



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Daniel J. Manelli  
Representative for Lobob Laboratories, Inc.  
Farkas & Manelli P.L.L.C.  
1233 20<sup>th</sup> Street, N.W.  
Suite 700  
Washington, DC 20036-2396

APR 3 1998

Re: P950031  
LOBOB CLEANER  
Filed: March 12, 1996  
Amended: June 25, and November 15, 1996; and April 4, May 9, June 16, July 2, and  
November 24, 1997

Dear Mr. Manelli:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of the premarket approval application (PMA) you submitted on behalf of your client, Lobob Laboratories, Inc., for the LOBOB CLEANER. This device is indicated for use to clean silicone acrylate and fluoro silicone acrylate rigid gas permeable contact lenses and all hard contact lenses. You may begin commercial distribution of the device upon receipt of this letter.

Expiration dating for this device has been established and approved at 3 years for the 2 fl. oz. and 4 fl. oz. bottle sizes. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh/pmapage.html>. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

On July 7, 1997, CDRH published an order in the FEDERAL REGISTER which reclassified contact lens care products from class III (premarket approval) into class II (special controls). Although your device is subject to the reclassification order, CDRH continued to process this application as a PMA to facilitate approval since the only outstanding issue at the time of reclassification was compliance with Good Manufacturing Practice regulations. This issue was subsequently resolved on March 24, 1998.

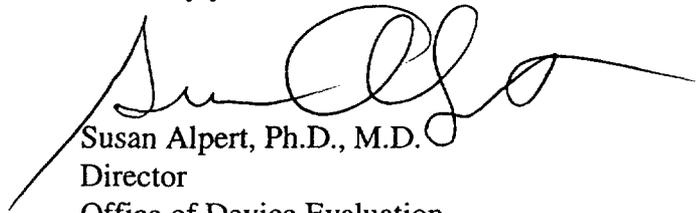
Future modifications of the device are subject to requirements of premarket notification (510(k)) and the "Guidance for Industry, Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products" dated May 1, 1997 which can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh>. You may obtain a hard copy of the guidance by faxing your request to the Division of Small Manufacturers Assistance (DSMA) [fax (301) 443-8818].

All correspondence regarding 510(k) submission should be submitted to the address below:

510(k) Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Eleanor M. Felton or James F. Saviola, O.D., at (301) 594-1744, or Kathy Poneleit at (301) 594-2186.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Alpert", with a long horizontal flourish extending to the right.

Susan Alpert, Ph.D., M.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

## Summary of Safety and Effectiveness

### I. General Information

- A. Premarket Approval Application (PMA) Number: P950031  
Date Filed: March 12, 1996  
Date Approved:
- B. Device Generic Name: cleaning solution
- C. Device Trade Name: LOBOB CLEANER
- D. Applicant's Name and Address: Lobob Laboratories, Inc.  
1440 Attenberry Lane  
San Jose, CA 95131
- E. Good Manufacturing Practice (GMP) Inspection:  
Date of Inspection: March 24, 1998  
Conclusion: The manufacturing site was found to be in compliance with device GMP requirements.

### II. Indications

LOBOB CLEANER is indicated for use to clean silicone acrylate and fluoro silicone acrylate rigid gas permeable contact lenses and all hard contact lenses.

### II. Summary

The applicant performed non-clinical and clinical testing on the device. The non-clinical testing supports the safety and effectiveness of the device from microbiology, toxicology, chemistry and manufacturing perspectives. Data were evaluated from a multi-center clinical study of a soft (hydrophilic) contact lens consisting of 72 eyes wearing the soft (hydrophilic) contact lens and followed for 3 months. Due to the absorption nature of hydrophilic contact lenses, these lenses are considered to be a worst case analysis of the contact lens solution.

### IV. Safety and Effectiveness Data

#### A. Non-clinical Data

The applicant conducted a battery of in-vivo and in-vitro acute toxicology studies that support the safety and biocompatibility of the solution with silicone acrylate and fluoro silicone acrylate RGP contact lens materials. Additionally, chemistry and manufacturing information was submitted demonstrating that the solution is suitable for use to clean silicone acrylate and fluoro silicone acrylate lens materials. The

adequacy of the manufacturing process, including sterilization and shelf-life expiration dating, was established through a review of the manufacturing and microbiology data submitted in the PMA as well as through an on-site GMP inspection.

#### B. Clinical Data

The clinical study included both males and females in numbers representative of the contact lens wearing population in the United States. Based on the detailed analysis of the data presented in the PMA, it was determined that the clinical findings, i.e., adverse reactions, positive slit lamp findings, patient symptoms, problems and complaints, visual acuity, lens replacements, discontinued patients, and lens wearing time were within expected limits for contact lens wearers. Although the potential exists for minor differences in physiological response by gender for the target population, the minimal number of clinically significant findings does not indicate gender difference to be of clinical importance for this device.

In addition, the applicant provided a marketing history for the subject device which indicated that the device has been marketed for approximately 27 years for use to clean conventional hard (PMMA) contact lenses and that over 9.6 million bottles have been sold with no significant reports of adverse reactions.

#### V. Conclusion

The Center for Devices and Radiological Health (CDRH) reviewed the PMA and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the device for the prescribed indications for use.

On July 7, 1997, CDRH published an order in the FEDERAL REGISTER which reclassified contact lens care products from class III (premarket approval) into class II (special controls). Although the device was subject to the reclassification order, CDRH continued to process this application as a PMA to facilitate approval since the only outstanding issue at the time of reclassification was compliance with Good Manufacturing Practices. This issue was subsequently resolved on March 24, 1998.

This PMA was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA submission duplicated information previously reviewed by that panel. CDRH approved this PMA in a letter to the applicant dated

APR 3 1998 and signed by the Director, Office of Device Evaluation.

**LABELING FOR LOBOB LABORATORIES CLEANER BOX**

**CLEANER: EXTERNAL BOX**

**Panel 1 (Right side)**

**LOBOB CLEANER is a sterile non-preserved cleaning solution for use with silicone acrylate and fluoro-silicone acrylate rigid gas permeable (RGP) contact lenses and all hard contact lenses. When used as directed, eliminates surface deposits, oils lipids, salts, cosmetic residue without the use of suspended abrasives.**

**LOBOB LABORATORIES, INC.  
1440 Atteberry Lane  
San Jose, CA 95131**

**Print date**

**Panel 2 (Front)**

**STERILE**

**LOBOB CLEANER**

**For silicone acrylate and fluoro-silicone acrylate rigid gas permeable (RGP) contact lenses and all hard contact lenses.**

**2 fluid oz. (60 ml)  
[4 fluid oz. (118 ml)]**

**Panel 3 (Back)**

**CONTAINS: A slightly alkaline aqueous sterile solution with cocoamphodiacetate and glycols. LOBOB CLEANER is non-preserved and contains no suspended abrasive material.**

**WARNING: Do not touch the dropper tip to any surface as this may contaminate the solution. Keep the bottle tightly closed. Keep out of reach of children. Not for use with soft lenses.**

**NOT FOR USE DIRECTLY IN THE EYE**

Panel 4 (Left side)

LOBOB CLEANER eliminates surface deposits, grease, oils and lipids from silicone acrylate and fluoro-silicone acrylate RGP contact lenses and all hard contact lenses.

**DIRECTIONS**

Wash hands with a mild soap. Place the lens in the cupped palm of the hand. Apply one or two drops of LOBOB CLEANER to both surfaces of the lens. Massage the lens and work up a sudsing pool for approximately 30 seconds. Or alternatively, apply one or two drops of LOBOB CLEANER to both lens surfaces and massage the lens between the fingers, or as directed by your eye care practitioner.

**CAUTION:** If performing the lens cleaning process over a basin, be certain that the drain is plugged to prevent loss.

**BOTTOM FLAP CENTER OF BOX:**

UPC Code

Lot#            Exp. Date

**TOP FLAP CENTER OF BOX:**

**FOR YOUR PROTECTION:**

Bottles are sealed with  
tamper -evident neckbands.

Do not use if tamper-evident seal on bottle  
is broken or missing.

**LOBOB CLEANER - BOTTLE LABEL**

The bottle labeling consists of a front and back panel

**FRONT PANEL:**

**STERILE**

**LOBOB  
CLEANER**

- Use LOBOB CLEANER to clean silicone acrylate and fluoro-silicone acrylate RGP contact lenses and all hard contact lenses.
- Use daily, or whenever lenses are removed, to eliminate surface deposits, oils, lipids, salts and cosmetic residue.

2 FL. OZ. (60 ml)  
[4 FL. OZ (118 ml)]

**BACK PANEL:**

**NOT FOR USE DIRECTLY IN THE EYE**

- Wash hands with a mild soap to remove foreign matter
- Handle lenses with care to avoid lens damage or loss
- Place the lens in the cupped palm of hand. Apply one or two drops of LOBOB CLEANER to both surfaces of lens. Massage the lens and work up a sudsing pool for approximately 30 seconds. Or alternatively, apply one or two drops of LOBOB CLEANER to both surfaces of the lens and massage the lens between the fingers or as directed by your eye care practitioner.
- Rinse the lens surfaces free of LOBOB CLEANER before disinfecting and storage
- Repeat the above directions as needed for oily or dirty lenses.

**DO NOT TOUCH THE TIP OF CONTAINER TO ANY SURFACE TO AVOID CONTAMINATION**

**A CLEAN LENS IS A COMFORTABLE LENS**

**CAUTION:** If LOBOB CLEANER is accidentally placed in the eye, remove the lens and flush with copious amounts of clean water. LOBOB CLEANER will sting and cause temporary redness and irritation if instilled into the eye. If the redness or irritation persists, consult a physician. If swallowed, drink extra water. Contains cocoamphodiacetate and glycols.

**NON-PRESERVED, NOT FOR USE WITH SOFT-LENSES**

Do not use if tamper-evident seal on bottle is broken or missing.

**LOT #, EXPIRY DATE**

**PRINT DATE**

**LOBOB LABORATORIES, INC.  
1440 ATTEBERRY LANE  
SAN JOSE, CA 95131**

(TEXT FOR LOBOB RGP INSERT  
LOBOB CLEANER)

FOR USE WITH SILICONE ACRYLATE AND  
FLUORO-SILICONE ACRYLATE RGP CONTACT  
LENSES AND ALL HARD CONTACT LENSES

**DESCRIPTION:**

LOBOB CLEANER is a sterile, non-preserved aqueous solution of cocoamphodiacetate and glycols, and contains no suspended abrasive particles.

**ACTION:**

LOBOB CLEANER eliminates surface deposits, grease, oils and cosmetic residue from silicone acrylate and fluoro-silicone acrylate rigid gas permeable (RGP) contact lenses and all hard contact lenses.

**INDICATIONS (USES):**

Use LOBOB CLEANER to clean silicone acrylate and fluoro-silicone acrylate RGP contact lenses and all hard contact lenses.

**CONTRAINDICATIONS (REASONS NOT TO USE):**

If you are allergic to any ingredient that is used in LOBOB CLEANER, do not use this product.

**WARNINGS:**

LOBOB CLEANER contains no preservatives to which some people may be allergic, but, see contraindications.

LOBOB CLEANER is not for use directly in the eye.

Serious damage to the eye and loss of vision may result from wearing contaminated or damaged contact lenses. Immediately contact your eye care practitioner to identify the cause of any unexplained eye discomfort, watering, vision change or redness of the eye, and to begin any necessary treatment.

Keep the bottle tightly closed when not in use.

Never touch the tip of the bottle to any surface as this may contaminate the solution.

Do not use with soft lenses.

**PRECAUTIONS**

LOBOB CLEANER is not for use directly in the eye. Rinse lenses thoroughly before placing in your lens case. If LOBOB CLEANER is accidentally placed in the eye, remove the lens and flush with copious amounts of clean water. LOBOB CLEANER will sting and cause temporary redness and irritation if instilled into the eye.

If the redness and irritation persists, consult a physician.

Always wash the hands with a mild soap and rinse well before handling your lenses. Never use soap containing oils or lanolin.

Store solution at room temperature. Overheating or freezing may affect the solution.

Use before the expiration date marked on the bottle label and the carton.

Keep out of the reach of children.

**ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO):**

Rarely the following problems may occur:

Stinging, burning or itching of the eyes (irritation)

Excessive watering (tearing) of the eyes.

Unusual eye secretions.

Continued redness of the eye.

Reduced sharpness of vision (visual acuity).

Blurred Vision.

Sensitivity to light (photophobia).

Dry eyes.

If you notice any of the above problems, remove and examine your lenses. If the problem stops and the lenses appear to be undamaged, clean, rinse, disinfect your lenses and reinsert them.

If the problem continues, or a lens appears to be damaged, immediately remove the lens and contact your eye care practitioner.

If any of the above problems occur, a serious condition may be present. Seek immediate professional identification of the problem and start treatment to avoid serious eye damage. See your "Instructions for Wearers" booklet for your lenses for more information.

**DIRECTIONS:**

Place the lens in the cupped palm of the hand. Apply one or two drops of LOBOB CLEANER to both surfaces of the lens. Massage the lens and work up a sudsing pool for approximately 30 seconds. Or alternatively, apply a few drops of LOBOB CLEANER to both lens surfaces and massage the lens between the fingers, or as directed by your eye care practitioner.

**HOW SUPPLIED:**

This cleaner is supplied in sterile 2 fl. oz. (60 ml) and 4 fl. oz. (118 ml) plastic dropper bottles. The bottle labels and the boxes are marked with a lot number and expiration date.

Print date