

8155-23

11/13/2008

1/7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 13 2008

Mr. John Wiegand
Director, Research and Development
Canberra Corporation
3610 Holland-Sylvania Rd.
Toledo, OH 43615

Subject: **Husky 806 H/D/N**
EPA Registration Number 8155-23
Application Dated August 11, 2008
Received Date August 18, 2008

Dear Mr. Wiegand:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment:

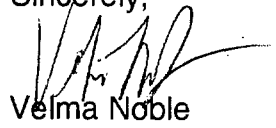
- Comply with PR Notice 2007-4

General Comments:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: stamped label

CONCURRENCES

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

HUSKY 806 H/D/N

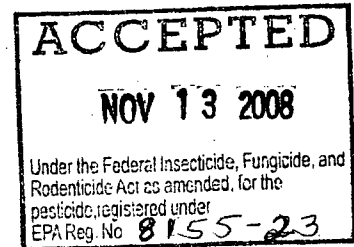
[ANTIBACTERIAL, ANTI-MICROBIAL]
[WILL NOT HARM NONPOROUS PLASTIC, ACRYLIC AND FROSTED ACRYLIC SURFACES]
[CONCENTRATE][One gallon makes 128 gallons of use-solution.]

[DISINFECTANT-CLEANER-SANITIZER-FUNGICIDE-MILDEWSTAT-VIRUCIDE*
DEODORIZER FOR HOSPITALS, INSTITUTIONAL AND INDUSTRIAL USE]

[DISINFECTANT FOR PERSONAL PROTECTIVE EQUIPMENT
DISINFECTANT FOR BARBER SHOPS, TANNING SALONS, HAIR SALONS, TATTOO PARLORS, SPAS]

[EFFECTIVE AGAINST VANCOMYCIN RESISTANT ENTEROCOCCUS FAECALIS (VRE)
EFFECTIVE IN HARD WATER UP TO 400 PPM HARDNESS (Calculated as CaCO₃)
IN THE PRESENCE OF 5% SERUM CONTAMINATION]

[PICTOGRAM]



ACTIVE INGREDIENT

Didecyl dimethyl ammonium chlorides.....	7.68%
OTHER INGREDIENTS.....	92.32%
TOTAL.....	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

[For Industrial and Institutional Use Only.]

See side [back] panel for [First Aid and] additional precautionary statements.

(Note to reviewer: Where First Aid Statement will not fit on front panel, referral statement will include "First Aid")

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

EPA REG. NO. 8155-23

EPA EST. NO. 8155-OH-1

NET CONTENTS: ONE GALLON

MANUFACTURED BY: CANBERRA CORPORATION
3610 HOLLAND-SYLVANIA RD.
TOLEDO, OHIO 43615

Cross-contamination is of major housekeeping concern, not only in hospitals, but also in schools, institutions and industry. This product has been formulated to aid in the reduction of cross-contamination in these areas. It is a one-step disinfectant-cleaner, that is effective against a broad spectrum of bacteria. It is virucidal*(including HIV-1), fungicidal and inhibits the growth of mold and mildew and their odors, when used as directed. It is an effective one-step sanitizer-cleaner for use on non-food contact surfaces. When used as directed, it will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors. It is an effective fungicide against Trichophyton mentagrophytes,(the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities.

This product is recommended for use in hospitals, medical and dental offices, nursing homes, public rest rooms, institutions, schools, colleges, athletic facilities, food processing plants, poultry processing areas, poultry premises, food storage areas, kitchens, restaurants and bars, barber shops, hair salons, tanning salons, massage parlors, tattoo parlors, spas, airports, boats, ships, cruise lines, transportation terminals, hotels and motels. This product contains no phosphorous. It is a no-rinse, neutral pH disinfectant-cleaner that disinfects, cleans and deodorizes in one labor saving step. It can be used with mop and bucket, trigger sprayers, sponge or by soaking. This product provides effective cleaning strength that will not dull most metal-interlock floor finishes, and does not require a rinse prior to recoat. This product is a neutral pH multi-surface cleaner, deodorizer and disinfectant. Use this product to pre-clean heavy soil deposits prior to disinfection.

Use it on the multi-touch surfaces responsible for cross-contamination. Use it on finished floors and conductive flooring. Use on washable hard nonporous surfaces: such as walls, floors, countertops, stovetops, sinks, appliance and refrigerator exteriors, cabinets, tables, chairs, desks, telephones, door knobs, garbage cans, shower stalls, tubs and glazed tiles, wash basins, hard nonporous surfaces of [barber shop][[tanning][hair] salon, [tattoo parlor][spa] surfaces, instruments, equipment and tools, coils and drain pans of air conditioning and refrigeration equipment and heat pumps [follow use directions for sanitizing non-food contact surfaces], and other hard nonporous surfaces of metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, plastic, enameled surfaces, vinyl and plastic furniture. Use of this product on surfaces that may contact food, must be followed by a potable water rinse.

Use this product to clean and disinfect nonporous personal protective safety equipment, protective eye ware, face shields, spectacles, goggles, protective headgear, hardhats, half mask respirators, full face breathing apparatus, gas masks, hearing protectors, and ear muffs. Rinse all equipment that comes in prolonged contact with skin before reuse with clean warm water (about 120° F), and allow to air dry. (Cleaning at the recommended 120°F temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement.)

Effective against Vancomycin Resistant Enterococcus faecalis(VRE) at 1 ounce per gallon of water [0.33 fl. oz. per 42 fl. oz. of water][9.83 ml. per 1250 ml of water][or equivalent dilution].

This product is a hospital-use disinfectant at 1 ounce per gallon of water [0.33 fl. oz. per 42 fl. oz. of water][9.83 ml. per 1250 ml of water][or equivalent dilution], modified in the presence of 250 ppm hard water and at 1 1/3 ounces per gallon of water [0.33 fl. oz. per 32 fl. oz. of water][9.83 ml. per 950 ml of water][or equivalent dilution], modified in the presence of 400 ppm hard water. It is bactericidal according to the AOAC Use-Dilution Test Method, virucidal* according to the Virucidal Qualification on hard inanimate surfaces, fungicidal according to the AOAC Fungicidal Test, and modified in the presence of 5% organic serum against:

- | | |
|--|---|
| Staphylococcus aureus(Vancomycin Intermediate Resistant -VISA) | Staphylococcus epidermidis |
| Staphylococcus aureus(Methicillin Resistant-MRSA) | Acinetobacter baumannii |
| Staphylococcus aureus | Salmonella typhimurium |
| Pseudomonas aeruginosa | Streptococcus pyogenes |
| Salmonella enterica | Serratia marcescens |
| Chlamydia psittaci | Enterobacter aerogenes |
| Shigella flexneri | Shigella sonnei |
| Escherichia coli(Methicillin Resistant) | Enterococcus faecalis |
| Enterococcus faecalis(Methicillin Resistant) | Klebsiella pneumoniae |
| Aspergillus niger | Candida albicans |
| *HBV Hepatitis B Virus | *HIV-1(AIDS Virus) |
| *Herpes simplex Type 1 | *Vaccinia |
| *Herpes simplex Type 2 | *Avian Influenza/Type A(Turkey/Wisc.)(H9N2) |

This product is a sanitizer for hard non-porous non-food contact surfaces at 1 - 1 1/3 ounces per gallon of water [0.33 fl. oz. per 42 fl. oz. or 0.33 fl. oz. per 32 fl. oz. of water][9.83 ml. per 1250 ml or 9.83 ml per 950 ml of water] [or equivalent dilution] against:

- | | |
|------------------------|-----------------------|
| Enterobacter aerogenes | Staphylococcus aureus |
|------------------------|-----------------------|

Note to Reveiwer - Copy in brackets | | is optional marketing information. Italicized is new copy.
Aug. 11, 2008 Amendment 8155-5 Compliance with PR Notice 2007-4

[FOR AUTOMATIC DILUTION]

[CONCENTRATED PRODUCT - DILUTE BEFORE USING]

[ATTACHING THIS PRODUCT TO THE AUTOMATIC DILUTION CENTER: Remove white shipping cap. DO NOT REMOVE [WHITE] PURPLE PLUG FROM BOTTLE THROAT! Screw on yellow [purple] dispensing cap from dilution center product tube. Push down while twisting.]

DIRECTION FOR USE

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

Preparation of use solution [dilution]:

For water hardness up to 250 ppm, [add] dilute 1 ounce per gallon of water [0.33 fl. oz. per 42 fl. oz. of water][9.83 ml. per 1250 ml of water][or equivalent dilution]; for water hardness up to 400 ppm, [add] dilute 1 1/3 ounces per gallon of water[0.33 fl. oz. per 32 fl. oz. of water][9.83 ml. per 950 ml of water] [or equivalent dilution], to disinfect hard non-porous surfaces. For heavy duty use, [add] dilute 4 ounces per gallon of water to disinfect hard non-porous surfaces.

Disinfection/Virucidal* Directions:

For heavily soiled areas, a preliminary cleaning is required. Apply use-solution to hard, inanimate, non-porous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge or sprayer. Treated surfaces must remain wet for 10 minutes. Allow surface to air dry. Prepare a fresh solution daily or when use solution becomes diluted or soiled.

For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface. Do not breathe spray mist. For food contact surfaces such as counters, tables and appliances, thoroughly rinse surfaces with potable water. Do not use on dishes, glasses and utensils.

Cleaning and Deodorizing:

[Add] Dilute 1 ounce of product per gallon of water. Thoroughly wet surfaces with a cloth, mop, sponge or sprayer. Remove excess solution with a cloth or allow to air dry.

(One of the following statements must be used for labels listing medical site uses and stainless steel or metal surfaces.)

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.

(or) This product is not for use on *critical or semi-critical* medical device surfaces.

[Barber Shop][Tanning][Hair] Salon, [Tattoo Parlor][Spa] Surfaces, Instruments, Equipment and Tools Disinfection Directions:

[Add] Dilute 1 ounce of product with a gallon of water [0.33 fl. oz. per 42 fl. oz. of water][9.83 ml. per 1250 ml of water] [or equivalent dilution] to disinfect hard, nonporous surfaces on equipment, instruments and tools. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For larger equipment and surfaces, thoroughly wet surfaces with cloth, mop, sponge or sprayer. Treated surfaces must remain wet for 10 minutes. For heavily soiled surfaces, instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or soiled. Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

Cleaning and Disinfecting Hard Nonporous Surfaces on Personal Protective Equipment:

Pre-clean equipment if heavily soiled to ensure proper surface contact. [Add] Dilute 1 ounce of product with a gallon of water [0.33 fl. oz. per 42 fl. oz. of water][9.83 ml. per 1250 ml of water] [or equivalent dilution] and apply use-solution to hard, nonporous surfaces of the equipment by brush, coarse spray device, sponge or by immersion. Thoroughly wet all surfaces to be disinfected. Treated surfaces must remain wet for 10 minutes. Remove excess solution from equipment. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or soiled. Prolonged soaking may cause damage to equipment. Comply with all OSHA regulations for cleaning respiratory protection (29CFR Sec. 1910.134).

Mold and Mildew Directions:

Note to Reveiwer - Copy in brackets | | is optional marketing information. Italicized is new copy.

Aug. 11, 2008 Amendment 8155-5 Compliance with PR Notice 2007-4

[Add] Dilute 1 ounce per gallon of water [0.33 fl. oz. per 42 fl. oz. of water][9.83 ml. per 1250 ml of water][or equivalent dilution], to control the growth of mold and mildew and their odors on hard, non-porous surfaces. Thoroughly wet all surfaces completely. Let air dry. Repeat application weekly or when growth or odor reappear.

Sanitizing Non-Food Contact Surface Directions:

[Add] Dilute 1 - 1 1/3 ounces per gallon of water [0.33 fl. oz. per 42 fl. oz. or 0.33 fl. oz. per 32 fl. oz. of water][9.83 ml. per 1250 ml or 9.83 ml per 950 ml of water] [or equivalent dilution] to sanitize hard, non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

To Sanitize Barber Shop [Tanning][Hair] Salon, [Tattoo Parlor][Spa] Surfaces, Instruments, Equipment and Tools: Immerse pre-cleaned salon [barber] instruments, tools or protective equipment [such as combs, brushes, rollers, razors, scissors, blades, manicure instruments] in a use-solution [dilution] of 1 - 1 1/3 ounces per gallon of water [0.33 fl. oz. per 42 fl. oz. or 0.33 fl. oz. per 32 fl. oz. of water][9.83 ml. per 1250 ml or 9.83 ml per 950 ml of water] [or equivalent dilution] for at least 60 seconds. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the use solution becomes visibly diluted, cloudy or soiled. Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

***KILLS HIV AND HBV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/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) or Hepatitis B Virus (HBV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OR HBV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: Clean-up should always be done wearing protective latex gloves, gowns, masks and eye protection.

Cleaning Procedure: Blood and other body fluids containing HIV or HBV must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time: For HIV:** Use 1 oz. of concentrate per gallon of water. Leave surface wet for 2 minutes. **For HBV:** Use 1 1/3 oz. of concentrate per gallon of water. Leave surface wet for 10 minutes. **For disinfection against all other bacteria and fungi claimed:** Use a 10 minute contact time. **Disposal of Contaminated Material:** Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste material.

POULTRY PREMISE DISINFECTION

Site Preparation: Remove gross contamination and debris. This may be accomplished using a shovel, broom, or vacuum depending on the area to be disinfected. The efficacy of germicidal cleaners is reduced in the presence of heavy organic matter. Once the heavy debris is eliminated, thoroughly clean all surfaces with soap or detergent and rinse with water.

Cleaning And Disinfection: For all general cleaning and disinfection use 1 ounce of this product per gallon of water. Apply use-solution using a cloth, mop, or low pressure coarse sprayer so as to thoroughly wet surface to be disinfected. Allow to remain wet for 10 minutes and then let air dry. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution after each use.

APPLICATIONS AND USE DILUTION

Poultry Premise: Remove all animals and feeds from premises, trucks, cars, coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use 1 ounce of this product per gallon of water. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. Ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

Hatcheries: Use 1 ounce of this product per gallon of water to treat the following hard non-porous surfaces: hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more. Rinse with potable water before reuse. Then allow to air dry.

Vehicles: Clean all vehicles including mats, crates, cabs, and wheels with high pressure water and this product. Use 1 ounce per gallon to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more.

Dressing Plant Use: Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the recommended use-solution, 1 ounce of this product per gallon of water. Scrub to loosen all soils. Allow to soak for 10 minutes and thoroughly rinse all wetted and cleaned surfaces with potable water.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Keep out of reach of children. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, protective clothing and rubber gloves. Harmful if swallowed and/or absorbed through the skin. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

FOR CONTAINERS 1 GALLON or LESS:

STORAGE AND DISPOSAL: Store in an area inaccessible to children. Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Otherwise, wrap empty container in plastic bag and discard in trash.

(For Industrial and Institutional Use Only) LOT CODE Designating Batch

FOR CONTAINERS OVER 1 GALLON:

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal. Store in an area inaccessible to children.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray, or mixture of rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency, or the hazardous waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

FOR CONTAINERS OVER 5 GALLONS:

ENVIRONMENTAL HAZARD Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System(NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

SMALL PACKAGE LABELS TO BE USED WITH MASTER CONTAINER LABEL

OPTIONAL PACK TYPES

PACKETS - Pre-measured tear open packets – For water hardness up to 250 ppm [Simply] [tear] open and pour contents into XX gallons of water [for a 1:128 dilution]. Keep packets in box until ready to use. [Pour contents of packet into XX gallons of water for a 1:128 dilution.]

or

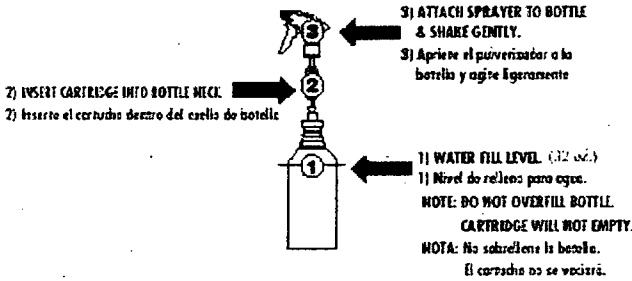
Pour contents of [2 or 4 oz] packet into [2 or 4] gallons of water. Keep packets in box until ready to use.

See Precautionary and First Aid Statements on Master Label

SEE MASTER LABEL FOR COMPLETE USE DIRECTIONS.

CARTRIDGES

(Note to reviewer: The following is to be used with the closed spray bottle system, which consists of a small cartridge containing the concentrate. This information will appear on the outside of the package containing the cartridge)



Cartridge Concentrate

E-Z DILUTE (Optional marketing language)

HUSKY 806 H/D/N

ACTIVE INGREDIENT:

Didecyl dimethyl ammonium chlorides.....	7.68%
OTHER INGREDIENTS.....	<u>92.32%</u>
TOTAL.....	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See Precautionary and First Aid Statements on Master Label

DIRECTION FOR USE

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

For water hardness up to 250 ppm CaCO₃

Completely empty package contents (Y) Fl. Oz. in (Y x 128) Fl. Oz. of water for a 1:128 dilution (1 fl. oz. per gallon of water).

For water hardness up to 400 ppm CaCO₃

Completely empty package contents (Z) Fl. Oz. in (Z x 96.2) Fl. Oz. of water for a 1:96.2 dilution (1.33 fl. oz. per gallon of water).

SEE MASTER LABEL FOR COMPLETE USE DIRECTIONS.

STORAGE AND DISPOSAL: Store in an area inaccessible to children. *Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Otherwise,* wrap empty container in plastic bag and discard in trash.

EPA REG. NO. 8155-23

EPA EST. NO. 8155-OH-1

NET CONTENTS: X Fl. Oz. (mL)

Manufactured by:

Canberra Corporation
3610 Holland-Sylvania Rd.
Toledo, Ohio 43615