Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

07 MAR 2019

FDA ADVISORY
No. 2019-006-A

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

SUBJECT: **Clarification on FDA Advisory No. 2019-006 re: Public Health Warning Against the Purchase and Use of Counterfeit Medical Device Product (Freshlook Colorblends (phemfilcon A) Contact Lenses)**

This is in line with the FDA Advisory No. 2019-006 re: Public Health Warning Against the Purchase and Use of Counterfeit Medical Device Product (Freshlook Colorblends (phemfilcon A) Contact Lenses).

Market Authorization Holder (MAH), Alcon Laboratories (Phils.), Inc., currently hold two (2) registrations for Freshlook Colorblends:

FDA Registration No.:	Validity:	Manufacturing site:	Remarks:
MDR-02166	04-Aug-2020	PT Ciba Vision Batam - Batam Island, Indonesia	• Current manufacturing site of Freshlook Colorblends Contact Lens being supplied in Philippines
DVR-4802	27-Nov-2018	Ciba Vision Corporation - Illinois, USA	• Previous manufacturing site of Freshlook Colorblends • This manufacturing site has already ceased production of Freshlook contact lens since November 2013 • The last lots produced bear an expiration dating October 2018

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.

Alcon Laboratories (Phils.), Inc. clarifies that Freshlook's stocks in the Philippines are currently being supplied by PT CIBA Vision Batam which is located in Indonesia and which continues to be operational to this day.

Therefore, Freshlook Contact Lens (Phemfilcon A) manufactured by PT Ciba Vision Batam - Batam Island, Indonesia and distributed by Alcon Laboratories (Phils.), Inc. is still available and legally sold in the Philippines with valid Certificate of Product Registration No. MDR-02166.

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.

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