Focus® Night and Day Soft Contact Lens - P010019

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	Focus® Night and DayTM (lotrafilcon A) Soft Contact Lens
Manufacturer:	Ciba Vision Corporation
Address:	11460 Johns Creek Parkway, Duluth, GA 30097
Approval Date:	October 11, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/P010019a.pdf

What is it? The device is a soft contact lens. The lens material is approximately 24% water and 76% lotrafilcon A (a fluorosilicone-containing hydrogel). The lens surface is treated to maintain wettability with tears.

How does it work? When placed on the eye, the lens focuses light onto the retina (the light-sensitive area in the back of the eye). The lens material permits a high level of oxygen to reach the eye, which helps to maintain the eye's natural function during wear.

When is it used? The lens is for either daily wear use (while awake) or for extended wear use of up to 30 continuous days and nights, after which it is discarded. The eyes should have a rest without lens wear for at least one night following each scheduled removal. When a lens is removed in between replacement times, it should be cleaned and disinfected before reinsertion. Not everyone can reach the maximum extended wear time of 30 continuous nights. Through careful monitoring, the eye care practitioner can determine an appropriate wearing time.

What will it accomplish? The lens corrects conditions in which the eye does not focus light properly (refractive error), such as near-sightedness (myopia) and far-sightedness (hyperopia). Approximately 93% of patients in a clinical study achieved at least 20/25 vision with the Focus Night and Day lenses.

When should it not be used? The lens should not be used when an inflammation or infection of the eye is present, or when there is any disease or injury in or around the eye or eyelids. It should not be used by individuals who have medical conditions that might interfere with contact lens wear.

About 5% of the people in the clinical study experienced infiltrative keratitis, a localized inflammation of the cornea. Less serious problems included conjunctivitis, dry eyes and mild burning or stinging.

Additional information: Summary of Safety and Effectiveness and Labeling will be available at: http://www.fda.gov/cdrh/pdf/p010019.html

Other:

- Food and Drug Administration: FDA Approves 30-Night Continuous Wear Contact Lenses http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01109.html
- National Institutes of Health (NIH): Information on contact lens: http://www.nlm.nih.gov/medlineplus/eyewear.html
- NIH: Drawing of the eye: http://www.nei.nih.gov/health/eyediagram/index.htm
- NIH: Prevention of corneal ulcers http://medlineplus.nlm.nih.gov/medlineplus/ency/article/001032.htm#visualFile
- Food and Drug Administration: Buying contact lenses online: http://www.fda.gov/cdrh/consumer/buycontactqa.html

(Updated 11/30/2001)