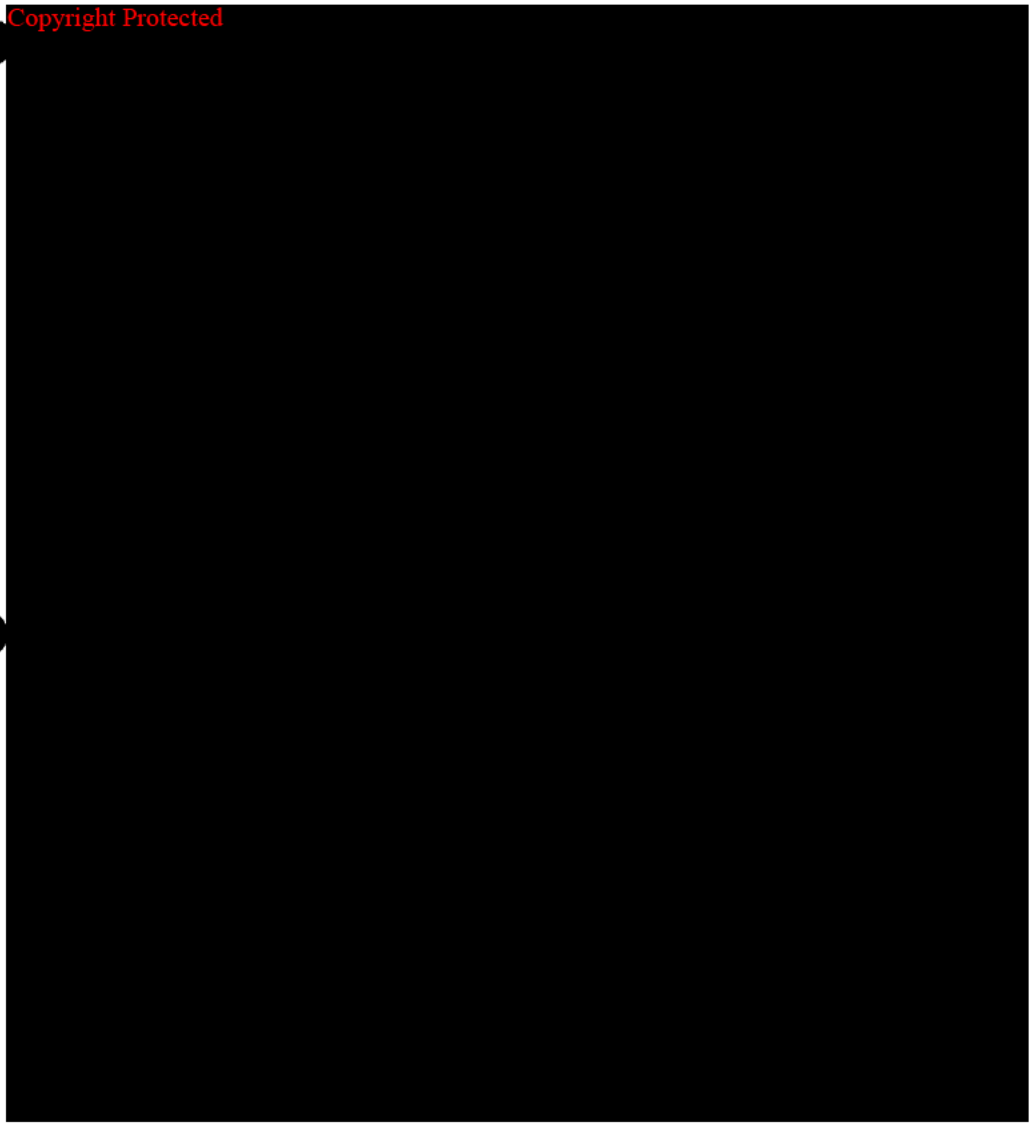
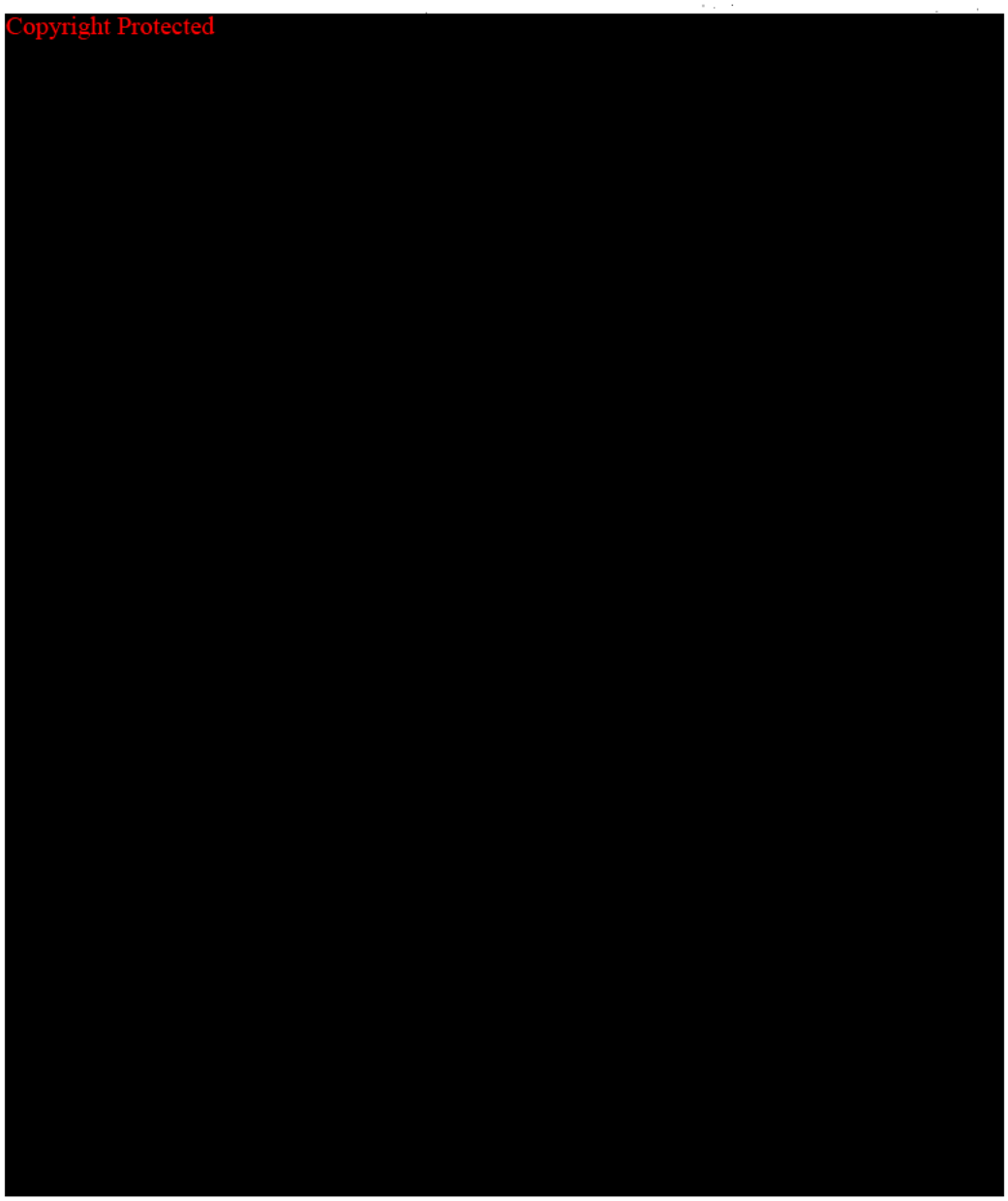
2470	Kammula	9/22						
2470	Mulli	9/22						

☆ U.S. GPO: 1984-459-836



FINAL REVIEW: David C. Segerson for Dr. Fin 9/25/87
(DIVISION DIRECTOR) (DATE)



Branch Chief

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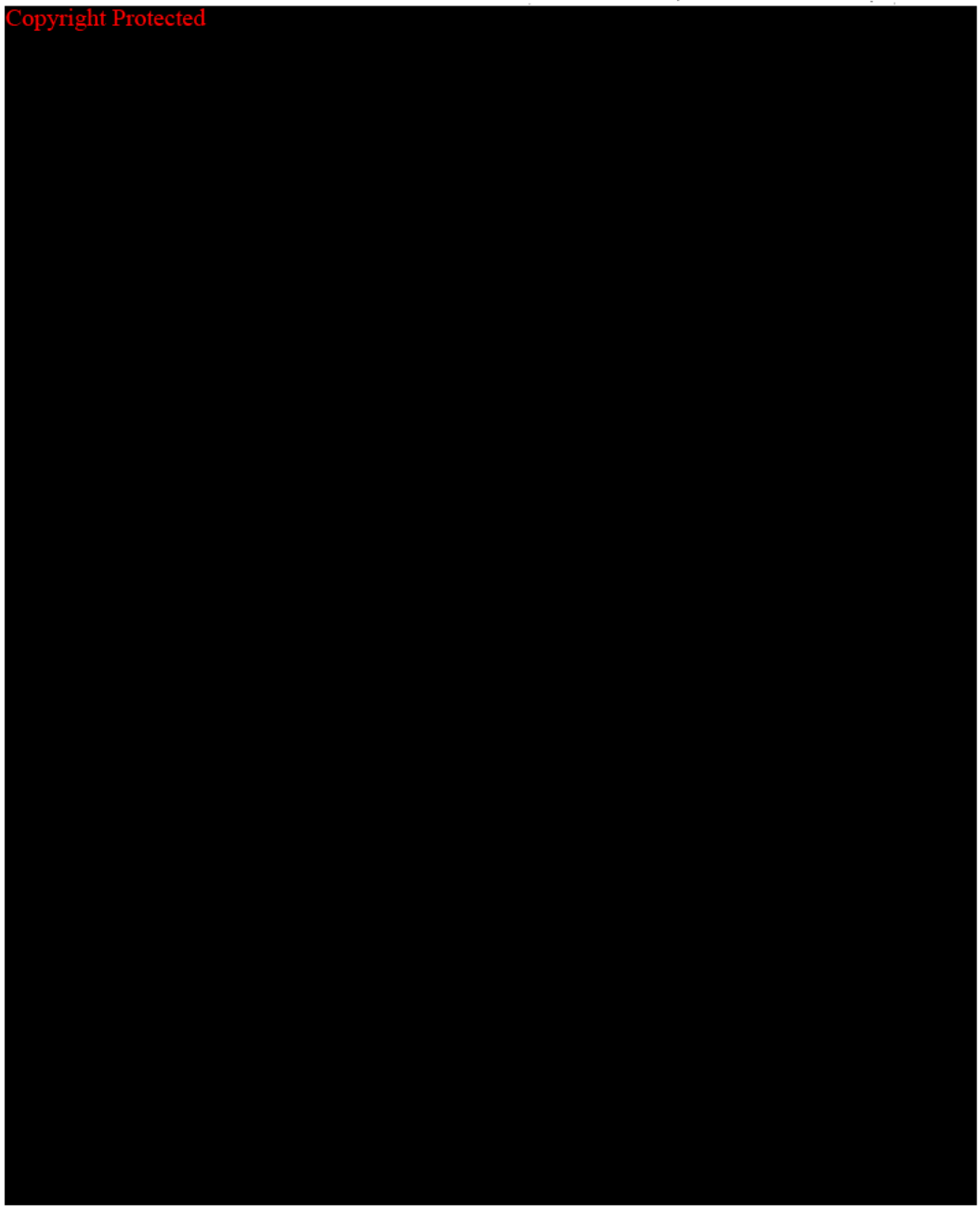
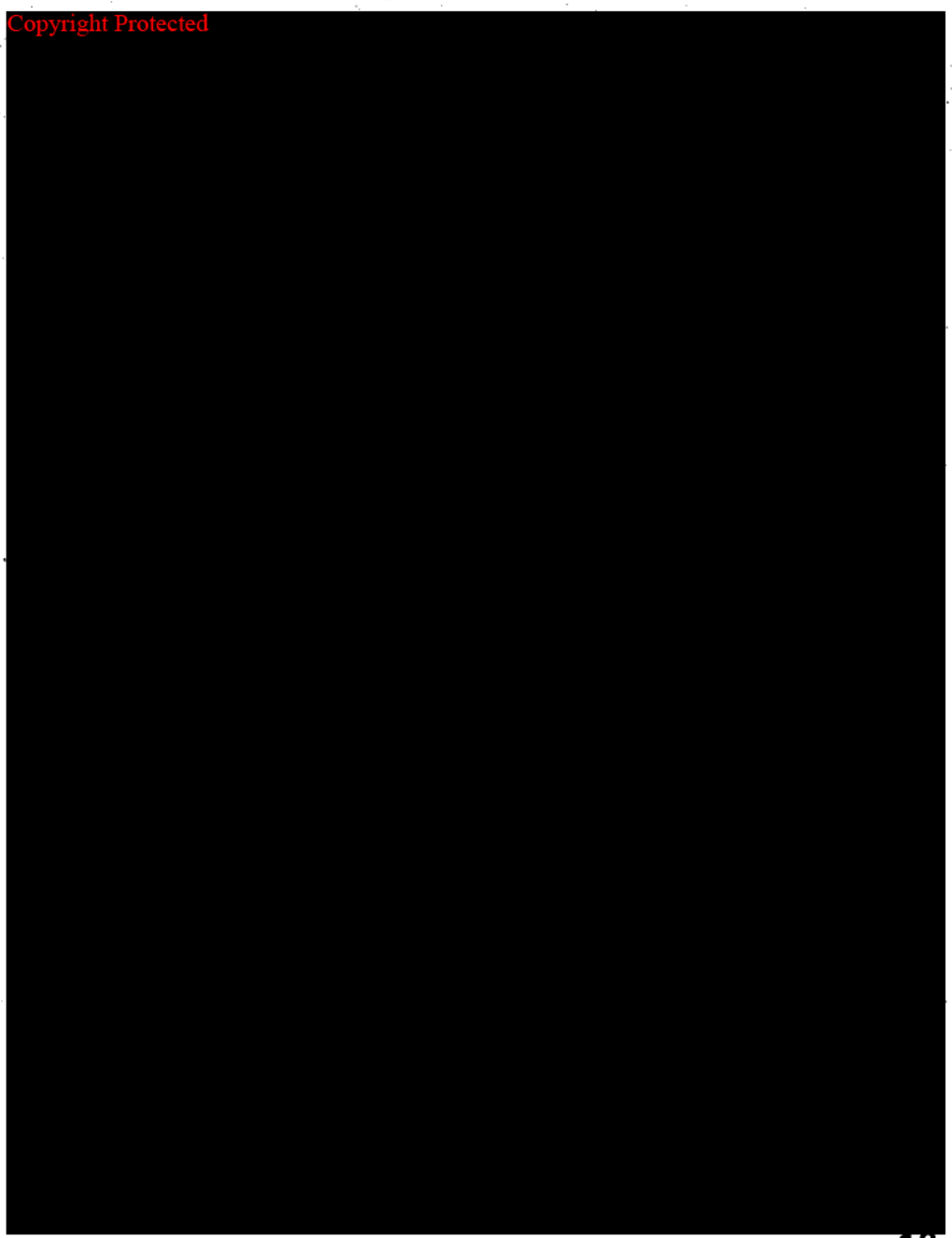


Pharmacia Inc.
800 Centennial Avenue
Piscataway, N.J. 08854

Telephone 201-457-8000
Telex 6858125 Pharfcuw
Telecopier 201-457-9002



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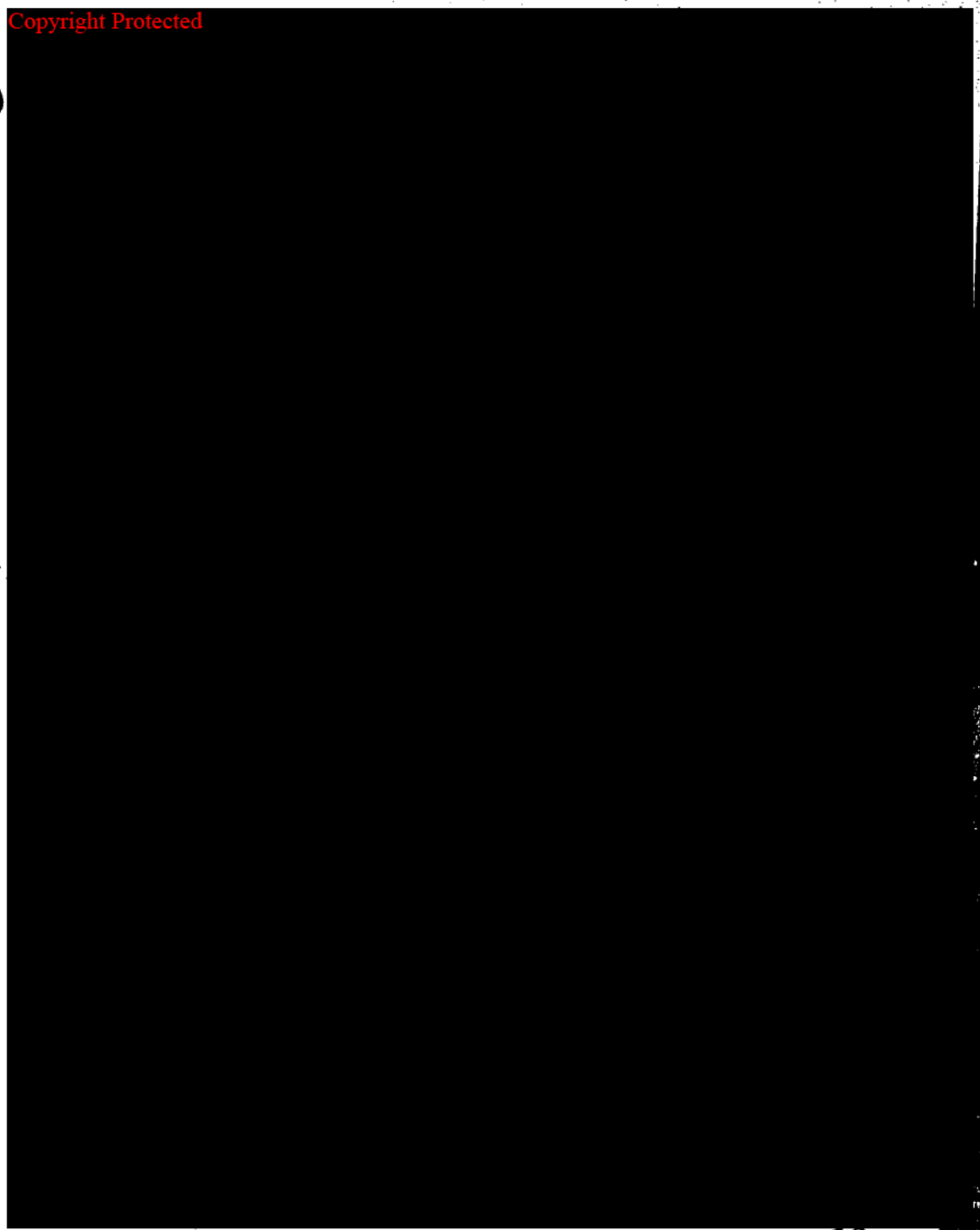

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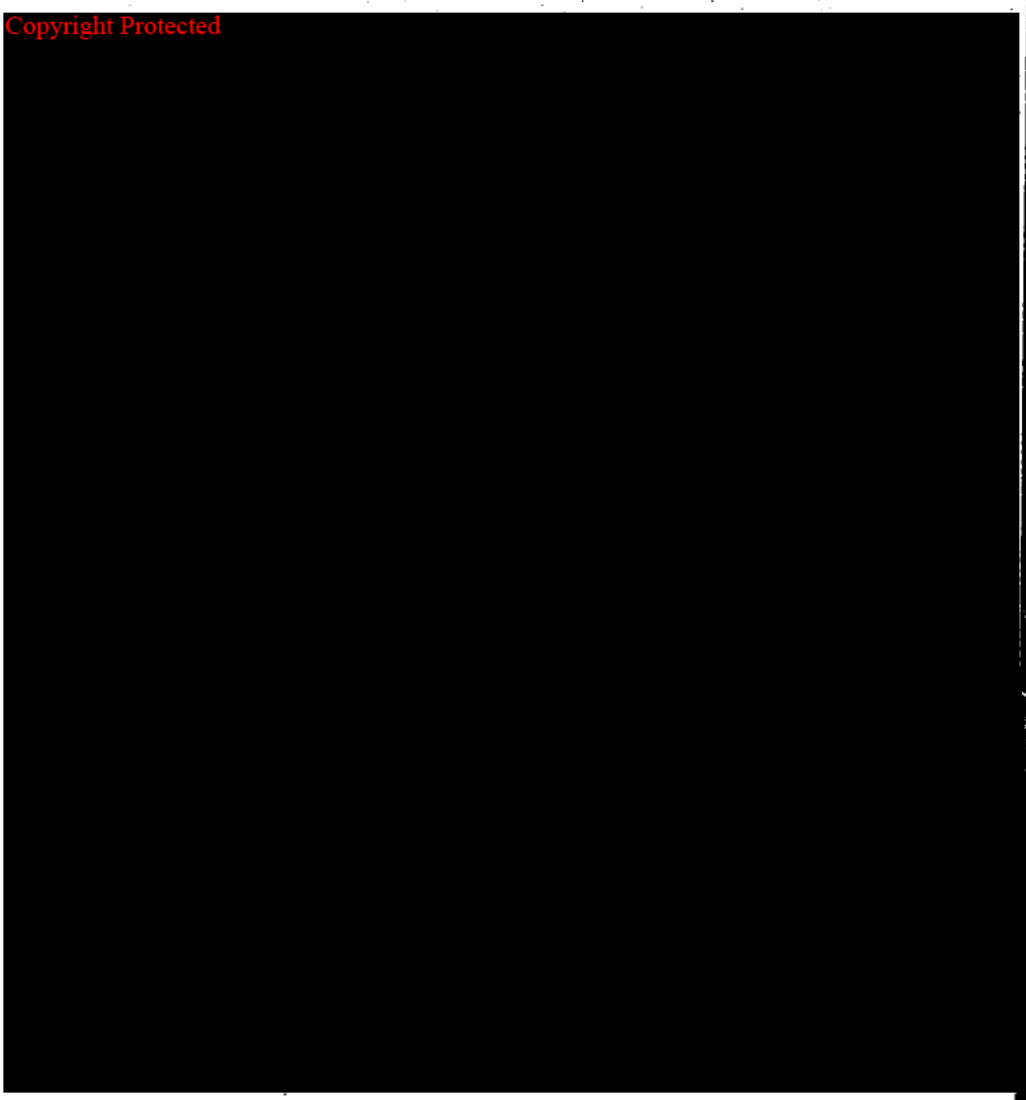

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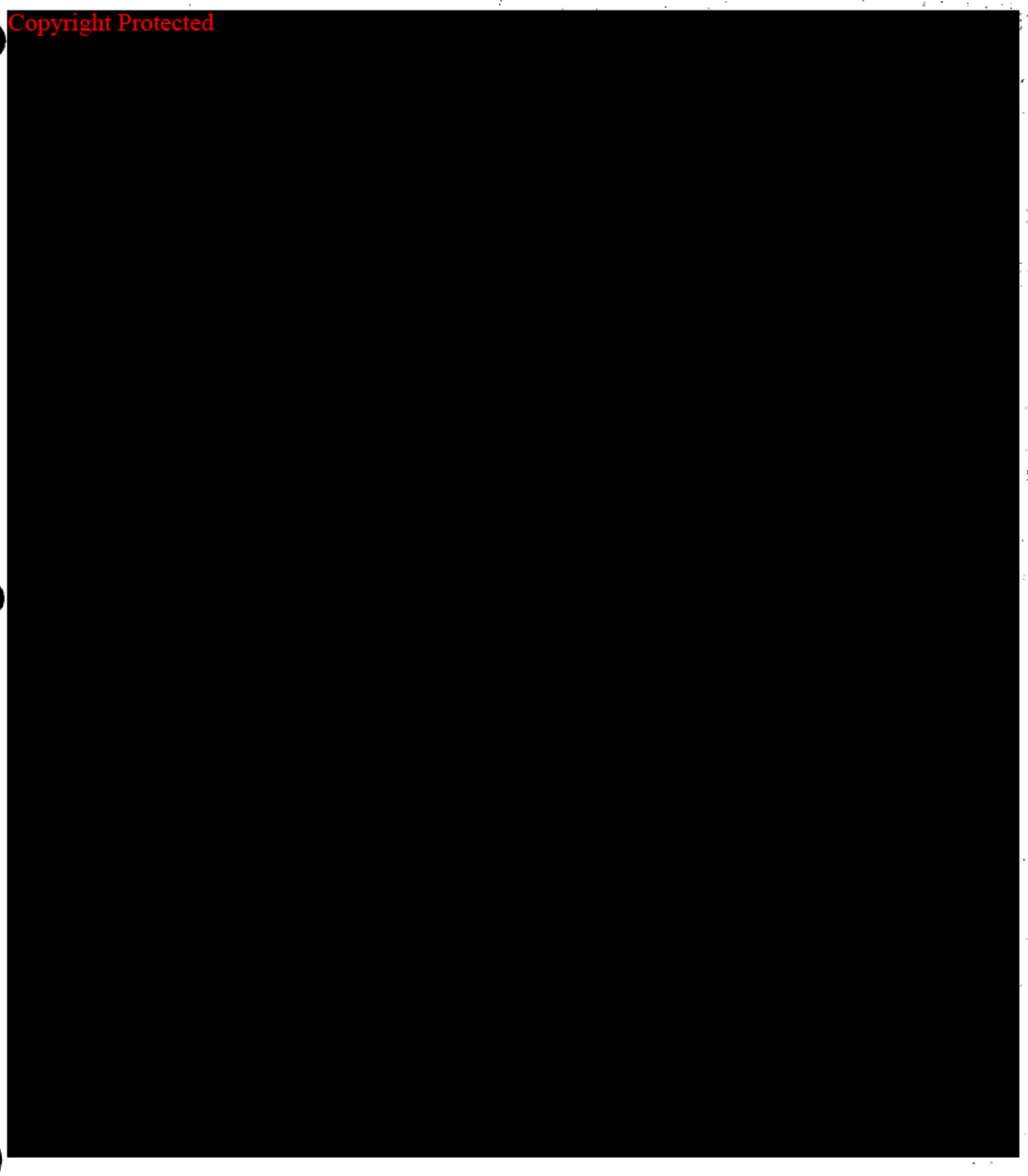

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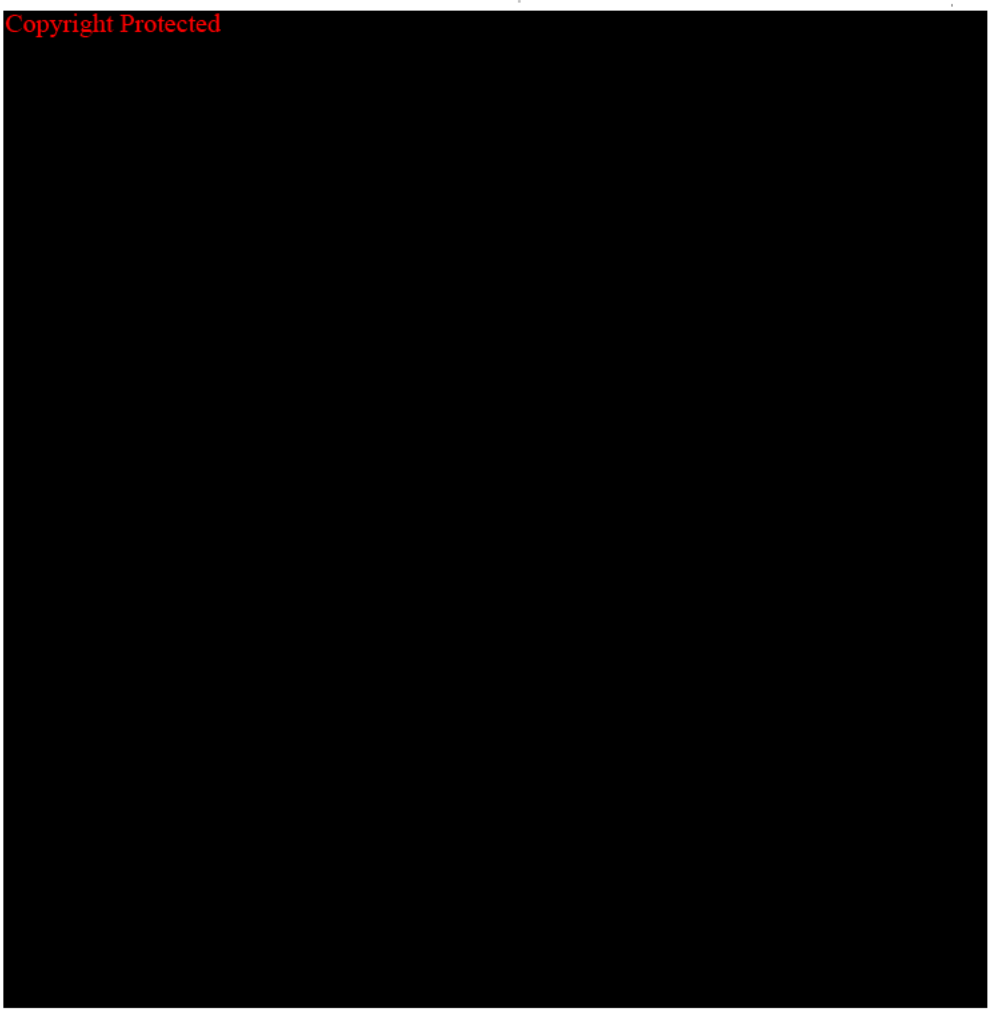

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LEGENDS TO FIGURES

Fig. 1. Schematic illustration of the penetration test.

Fig. 2. Schematic illustration of the self migration method in a Pasteur pipette with was sealed in its thin end.

Table 1. Criteria for a normal sperm sample

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(b)(4)

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(b)(4)

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Table 2. (b)(4)

(b)(4)

Appendix C

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Mr. Charles H. Newman
President
Newman Associates (on behalf of Irvine Scientific)
25283 Cabot Road
Suite 207
Laguna Hills, California 92653

Re: K861188/A
Sperm Capacitation Medium
Dated: July 10, 1986
Received: October 15, 1986
Regulatory Class: II
21 CFR 884.5250

Dear Mr. Newman:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). This device has been placed into the regulatory class shown above, by a final regulation published in the Federal Register. All classes of devices are regulated by the general controls provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices must also meet present or future performance standards; class III devices will be required to undergo premarket approval at some time in the future. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of OB-GYN, ENT
and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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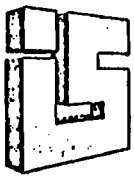

IRVINE SCIENTIFIC
Santa Ana, CA 92705

Sperm Capacitation Medium

Ham's F-10 Media Modified for Sperm Capacitation Procedures

10 X 12mL
Cat. No. 9931

Sterile Filtered
Store at 2°— 8°C

For In Vitro Use Only.

Sperm Capacitation Medium

Ham's F-10 Media Modified for Sperm Capacitation Procedures

12mL
Cat. No. 9931

Sterile Filtered
Store at 2°— 8°C

For In Vitro Use Only.

Directions for Use

This "Preparation of Semen for Intrauterine Insemination" is taken from an article which appeared in THE FEMALE PATIENT, Vol. 9, December 1984, written by Paul S. Weathersbee, Ph.D. and Lawrence B. Werlin, M.D., Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, University of California, Irvine Medical Center, Orange, California.

(1) Patient produces a semen sample by masturbation, following a two (2) to three (3) day period of sexual abstinence.

(2) Allow sample to liquefy at room temperature for twenty (20) to thirty (30) minutes.

(3) If total seminal volume is 3 ml or less, transfer the sample to a sterile 15 ml conical centrifuge tube and add room-temperature Ham's F-10 based insemination media (Irvine Scientific, Santa Ana, Calif.) to a final volume of 10 ml. Should the semen volume be greater than 3 ml and/or the sample highly viscous, treat these samples in the same manner, but only after they've been split into two (2) equal fractions.

(4) Centrifuge tubes at ambient temperature for ten (10) minutes at 300 xg.

(5) Remove supernatant above "sperm pellet" by decanting the tubes. The sperm should then be resuspended by

gently flicking the bottom of the tube with the index finger or, should it be available, through the use of a vortex mixer. The sperm are then resuspended in 4 ml of fresh media, the tube re-capped, and gently mixed by inversion. Samples that were fractionated for the first centrifugation can be recombined into one (1) tube.

(6) Recentrifuge tubes as in step 4.

(7) Once again, remove supernatant by decanting, resuspend sperm gently by manual or mechanical agitation, and add fresh media to a final volume of 0.5 ml or less.

(8) The sample is then drawn into a sterile syringe fitted with a 20 gauge needle and is ready for insemination using a 5 french pediatric feeding tube, or a 3.5 inch 16 gauge angiocatheter.