

MAR 11 2004

Christina Griffin,
Agent for PDI, Healthcare Division of Nice-Pak Products, Inc.
c/o Delta Analytical Corp.
7910 Woodmont Avenue, Suite 1000
Bethesda, MD 20814

Subject: Sani-Cloth Germicidal Disposable Cloth
EPA Reg. No. 9480-5
Your Re-Submission Dated 12/29/03

The re-submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, which provides a final printed Master Label which incorporates the required label changes listed in the EPA letter dated 11/3/03, is acceptable providing you re-submit three copies of the final printed label within 90 days from the date of this letter, which makes the following label changes. These final required changes were either overlooked or new to the label.

Page 3/12

1. For the two stand alone virus claims "[Virucidal*]" and "[...bacteria, and viruses*]", add to each the two tested viruses the Agency found the product effective against.
2. Delete "Greater" in "Greater quaternary dispersal...". This is an unqualified and unsubstantiated claim (ie., it's not clear what it is greater than).
3. Add "Common household germs" to "...help[s] control *common household* germs on treated surfaces...".
4. Globally delete the optional claim brackets around "[between treated surfaces]". "Cross contamination" cannot be separated from "[between treated surfaces]".

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1. Delete or qualify the "% larger" in the claim "[New, (number)% larger towels]". Qualify as to what they are larger than.
2. Add "common" to the last claim "[Disinfects common household kitchen and bathroom bacteria]"

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

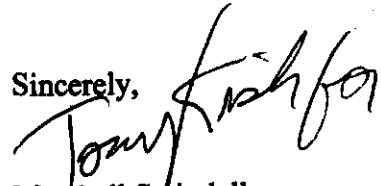
Page 5/12

In the hospital and health care settings section, delete or qualify the unqualified and general use sites for surfaces made of "stainless steel, Formica, glass". These are not acceptable when listed alone and must be related either to specific uses, or related to existing uses listed on the label using revised wording (eg., "uses listed on this label consisting of stainless steel, Formica, and glass").

A copy of the label stamped "Accepted with comments" is enclosed.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

3/14

SANI-CLOTH
GERMICIDAL DISPOSABLE CLOTH

ACTIVE INGREDIENTS

n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	0.14%
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	0.14%
Isopropyl Alcohol	8.00%
<u>OTHER INGREDIENTS</u>	91.72%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back [side] panel for additional precautionary statements

NET WT
[NET CONTENTS # OF CLOTHS SIZE]

[The following registration and establishment number information and registrant address information is mandatory, but may appear in any appropriate place on the label:]

EPA Reg. No.: 9480-5

EPA Est. No. : 9480-NY-1

[or EPA Est. No. A=9480-NY-1, B=9480-IN-1

Alpha character will precede batch code on product]

[Manufactured by:]
PDI, The Healthcare Division of Nice-Pak Products, Inc.
Two Nice-Pak Park
Orangeburg, NY 10962-1376
[For information call: [phone number to be inserted]] [website address]

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 11 2004

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

9480-5

THE INFORMATION IN THIS BOX IS NOT PART OF THE LABELING

Statements in brackets [] are optional or instructional. Italicized words in brackets are not included. Sequence of phrases is optional unless specified in 40 CFR 156.10. Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR. The terms "wipe(s)", "towel(s)" and "cloth(s)" can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment. Lists of uses and use sites can be used partially or in their entirety. Any individual statement, claim, restriction or other wording must be used in its entirety, and can not be expanded or shortened by combination, partial deletion, merging, or similar.

4/14

PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals.

CAUTION: Avoid contact with eyes.

FIRST AID

If in eye: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

PHYSICAL OR CHEMICAL HAZARD:

Combustible. Do not use or store near heat or open flame.

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[[All statements below within the brackets (all of pages 3 and 4) are optional; choose from the following as appropriate; location is optional:]]

5/14

[Lemon Scent]

[Citrus Scent]

[Orange Scent]

[Floral Scent]

[Fresh Air Scent]

[Mint Scent]

[Sani-Cloth Germicidal Disposable Wipes *[or this product]* help[s] control germs on treated surfaces while keeping your office *[or workplace or station or business]* clean and dust-free]

[Sani-Cloth Germicidal Disposable Wipes *[or this product]* control[s] the spread of germs on most treated hard, non-porous surfaces *[and has a clean, fresh scent]*]

[For use in critical care areas *[Where control of the hazards of cross contamination between treated surfaces is of prime importance]*]

[Antibacterial]

[Aids in reducing *[or in the reduction of]* cross contamination *[between treated surfaces]*]

[Bactericidal]

[Virucidal*]

[Effective in 5 minutes against Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, and Klebsiella pneumoniae]

[Kills Staphylococcus aureus and Salmonella choleraesuis]

[Kills common household germs Staphylococcus aureus and Salmonella choleraesuis]

[*Exhibits effective virucidal activity; kills Influenza A2/Hong Kong (representative of the common flu virus) and Herpes Simplex Type 2 (causative agent of genital herpes)]

[*Kills Influenza A2/Hong Kong (Hong Kong flu) and Herpes Simplex Type 2]

[*Also effective against flu viruses Influenza A2/Hong Kong (Hong Kong flu)]

[An effective way to disinfect hard, non-porous environmental surfaces]

[An effective way to clean, deodorize against odor-causing organisms and disinfect hard, non-porous surfaces]

[Cleans and disinfects]

[Cleans, deodorizes and disinfects]

[Cleans and disinfects common hard, non-porous surfaces]

[Effectively disinfects common hard, non-porous household surfaces]

[Use to clean, deodorize, and disinfect hard, non-porous surfaces in the nursery]

[Kills many common household bacteria, and viruses*]

[Disinfects hard, non-porous environmental surfaces]

[Disinfects environmental surfaces]

[Nursery wipes]

[Household surface wipes]

[Telephone *[cleaner [and]]* disinfectant wipes]

[A disinfectant cloth for use on telephone surfaces and other telecommunications equipment surfaces]

[Cleans and disinfects *[cell phone surfaces]* *[telephone surfaces,]* *[telephone equipment surfaces,]* *[dictating equipment surfaces,]* *[and other telecommunications equipment [surfaces] [devices]]*]

[Disinfects headsets and telephones]

[Antibacterial Cell Phone wipe]

[Quick drying]

[Assures proper dilution strength for product effectiveness and standardized technique]

[Greater quaternary dispersal with no hazard of cross contamination]

[Non-woven disposable cloth]

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9480-5

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g:\labels\pdr\9480-5\2003\FINAL LBL 120803.doc

December 8, 2003 Page 3 of 12

[A dual chain Quaternary/Alcohol solution impregnated in a wiping cloth]
 [Convenient]
 [Premeasured]
 [Premoistened]
 [Disposable]
 [No mixing]
 [Moist Wipes]
 [Strong, Real Cloth Wipes]
 [Pre-Moistened Towelettes]
 [Multi-purpose cleaner]
 [Multi-purpose cleaner and disinfectant]
 [To Clean and Deodorize]
 [Use on hard, non-porous surfaces only. [Test wipe on small inconspicuous area first.]]
 [To Clean: Wipe surfaces and let air dry]
 [For most hard, non-porous surfaces]
 [Not recommended for natural marble, unpainted wood, brass, or colored grout]
 [Easy, One Step Cleaning and Disinfecting]
 [Bonus - *[number to be inserted]* [free] towels]
 [*[number to be inserted]* towels for the price of *[price to be inserted]*]
 [Now with *[number to be inserted]* extra towels]
 [More towels]
 [*[number to be inserted]* towels free!]
 [Value Pack]
 [New, *[number]*% larger towels]
 [Convenient, quick and easy cleaning all around your [home] [business] [office] [workplace]]
 [Each pre-moistened and disposable wipe cleans, deodorizes and kills common household germs all around your [home] [business] [office] [workplace]]
 [These wipes are a convenient and quick way to disinfect surfaces all around your [home] [business] [office] [workplace]]
 [The uniquely designed cap with recessed reservoir enables you to keep every wipe its freshest...even the leftovers from your last pull]
 [One step [cleaning and] disinfecting]
 [An Effective One-Step [Cleaner-] Disinfectant]
 [Effectively disinfects in the presence of organic soil (5% blood serum)]
 [Bath and Kitchen wipes]
 [Bath and Kitchen wipes for hard, non-porous surfaces]
 [Bath and Kitchen disinfectant wipes]
 [*Use wipes to kill Influenza A2/Hong Kong, Salmonella, and Staphylococcus on most bath and kitchen hard, non-porous surfaces]
 [Computers [and keyboards]]
 [Quick and Easy Cleaning Everywhere]
 [Disinfects household kitchen and bathroom bacteria]

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7/14
[choose from the following areas of use as appropriate; they may be listed in any order; at least one use site (including corresponding list of surfaces) must be used on the label; "Kitchen" areas of use must be included if "food contact surfaces" directions (see next page) are used.]

[AREAS OF USE

[Kitchen** [Counter tops,] [exterior surfaces of [or outside of] appliances,] [sinks,] [faucets,] [table tops]] [exterior surfaces of [or outside of] refrigerators,] [exterior surfaces of [or outside of] stove]
[Bathroom: [Toilet seats,] [bathroom fixtures,] [vanity tops,] [shower stalls,] [bathtubs,] [tiles,] [sinks]]
[General use: [Doorknobs,] [laundry rooms,] [garbage cans,] [pet areas] [telephones,] [cell phones,] [telephone equipment surfaces,] [dictating equipment surfaces,] [and other telecommunications equipment [surfaces] [devices]] [headsets] [computers [and keyboards]] [car,] [desktop,] [office,]
[Nursery: [Changing tables,] [cribs,] [diaper pails,] [trash cans,] [toys]
[**A thorough rinse with potable water is required for surfaces in direct contact with food.]

[Optional: None, one, or both of the following paragraphs may be used as appropriate; paragraph # "B" may be used before "A" on the label if both are used]

[A]

[Hospital and Health Care Settings]

[A non-woven disposable cloth for use in hospitals and other critical care areas where control of the hazards of cross-contamination between treated surfaces is required. Use on hard, non-porous surfaces and equipment including stainless steel, Formica, glass, tables, carts, metal baskets, counters, cabinets, telephones. Some organisms are removed from the surface by thoroughly wiping the surface with the towel. Most remaining organisms are killed within five (5) minutes by exposure to the liquid in the towel.]

[B]

[B 1] **[Areas of Use:** Hard, non-porous surfaces in: [Surgery,] [Hospitals,] [Emergency Room,] [E.R.,] [Recovery Room,] [ICU,] [CCU,] [Anesthesia,] [Laboratory,] [Physical therapy,] [Respiratory therapy,] [Radiology,] [X-Ray,] [CAT Lab,] [New-born nursery,] [Pediatrics,] [Central Supply,] [Operating Room,] [Nursing homes,] [Home Health Care,] [Physician's offices,] [Dental offices,] [Ambulances,] [Clinics]]
[Section B 1 must be used if section B2 (below) is on the label]

[B 2] **[May be used on:** Hard, non-porous surfaces of: [Exam tables,] [Gurneys,] [IV poles,] [Bed railings,] [Outside surfaces of equipment,] [Toilet seats [and] [outside surfaces of toilets,] [Tables,] [Chairs,] [Stretchers].

[If paragraph A and/or paragraph B are used, then all of the following paragraph must be used on label.]

["This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection."]

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[Use one of the following as applicable to type of container.]

TOWELETTE [or WIPE] [or TOWEL] [or CLOTH]

[DISPENSER DIRECTIONS:

To start feed: Remove lid and discard inner seal from canister. Find center of wipe roll, remove first wipe for use, twist corner of next wipe into a point and thread through the hole in the canister lid. Pull through about one inch. Replace lid. Dispense remaining wipes as necessary by pulling out at an angle. When not in use keep center cap of lid closed to prevent moisture loss.]

[TRAVEL PACK:

Peel back label slowly. Pull out wipes as needed and reseal label. Unfold wipe.]

[PACKET:

Tear open packet. Unfold wipe.]

[Use one or more of the following as appropriate; they may be used in any order as long as the entire paragraph is used; food contact directions must be used if "kitchen" is one of the areas of use or listed in the claims section:]

[CLEANING: Wipe surface with towelette until clean. Let air dry.]

TO DISINFECT:

[NON-FOOD CONTACT SURFACES

Use a wipe to remove gross filth [or heavy soil]. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for a full five (5) minutes. Use additional wipe(s) if needed to assure continuous 5 minute wet contact time. Let air dry.]

[FOOD CONTACT SURFACES

Use a wipe to remove gross filth [or heavy soil]. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for a full five (5) minutes. Use additional wipe(s) if needed to assure continuous 5 minute wet contact time. Let air dry followed by a thorough potable water rinse.]

[ULTRASOUND TRANSDUCERS

For use on external surfaces of Ultrasound Transducers only

To disinfect: Pre-clean ultrasound gel from external transducer to be disinfected [by using a clean wash cloth]. Then thoroughly wet the probe with a towelette. Treated surface must remain visibly wet for a full five (5) minutes. Use additional Use additional wipe(s) if needed to assure continuous 5 minute wet contact time. Let air dry.]

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[The following headings are optional; choose as appropriate:]
[Hospital Use] [Nursing Homes] [Doctor's Offices] [Hospices] [Healthcare Settings]

ACCEPTED 9/14
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[If directions for HIV are to be used, then use the following heading:]

***SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS**

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[Use A, B, OR C:]

[A]

***KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/ OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in 30 seconds at room temperature (68° - 77°F or 20°-25°C) in health care or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

[B]

***KILLS HIV-1(AIDS VIRUS) ON THE PRE-CLEANED EXTERNAL SURFACES OF ULTRASOUND TRANSDUCERS [PROBES] PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in 30 seconds at room temperature (68°-77°F or 20°-25°C) in health care or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

[C]

***KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/ OBJECTS AND PRE-CLEANED EXTERNAL SURFACES OF ULTRASOUND TRANSDUCERS [PROBES] PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in 30 seconds at room temperature (68° - 77°F or 20°-25°C) in health care or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

[If paragraph A, B, or C are used, then all of the language below must be used on label:]

PERSONAL PROTECTION: When using this product, wear disposable protective gloves, protective gowns, face masks, or eye coverings as appropriate when handling HIV-1 infected blood or body fluids.

CLEANING PROCEDURE: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfection by the germicidal cloth. Open and unfold first germicidal cloth to remove gross filth [heavy soil].

DISPOSAL OF INFECTIOUS MATERIALS: Dispose of used towelette in accordance with local regulations for infectious waste disposal.

CONTACT TIME: Use second germicidal cloth to thoroughly wet surface. Allow to remain wet 30 seconds, let air dry. Although efficacy at a 30 second contact time has been shown to be adequate against *HIV-1 (AIDS VIRUS) this time is not sufficient for the other non-HIV organisms listed on this label. Therefore a 5 minute wet contact time must be used for all listed non-HIV organisms.

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10/14

[Use storage/disposal statement A if towelette dispenser directions used. Use storage/disposal statement B if travel pack or packet directions used.]

[A]

STORAGE AND DISPOSAL

Towelette: Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.
Dispenser: Do not reuse empty container. Wrap container and put in trash collection.

[B]

STORAGE AND DISPOSAL

Towelette: Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.
Travel Pack [or Packet]: Put empty travel pack [or packet] in trash collection.

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11/14

[The following graphics and statements are optional.
They may be placed anywhere on label/container.]



[This graphic shows use of the wipe dispenser.]



NOT A BABY WIPE

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NOT FOR USE ON SKIN

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12/14

[The following graphics and statements are optional.]
They are used to show examples of places the product can be used]

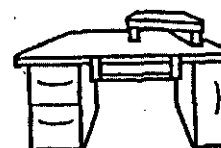
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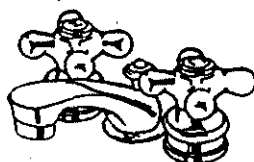
CAR



DESKTOP



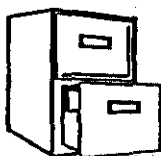
DOOR KNOB



FAUCET



CHANGING TABLES



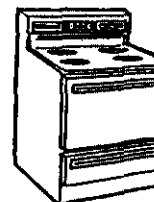
OFFICE



EXTERIOR OF
REFRIGERATOR



KITCHEN COUNTERTOPS
& SINKS

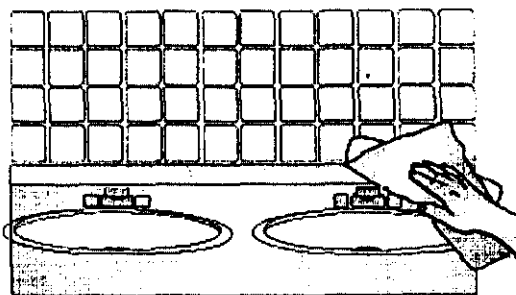
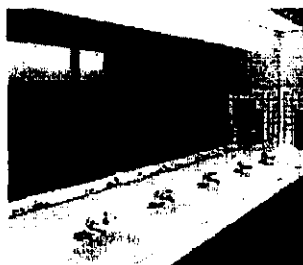


EXTERIOR OF
STOVE

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

9480-5



TUB



SHOWER STALLS



PHONES

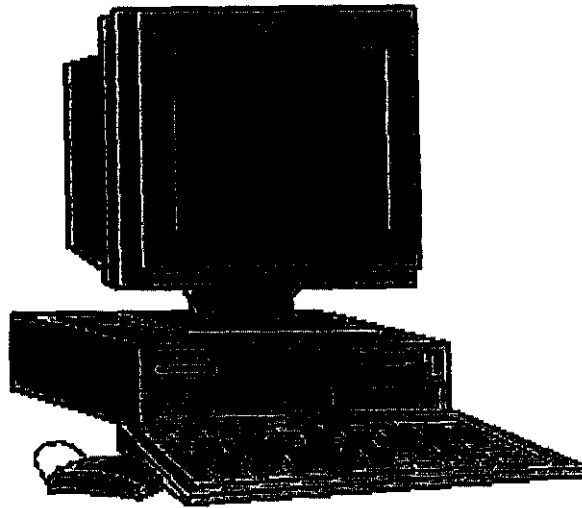
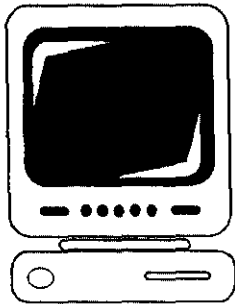


TOILET SEATS

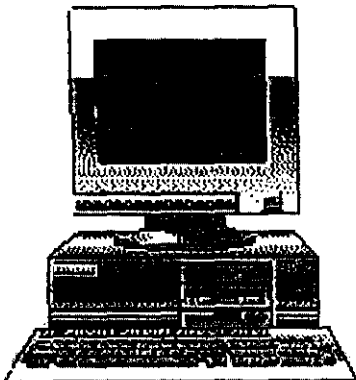
THE INFORMATION IN THIS BOX IS NOT PART OF THE LABELING

Statements in brackets [] are optional or instructional. Italicized words in brackets are not included. Sequence of phrases is optional unless specified in 40 CFR 156.10. Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR. The terms "wipe(s)", "towel(s)" and "cloth(s)" can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment. Lists of uses and use sites can be used partially or in their entirety. Any individual statement, claim, restriction or other wording must be used in its entirety, and can not be expanded or shortened by combination, partial deletion, merging, or similar.

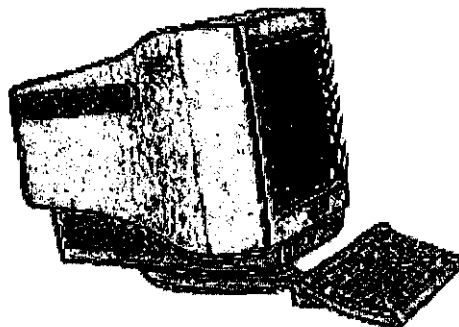
[The following graphics and statements are optional.]
They are used to show examples of places the product can be used]



[COMPUTER KEYBOARDS]



[COMPUTERS]



ACCEPTED
with COMMENTS
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