Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

08 JAN 2019

FDA ADVISORY
No. 2019-006

TO: **The General Public and All Healthcare Concerned Professionals**

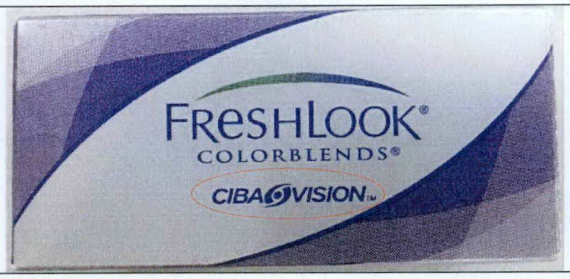
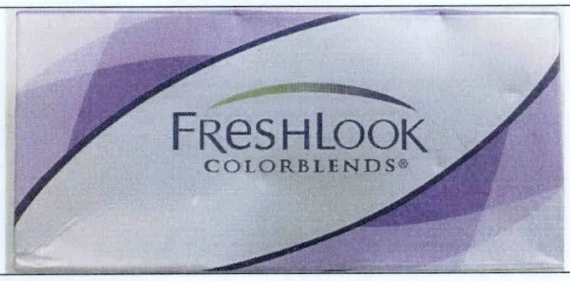
SUBJECT: **Public Health Warning Against the Purchase and Use of Counterfeit Medical Device Product (Freshlook Colorblends (phemfilcon A) Contact Lenses)**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit medical device product **Freshlook Colorblends (phemfilcon A) Contact Lenses** please see particulars/details of the authentic vs. the counterfeit product as provided below:

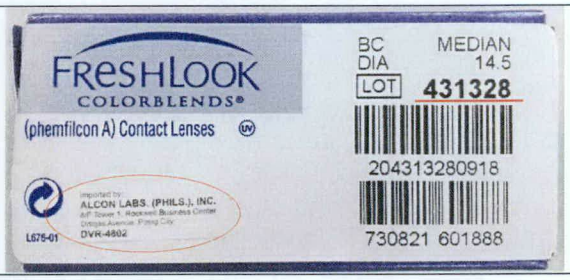
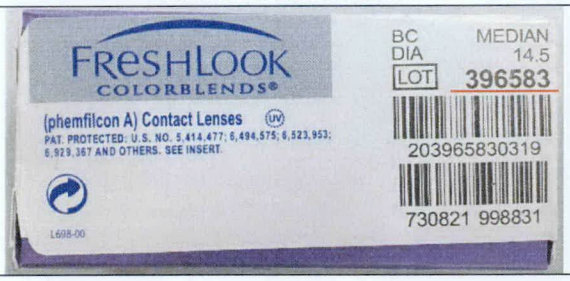
AUTHENTIC	COUNTERFEIT
	

Label differences – blister pack	
SPH -5.75	SPH -0.00
Lot No.: 431328	Lot No.: 396583
Expiration: 2018-09	Expiration: 2021-05

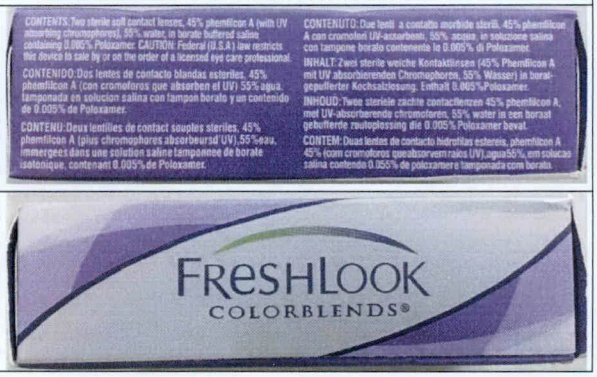
Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

AUTHENTIC	COUNTERFEIT
	

Label differences – box (front)	
Indicates "Ciba Vision"	None

AUTHENTIC	COUNTERFEIT
	

Label differences – box (rear)	
Imported by: ALCON LABS. (PHILS.) INC	None
Importer Address: 8/F Tower 1, Rockwell Business Center, Ortigas Avenue, Pasig City	None
FDA Registration No.: DVR-4802	None
Lot No.: 431328	Lot No.: 396583

AUTHENTIC	COUNTERFEIT
	

Label differences – box (sides)	
Indicates "FOR DAILY WEAR ONLY"	None
Manufacturer: CIBA VISION Corp.	None
Manufacturer address: 11460 Johns Creek Pkwy, Duluth, GA 30097 USA	None

FDA, in coordination with the Market Authorization Holder (MAH), Alcon Laboratories (Phils.), Inc., has verified that the aforementioned medical device product is a **COUNTERFEIT.**

According to Alcon Laboratories (Phils.), Inc., the CIBA Vision Corporation – Illinois, USA already ceased production of Freshlook family soft contact lenses, which includes Freshlook (phemfilcon A) Colorblends Contact Lenses (DVR-4802) in November 2013 and last lots produced bear an expiration dating October 2018.

Accordingly, since this counterfeit medical device has not gone through evaluation and testing process of the FDA, the agency cannot guarantee its quality and safety. The consumption of such violative product may pose potential health hazards to the consuming public.

In light of the above, the public is advised not to purchase and use the aforementioned violative product and to be vigilant against medical device that might not be duly registered with FDA. Always check if a medical device has been registered with the FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph.

All concerned establishments and/or entities are warned not to distribute the above-identified violative medical device product, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this product is not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of the above counterfeit medical device, utilize our online reporting facility, eReport, at www.fda.gov.ph/ereport, or e-mail us via report@fda.gov.ph, or call us at the Center for Device Regulation, Radiation Health and Research (CDRRHR) hotline (02) 857-1900 local 8301.

NELA CHARADE G. PUNO, RPh
Director General

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