SEP 24 1999

510(k) Summary

K991620

Submitter:

Consumer Health Care Group
Pfizer Inc
New York, NY 10017

Contact Person:

John Tomaszewski
Director, Regulatory Affairs
Telephone Number (212) 573-2394
Facsimile Number (212) 537-1186

Name of Device
Trade Name: Visine for Contacts
Common Name: Lubricating/rewetting eye drops
Classification Name: In-eye contact lens solution

Legally Marketed Devices:

Lens Express/Lubricant Drops - Paco
Clear Eyes CLR - Ross Products

Product Description:

Visine for Contacts is specially formulated to use while wearing contact lenses to moisten lenses, soothe, refresh and moisturize dry, irritated eyes. Visine for Contacts is safe and effective for individuals with eyes sensitive to thimerosal. It moistens lenses and helps remove particulate matter that may cause irritation and/or discomfort.

Intended Use:

Visine for Contacts may be used for the moistening of daily and extended wear soft lenses while in the eyes as needed. For the temporary relief of burning and irritation due to dryness of the eye. For use as a protectant against further irritation or to relieve dryness of the eye.

Indications:

VISINE FOR CONTACTS Rewetting Drops may be used with daily and extended wear soft (hydrophilic) contact lenses for the following:

- Moistening of daily wear soft lenses while on the eyes during the day
- Moistening of extended wear soft lenses upon awakening and as needed during the day

- Moistening of extended wear soft lenses prior to retiring at night

  Placing 1 or 2 drops of VISINE FOR CONTACTS Rewetting Drops on the eye followed by blinking 2 or 3 times will relieve minor irritation, discomfort and blurring which may occur while wearing lenses.

Technological Characteristics: Visine for Contacts is substantially equivalent to currently marketed devices, such as Clear Eyes CLR and Lens Express, with the same intended use. As compared to Clear Eyes CLR and Lens Express, Visine for Contacts contain the same basic components, the rewetting agents include hydroxypropyl methylcellulose and glycerin. Visine for Contacts also contains potassium sorbate and EDTA as preservatives, and a buffering system of sodium borate and boric acid.

Safety: Studies showed no clinically or statistically significant differences between Visine For Contacts and currently marketed products for any parameters. Therefore, Visine for Contacts is as safe as the marketed products when used as directed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 24 1999

Pfizer Pharmaceuticals Group
John Tomaszewski, MS, RAC
Director, Consumer Healthcare
Regulatory Affairs
235 East 42nd Street, 6th Floor/MS-5
New York, NY 10017-5755

Re: K991620
Trade Name: Visine For Contacts
Regulatory Class: II
Product Code: 86 LPN
Dated: August 24, 1999
Received: August 25, 1999

Dear Mr. Tomaszewski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991620

Device Name: VISINE FOR CONTACTS
Indications for Use:

VISINE FOR CONTACTS Rewetting Drops may be used with daily and extended wear soft (hydrophilic) contact lenses for the following:

- Moistening of daily wear soft lenses while on the eyes during the day
- Moistening of extended wear soft lenses upon awakening and as needed during the day
- Moistening of extended wear soft lenses prior to retiring at night

Placing 1 or 2 drops of VISINE FOR CONTACTS Rewetting Drops on the eye followed by blinking 2 or 3 times will relieve minor irritation, discomfort and blurring which may occur while wearing lenses.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W C Brown, Ph.D

(Division Sign-Off)
Division of Ophthalmic Devices

Prescription Use 510(k) Number K991620 ~~OR~~ Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)