



PMS

P910003

Memorandum

Date JUL -7 1995

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Wesley-Jessen's WESLEY-JESSEN® COE-405
DISINFECTION TABLET - ACTION

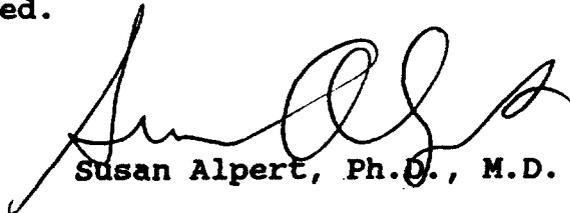
To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above referenced medical device (Tab B); and
- (2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.



Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by EM Felton, CDRH, HFZ-460, June 27, 1995, 594-1744.

DRAFT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

WESLEY-JESSEN; PREMARKET APPROVAL OF WESLEY-JESSEN® COE-405
DISINFECTANT TABLET

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Wesley-Jessen, Des Plaines, IL, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of the WESLEY-JESSEN® COE-405 DISINFECTANT TABLET. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on JUL - 7 1995, of the approval of the application.

DATE: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Drive, Rockville, MD 20857.

J

FOR FURTHER INFORMATION CONTACT:

David M. Whipple,
Center for Devices and Radiological Health (HFZ-460),
Food and Drug Administration,
9200 Corporate Blvd.,
Rockville, MD 20850,
301-594-1744.

SUPPLEMENTARY INFORMATION: On February 13, 1991, Wesley-Jessen, Des Plaines, IL 60018, submitted to CDRH an application for premarket approval of Wesley-Jessen® COE-405 Disinfection Tablet. When the WESLEY-JESSEN® COE-405 DISINFECTION TABLET is dissolved in a sterile contact lens saline solution, the solution is indicated for use in the chemical (not heat) disinfection of soft (hydrophilic) contact lenses.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On JUL -7 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

B

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

OPPORTUNITY FOR ADMINISTRATIVE REVIEW

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

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Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under the Federal Food, Drug, and Cosmetic Act section 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Rick Main
Regulatory Affairs
Wesley-Jessen
2000 Clearwater Drive
Des Plaines, IL 60018

JUL 7 1995

RE: P910003
WESLEY-JESSEN® COE-405 DISINFECTION TABLET
Filed: February 13, 1991
Amended: June 3 and 10, 1991; February 10, 1992; May 13,
June 1, and December 7 and 16, 1993; and March 8, and
June 21, 1995

Dear Mr. Main:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the WESLEY-JESSEN® COE-405 DISINFECTION TABLET. When the WESLEY-JESSEN® COE-405 DISINFECTION TABLET is dissolved in a sterile contact lens saline solution, the solution is indicated for use in the chemical (not heat) disinfection of soft (hydrophilic) contact lenses. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

Expiration dating for the 60 mg disinfection tablet has been established and approved at 9 months for the 15, 30, and 60 tablet package 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 publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, 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).

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Page 2 - Mr. Rick Main

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

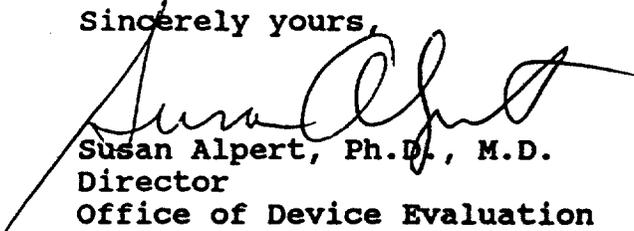
You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA 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 Mr. David M. Whipple at (301) 594-1744.

Sincerely yours,



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

Enclosure



CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

- (1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).
- (2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:
 - (a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

- (b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

- (1) A mixup of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
 - (a) has not been addressed by the device's labeling or
 - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.
- (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

- (1) may have caused or contributed to a death or serious injury or
- (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 240
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Summary of Safety and Effectiveness

I. General Information

- A. Premarket Approval Application (PMA) Number: P910003
Date Filed: February 13, 1991
Date Approved: JUL - 7, 1995
- B. Device Generic Name: 60 mg disinfection tablet
- C. Device Trade Name: WESLEY-JESSEN® COE-405 DISINFECTION TABLET
- D. Applicant's Name and Address: Wesley-Jessen
2000 Clearwater Drive
Des Plaines, IL 60018
- E. Good Manufacturing Practice (GMP) Inspection:
The manufacturing site was found to be in compliance with device GMP requirements on May 26, 1995.

II. Indications

When the WESLEY-JESSEN® COE-405 DISINFECTION TABLET is dissolved in a sterile contact lens saline solution, the solution is indicated for use in the chemical (not heat) disinfection of soft (hydrophilic) contact lenses.

III. Summary

The applicant performed non-clinical and clinical testing on the device in accordance with the FDA Testing Guidelines for Class III Soft (Hydrophilic) Contact Lens Solutions dated July 1985. The non-clinical testing supports the safety and effectiveness of the device from microbiology, toxicology, chemistry and manufacturing perspectives. A prospective clinical study was conducted from April 24, 1989 to June 11, 1990. At the termination of the study period 508 eyes using the subject device had been followed for 6 months and completed the study, 28 eyes had discontinued (none associated with pathology) and 26 eyes were incomplete having been followed for 3 months. The study population included 87 males and 194 females which is 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 soft (hydrophilic) 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.

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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 soft (hydrophilic) contact 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. Additionally, microbiology data were submitted demonstrating that the solution is effective in disinfecting soft (hydrophilic) lenses.

B. Clinical Data

Accountability: 562 eyes enrolled, 508 eyes completed

| Visual Acuity: | <u>Initial Best Corrected</u> | <u>Initial Visit with Lens</u> | <u>Final Visit with Lens</u> |
|-----------------|-------------------------------|--------------------------------|------------------------------|
| 20/30 or better | 506 | 507 | 502 |
| 20/40 or worse | 2 | 1 | 2 |
| Not Reported | 0 | 0 | 4 |

Mean Wear Time:
Daily Wear 13.8 hours
Extended Wear 6.9 days

Adverse Reactions: None reported for 562 eyes enrolled

| Slit Lamp Findings: | <u>Initial Visit</u> (0/508 eyes)-0% | <u>Final Visit</u> (4/508 eyes)-0.8% |
|---------------------|---|---|
| Staining | 0 | 2 |
| Injection | 0 | 2 |

Symptoms, Problems, Complaints: (528 reports/3587 exams)-14.7%
Categories reported-16
Vision Related (e.g. variable vision) (82/528)-15.5%
Comfort (e.g. discomfort) (379/528)-71.8%
Other (e.g. deposits) (67/528)-12.7%

Keratometry: >1.00 D change (0 reports/508 eyes)-0%

Lens Replacements: (255 replaced/562 dispensed)-45.4%
Categories reported-11
Vision Related (e.g. fit, VA) (38/255)-14.9%
Lens Related (e.g. torn) (211/255)-82.7%
Other (e.g. dirty lens, lost) (6/255)-2.4%

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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. This PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory panel, 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 JUL - 7 1995, and signed by the Director, Office of Device Evaluation.

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PACKAGE INSERT

Important - Please read carefully and keep this package insert for future reference.

WESLEY-JESSEN[®] COE-405
DISINFECTION TABLET

For use with soft (hydrophilic) contact lenses in a chemical (not heat) lens care system.

DESCRIPTION: Each 60 mg tablet contains: sodium perborate monohydrate, sodium carbonate, adipic acid, and polyethylene glycol producing a 0.1% hydrogen peroxide solution when dissolved in a contact lens sterile saline solution. A specially designed lens cup must be used with this tablet.

THE TABLETS CONTAIN NO PRESERVATIVES, such as thimerosal or chlorhexidine.

ACTIONS: Disinfecting soft (hydrophilic) contact lenses with the WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET dissolved in a sterile contact lens saline solution helps to destroy harmful microorganisms on the lenses.

INDICATIONS (Uses): When the WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET is dissolved in a sterile contact lens saline solution, the solution is indicated for use in the chemical (not heat) disinfection of soft (hydrophilic) contact lenses.

CONTRAINDICATIONS (REASONS NOT TO USE):

If you are allergic to any ingredient in the WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET, DO NOT USE THIS PRODUCT.

WARNINGS: PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS
COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use and care of your lenses and lens care products, including the lens cup.

Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.

Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. clinical studies have shown the risk of serious adverse reactions is increased when these lenses are worn overnight.

Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement as prescribed by your eye care practitioner. Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. studies have also shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement.

Studies have also shown that smokers have a higher incidence of adverse reactions.

If you experience eye discomfort, excessive tearing, vision changes., redness of the eye, immediately remove your lenses and promptly contact your eye care practitioner.

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.

- DO NOT USE THE WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET OR ITS SOLUTION DIRECTLY ON THE EYE AS IT MAY CAUSE BURNING, STINGING, REDNESS AND IRRITATION TO YOUR EYES. IMMEDIATELY REMOVE THE LENSES AND FLUSH YOUR EYES WITH WATER. IF PROBLEMS CONTINUE, IMMEDIATELY CONTACT YOUR EYE CARE PRACTITIONER.
- Never use WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET or the solution containing it in a thermal disinfection unit.
- Never reuse the solution containing the dissolved WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET.
- DO NOT reinsert your lenses-into your eyes after disinfection without thoroughly rinsing each lens using the lens storage cup with a sterile contact lens saline solution. Failure to adequately rinse your lenses may cause burning, stinging, redness and irritation to your eyes.
- Keep out of reach of children.
- Do not take internally.
- Use only the specially designed lens cup or incomplete disinfection of your lenses might occur.

PRECAUTIONS:

- Use only one WESLEY-JESSEN^R COE-405 DISINFECTION TABLET from a sealed aluminum foil package each time to disinfect your lenses and discard the solution containing the dissolved disinfection tablet after each use.
- Use only the Lens Storage Cup for disinfecting your lenses.
- After rinsing the lenses with a sterile contact lens saline solution and reinserting them onto your eyes, discard the disinfection solution, rinse the storage cup with sterile contact lens saline solution and allow to air dry.
- Do not use the WESLEY-JESSEN^R COE-405 DISINFECTION TABLET if the aluminum foil packaging is torn or otherwise damaged.
- Do not use the tablet if it appears discolored or moist.
- Store at room temperature.
- Do not store the WESLEY-JESSEN^R COE-405 DISINFECTION TABLET removed from their aluminum foil packaging.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO):

The following problems may occur:

- Eyes sting, burn, or itch (irritation)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (visual acuity)
- Blurred vision
- Sensitivity to light ~ (photophobia) Dry eyes.

If you notice any of the above:

- IMMEDIATELY REMOVE YOUR LENSES

If the problem stops and the lens appears to be undamaged, thoroughly clean, rinse, and disinfect the lens and reinsert them. If the problem continues or a lens appears to be damaged, immediately remove the lens and consult your eye care practitioner.

If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. Seek immediate professional identification and treatment of the problem to avoid serious eye damage.

DIRECTIONS: Use the WESLEY-JESSEN^R COE-405 DISINFECTION TABLET only with a sterile contact lens saline solution and the specially designed lens storage cup or incomplete disinfection of your lenses might occur which may result in serious eye damage.

CLEAN/RINSE/DISINFECT: Prior to cleaning and rinsing of your lenses, follow the instructions below each time you remove your contact lenses:

- Always wash, rinse and dry your hands before handling your contact lenses.
- Always handle the same lens first to avoid mixups.
- Take the lens storage cup, unscrew the lens holder and place it with the cap end on a flat surface with the lens baskets facing up.

- Fill the lens storage cup to the fill line with a sterile contact lens saline solution.
- Remove one WESLEY-JESSEN^R COE-405 DISINFECTION TABLET from aluminum foil, place the WESLEY-JESSEN^R COE-405 DISINFECTION TABLET into the filled lens storage cup. Set the lens storage cup down on a flat surface.
- CLEAN your lenses one at a time with a recommended contact lens cleaning solution following the manufacturers directions.
- RINSE each lens thoroughly with a sterile contact lens saline solution following the instructions provided with the recommended contact lens cleaning solution.
- DISINFECT: Place rinsed lenses in appropriate ~(R or ~L) lens baskets.
- Screw the cap tightly on the lens storage cup containing the solution.
- With the cap tightened, shake the lens storage cup for approximately 3 seconds to dissolve the tablet and place it on a flat surface.
- Let the lens storage cup sit for a minimum of 4 hours to disinfect the lenses.*

After disinfecting and prior to insertion on the eye

- Unscrew the cap, discard the disinfecting solution, rinse the lens baskets/storage cup with a sterile contact lens saline solution. Then fill the lens storage cup to the top line with a sterile contact lens saline solution.
- Screw the cap tightly onto the lens storage cup and shake for 5-10 seconds to remove excess hydrogen peroxide from the lenses to eliminate irritation.

Your lenses are now ready to wear.

After reinserting your lenses, always empty your lens storage cup, rinse and allow to air dry.

HOW SUPPLIED: WESLEY-JESSEN^R COE-405 DISINFECTION TABLET is supplied in aluminum foil strips containing 15, 30 or 60 tablets. Each box contains 15, 30 or 60 tablets.

* If lenses are left in the disinfection solution for more than one week, discard the solution in the lens storage cup and repeat the disinfection procedure with fresh contact lens sterile saline solution and a new WESLEY-JESSEN^R COE-405 DISINFECTION TABLET as directed above.

TAMPER RESISTANT: CARTON END-PANELS SEALED, DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Manufactured for:

Wesley-Jessen^R
Corporation
Chicago, IL 60610

Printed Month/Year

(Box Front Panel)

WESLEY-JESSEN COE-405
DISINFECTION TABLET

for soft (hydrophilic)
contact lenses

(Box Right Side Panel)

CONTAINS NO PRESERVATIVES,
SUCH AS THIMEROSAL OR CHLORHEXIDINE

DESCRIPTION: Each 60 mg tablet contains: sodium perborate monohydrate, sodium carbonate, adipic acid, and polyethylene glycol producing a 0.1% hydrogen peroxide solution when dissolved in a contact lens sterile saline solution. A specially designed lens cup must be used with this tablet.

ACTIONS: Disinfecting soft (hydrophilic) contact lenses with the WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET dissolved in a sterile contact lens saline solution helps to destroy harmful microorganisms on the lenses.

CONTRAINDICATIONS (REASONS NOT TO USE):

If you are allergic to any ingredient in the WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET, DO NOT USE THIS PRODUCT.

(Box Back Panel)

DIRECTIONS: Use the WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET only with a sterile contact lens saline solution and the Lens Storage Cup or incomplete disinfection of your lenses might occur which may result in serious eye damage.

CLEAN/RINSE/DISINFECT: Prior to cleaning and rinsing of your lenses, follow the instructions below each time you remove your contact lenses:

- Always wash, rinse and dry your hands before handling your contact lenses.
- Always handle the same lens first to avoid mixups.
- Take lens storage cup, unscrew the lens holder and place it with the cap end on a flat surface with the lens baskets facing up.
- Fill the lens storage cup to the fill line with a sterile contact lens saline solution.
- Remove one WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET from aluminum foil, place the WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET into the filled lens storage cup. Set the lens storage cup down on a flat surface.
- CLEAN your lenses one at a time with a recommended soft contact lens cleaning solution following the manufacturers directions.
- RINSE each lens thoroughly with a sterile contact lens saline solution following the instructions provided with the solution.

- DISINFECT: place the cleaned and rinsed lenses in appropriate (R or L) lens baskets.
- Screw the cap tightly onto the lens storage cup containing the solution.
- With the cap tightened, shake the lens storage cup for approximately 3 seconds to dissolve the tablet and place it on a flat surface.
- Let the lens storage cup sit for a minimum of 4 hours to disinfect the lenses.*

After disinfecting and prior to insertion on the eye

- Unscrew the cap, discard the disinfecting solution, rinse the lens baskets/storage cup with a sterile contact lens saline solution. Then fill the lens storage cup to the top line with sterile contact lens saline solution.
 - Screw the cap tightly onto the lens storage cup and shake for 5-10 seconds to remove excess hydrogen peroxide from the lenses to eliminate irritation.
- Your lenses are now ready to wear.
- After reinserting your lenses, always empty your lens storage cup, rinse and allow to air dry.

*You may store the lenses overnight in this solution if it is more convenient. If the lenses are left in the disinfection solution for more than one week, discard the solution in the lens storage cup and repeat the disinfection procedure with fresh sterile contact lens saline solution and a new WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET as directed above.

Manufactured for:

Wesley-Jessen Corporation
Chicago, IL 60610

(Box Left Side Panel)

WARNING: Do not use the WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET or its solution directly on the eye. Always thoroughly rinse each disinfected lens with a sterile contact lens saline solution prior to inserting them onto the eye. Failure to adequately rinse your lenses may cause burning, stinging, redness and irritation to your eyes.

Do not use the tablet if it appears discolored or moist.

Do not store tablets removed from their aluminum foil packaging. Never use the WESLEY-JESSEN[®] COE-405 DISINFECTION TABLET or its solution in a Heat Disinfection Unit. Store at room temperature.

Keep out of reach of children.

Do not take internally.

Use only the specially designed lens cup or incomplete disinfection of your lenses might occur which may result in serious eye damage.

TAMPER RESISTANT: CARTON END-PANELS SEALED. DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Lot Number:

Expiration Date:

(Box Bottom Panel)

Expiration Date: _____

Lot Number: _____



[Immediate Packaging (aluminum foil) Labeling]

WESLEY-JESSEN
COE-405
DISINFECTION TABLET

Manufactured for:
Wesley-Jessen Corporation
Chicago, IL 60610

Lot _____

Exp. _____