1/10 7078-7 PM 31

JUL 30 1986

SURGIKOS, Inc.
P.O. Box 130
Arlington, TX 76010

Attention: Walter J. McQuade

Gentlemen:

Subject: NEPHREX® Concentrate Formula for Disinfecting
Hemodialysate Delivery Systems
EPA Registration No. 7078-7
Your Amendment Application Dated June 24, 1986

The amendment application referred to above to change the product name to NEPHREX® Concentrate Formula for Disinfecting Hemodialysate Delivery Systems and make label corrections is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

   a. On the center panel, change the term "Disinfecting Solution" to read "Disinfecting Concentrate."

   b. On the center panel, the full new product name must replace the redundant claim "NEPHREX Concentrate Formula for Decontaminating Hemodialysate Delivery Systems."

   c. On the center panel under NOTE change the paragraph to read somewhat as follows: "This product is a concentrate and must be activated then diluted to a Disinfecting Solution immediately prior to use. The Activator must be added to the NEPHREX® Concentrate fluid before this product is effective for diluting to a Disinfecting Solution. See the directions on the left panel."

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d. On the left panel change the second sentence to read as follows: "NEPHREX Concentrate is formulated to be diluted immediately after activation at a 34:1 dilution for disinfection of hemodialysate delivery systems in 15 minutes."

e. On the left panel, change the first heading "Direction for Activation and Use" to read "Direction for Activation and Dilution." Add under this heading a subheading "Single Patient Delivery Systems" or if appropriate "Single Patient or Multipatient Delivery Systems."

f. On the left panel, last paragraph, delete or clarify the statement "For machine storage, use unactivated Nephrex solutions." If the statement is retained, clarify whether the unactivated solution is to be diluted or not, and add an instruction to drain the unactivated solution and disinfect with an activated diluted solution just prior to use of the machine.

2. Submit five copies of the 32 fl oz and five copies of the 128 fl oz final printed labeling before you release the product for shipment.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of each size labeling is enclosed for your records.

Sincerely yours,

John H. Lee
Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)

Enclosure

3/10.

CENTER PANEL

Disinfecting Solution

Rapid-Acting/Nonrusting/Nonstaining
Pseudomonacidal Bactericidal
Virucidal† Fungicidal

NEPHREX™
Concentrate Formula for Decontaminating Hemodialysate Delivery Systems

Active Ingredient
Glutaraldehyde.....26%
Inert Ingredients..... 74%
Total.....100%

NOTE: This product is a concentrate and must be activated and diluted immediately prior to use. Activator must be added to fluid before this product is effective. See directions.

Reorder Number 2400

E.P.A. Reg. No. 7078-7
E.P.A. Est. No. 36126-PR-1

KEEP OUT OF REACH OF CHILDREN
DANGER: See right side panel for precautions.

†See Directions for Disinfection

SURGIKOS

ACCEPTED
with COMMENTS
In EPA Letter Dated:

JUL 30 1986

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 7078-7

*Trademark
BC8

LEFT PANEL

Follow specific equipment manufacturer's recommendation for cleansing and disinfecting the hemodialysate delivery system. NEPHREX Concentrate is formulated to be diluted 34:1 for disinfection of hemodialysate delivery systems in 15 minutes.

Directions for Activation and Use -

Add contents of attached vial to this container of NEPHREX Concentrate. Mix; activated NEPHREX Concentrate is ready to use. When activated, solution changes color to blue. Dilute activated NEPHREX Concentrate immediately after activation with 34 equivalent parts or less of softened water. For proportioning type hemodialysate delivery systems, place activated NEPHREX Concentrate into the hemodialysate delivery system and dilute activated NEPHREX Concentrate with 34 equivalent parts or less of softened water.

NOTE: Use of an insufficient quantity of activated NEPHREX Concentrate will result in inadequate treatment of the hemodialysate delivery system. Some systems will require a larger quantity of activated NEPHREX Concentrate than provided in this container. Additional quantities of activated NEPHREX Concentrate are prepared by mixing at 50:1 volume ratio, 50 parts of NEPHREX Concentrate with 1 part of activator. Use activated NEPHREX Concentration as described in the Directions for Activation and Use.

Directions for Disinfection -

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. For use in Hospitals, Dialysis Centers, and Health Care Institutions.

It is recommended that disinfection be carried out immediately after and just prior to use of the hemodialysate delivery system.

Flush equipment thoroughly with water prior to filling the delivery system with NEPHREX Solution. After filling the delivery system, hold NEPHREX Solution in the system for a minimum of 15 minutes. Within 15 minutes contact time at 20°C, NEPHREX Solution will destroy vegetative pathogens including *Pseudomonas aeruginosa* and hydrophilic and lipophilic viruses (*Poliovirus* Type 1, *Coxsackievirus* B-1, *Influenza* Type A_2 [Hong Kong], *Herpes simplex*, Type I) on inanimate surfaces. Prior to machine use, drain NEPHREX Solution and thoroughly rinse with water. To assure complete rinsing, test final rinse water using NEPHREX Residual Test Kit.

This is a single use product.

NOTE: Activated NEPHREX Concentrate should not remain in hemodialysate delivery systems for more than 12 hours. For machine storage, use unactivated NEPHREX Solution.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

JUL 30 1986

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2028-7

BC8

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RIGHT PANEL

NEPHREX Solution is recommended for decontaminating single patient and multi-patient hemodialysate delivery systems. NEPHREX Solution has been shown to be an effective disinfectant (virucide, fungicide, bactericide, pseudomonacide) when tested by AOAC and EPA test methods. NEPHREX Solution may not totally eliminate all vegetative microorganisms in hemodialysate delivery systems due to their construction and/or assembly but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. This product should be used in a disinfection program which includes bacteriological monitoring of the hemodialysate delivery system. NEPHREX Solution is not recommended for use in hemodialyzers or reverse osmosis (RO) membranes.

Consult the guidelines for hemodialysis systems which are available from the Hepatitis Laboratories, CDC, Atlanta, Georgia, 30301.

Precautionary Statements -

DANGER:
HAZARD TO HUMANS
FOLLOW ALL LABEL DIRECTIONS

Prevent contact with skin or eyes by using eye protection and rubber gloves when handling or pouring.

Eyes	--	Corrosive, causes eye damage. Do not get in eyes. In case of contact, flush with water immediately and get medical attention.
Ingestion	--	Harmful if swallowed. Avoid contamination of food.
Inhalation	--	Avoid spillage. Use in a well ventilated area.
Skin	--	Avoid skin contact as possibility of sensitization exists. Can cause skin irritation. For skin contact, flush thoroughly with water. Get medical attention if irritation occurs.

Storage and Disposal -

Keep in a cool place. Triple rinse empty container with water and dispose in an incinerator or landfill approved for pesticide containers.

Contents: 32 fl. oz. (0.95 liters)
Made in U.S.A.
Control Number on Bottom

Distributed by:
SURGIKOS
a Johnson & Johnson company
SURGIKOS, Inc., Arlington, Texas 76010

ACCEPTED
with COMMENTS
In EPA Letter Dated:

JUL 30 1986

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 7078-7

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ACTIVATOR LABEL

NEPHREX™

ACTIVATOR VIAL

For use with NEPHREX Concentrate Fluid Only.

DANGER: Contact with eyes causes damage. In case of contact with eyes, flush with water immediately and get medical attention. For skin contact, flush thoroughly with water.

DISPOSAL: Rinse empty container thoroughly with water and discard it.

Net Contents: 28 grams
Made in U.S.A.
Control Number on Bottom

Distributed by:
SURGIKOS
a Johnson & Johnson Company
SURGIKOS, Inc., Arlington, Texas 76010

ACCEPTED
with COMMENTS
In EPA Letter Dated:

JUL 30 1986

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2074-7

BC8

7/10

CENTER PANEL

Disinfecting Solution

Rapid-Acting/Nonrusting/Nonstaining
Pseudomonacidal Bactericidal
Virucidal† Fungicidal

NEPHREX™
Concentrate Formula for Decontaminating Hemodialysate Delivery Systems

Active Ingredient
Glutaraldehyde.....26%
Inert Ingredients..... 74%
Total.....100%

NOTE: This product is a concentrate and must be activated and diluted immediately prior to use. Activator must be added to fluid before this product is effective. See directions.

Reorder Number 2400

E.P.A. Reg. No. 7078-7
E.P.A. Est. No. 36126-PR-1

KEEP OUT OF REACH OF CHILDREN
DANGER: See right side panel for precautions.

†See Directions for Disinfection

SURGIKOS

ACCEPTED
with COMMENTS
In EPA Letter Dated:

JUL 30 1986

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 7078-7

*Trademark
BB8

8/10

LEFT PANEL

Follow specific equipment manufacturer's recommendation for cleansing and disinfecting the hemodialysate delivery system. NEPHREX Concentrate is formulated to be diluted 34:1 for disinfection of hemodialysate delivery systems in 15 minutes.

Directions for Activation and Use -

Add 3 cc (4.4 gms) of activator to 150 cc (159 gms) of NEPHREX Concentrate. Mix; activated NEPHREX Concentrate is ready to use. When activated, solution changes color to blue. Dilute activated NEPHREX Concentrate immediately after activation with 34 equivalent parts or less of softened water. For proportioning type hemodialysate delivery systems, place activated NEPHREX Concentrate into the hemodialysate delivery system and dilute activated NEPHREX Concentrate with 34 equivalent parts or less of softened water.

NOTE: Use of an insufficient quantity of activated NEPHREX Concentrate will result in inadequate treatment of the hemodialysate delivery system. Some systems will require a larger quantity of activated NEPHREX Concentrate than specified in the directions above. Additional quantities of activated NEPHREX Concentrate are prepared by mixing at 50:1 volume ratio, 50 parts of NEPHREX Concentrate with 1 part of activator. Use activated NEPHREX Concentration as described in the Directions for Activation and Use.

Directions for Disinfection -

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. For use in Hospitals, Dialysis Centers, and Health Care Institutions.

It is recommended that disinfection be carried out immediately after and just prior to use of the hemodialysate delivery system.

Flush equipment thoroughly with water prior to filling the delivery system with NEPHREX Solution. After filling the delivery system, hold NEPHREX Solution in the system for a minimum of 15 minutes. Within 15 minutes contact time at 20°C, NEPHREX Solution will destroy vegetative pathogens including Pseudomonas aeruginosa and hydrophilic and lipophilic viruses (Poliovirus Type 1, Coxsackievirus B-1, Influenza Type A_2 [Hong Kong], Herpes simplex, Type I) on inaminate surfaces. Prior to machine use, drain NEPHREX Solution and thoroughly rinse with water. To assure complete rinsing, test final rinse water using NEPHREX Residual Test Kit.

This is a single use product.

NOTE: Activated NEPHREX Concentrate should not remain in hemodialysate delivery systems for more than 12 hours. For machine storage, use unactivated NEPHREX Solution.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

JUL 30 1986

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 707-7

BB8

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RIGHT PANEL

NEPHREX Solution is recommended for decontaminating single patient and multi-patient hemodialysate delivery systems. NEPHREX Solution has been shown to be an effective disinfectant (virucide, fungicide, bactericide, pseudomonacide) when tested by AOAC and EPA test methods. NEPHREX Solution may not totally eliminate all vegetative microorganisms in hemodialysate delivery systems due to their construction and/or assembly but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. This product should be used in a disinfection program which includes bacteriological monitoring of the hemodialysate delivery system. NEPHREX Solution is not recommended for use in hemodialyzers or reverse osmosis (RO) membranes.

Consult the guidelines for hemodialysis systems which are available from the Hepatitis Laboratories, CDC, Atlanta, Georgia, 30301.

Precautionary Statements -

DANGER:
HAZARD TO HUMANS
FOLLOW ALL LABEL DIRECTIONS

Prevent contact with skin or eyes by using eye protection and rubber gloves when handling or pouring.

Eyes -- Corrosive, causes eye damage. Do not get in eyes. In case of contact, flush with water immediately and get medical attention.

Ingestion -- Harmful if swallowed. Avoid contamination of food.

Inhalation -- Avoid spillage. Use in a well ventilated area.

Skin -- Avoid skin contact as possibility of sensitization exists. Can cause skin irritation. For skin contact, flush thoroughly with water. Get medical attention if irritation occurs.

Storage and Disposal -

Keep in a cool place. Triple rinse empty container with water and dispose in an incinerator or landfill approved for pesticide containers.

Contents: 128 fl. oz. (3.8 liters)
Made in U.S.A.
Control Number on Bottom

Distributed by:
SURGIKOS
a Johnson & Johnson company
SURGIKOS, Inc., Arlington, Texas 76010

ACCEPTED
with COMMENTS
In EPA letter dated:

JUL 30 1986

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 7078-7

2400C1-1
BB8

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ACTIVATOR LABEL

NEPHREX[tm]

ACTIVATOR VIAL

For use with NEPHREX Concentrate Fluid Only.

DANGER: Contact with eyes causes damage. In case of contact with eyes, flush with water immediately and get medical attention. For skin contact, flush thoroughly with water.

DISPOSAL: Rinse empty container thoroughly with water and discard it.

Net Contents: 112 grams
Made in U.S.A
Control Numbe[illegible] n Bottom

Distributed by:
SURGIKOS
a Johnson & Johnson Company
SURGIKOS, Inc., Arlington, Texas 76010

ACCEPTED
with COMMENTS
In EPA Letter Dated:

JUL 30 1986

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 7078-7

BBB