Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

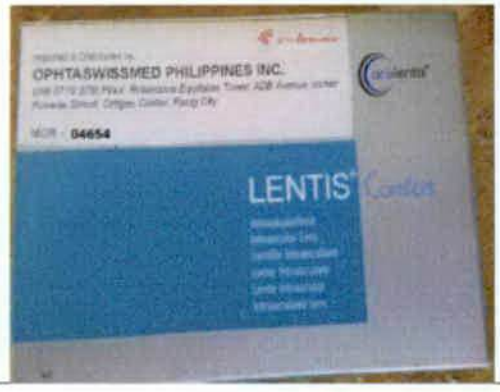
27 OCT 2017

FDA ADVISORY
No. 2017-288

TO: **ALL CONCERNED HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Product Recall of All Lentis Intraocular Lens with expiry date between 2017-01 and 2020-05**

All concerned healthcare professionals and establishments are hereby advised by the Food and Drug Administration (FDA) regarding the voluntary product recall of all Lentis Intraocular Lens (IOL) having an expiry date between 2017-01 and 2020-05 (see photos of the product below) distributed and imported by Ophthaswissmed Philippines Inc.

DESCRIPTION	CODES	PICTURES
LENTIS **MDR-04652**	L-301-1 L-302-1 LS- 302Y L-303 L-312 LS- 312Y L-313 LS-313 Y L-323 LS- 311Y LS-412Y LU-814 VR PCA81 PCX 81NY LU-323 LU-323 Y	
LENTIS COMFORT **MDR- 04654**	LS-313 MF15	

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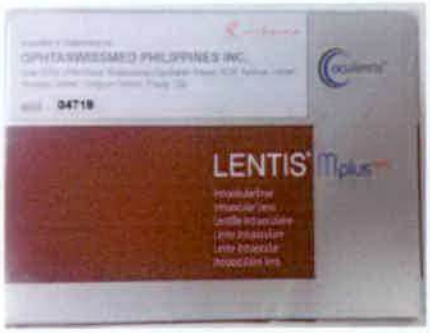
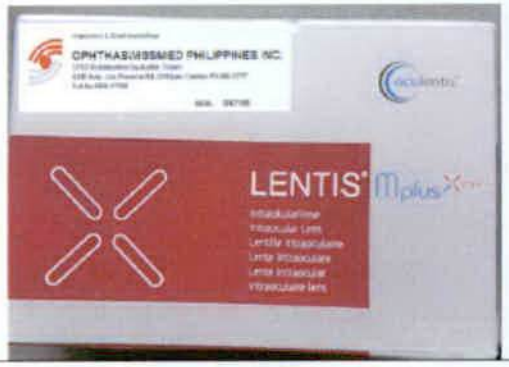
LENTIS T PLUS **MDR- 04647**	LS 313 T1-T6	
LENTIS T PLUS X **MDR- 04707**	LU-313 T LU-313 TY	

LENTIS COMFORT TORIC **MDR- 04708**	LS-313 T1-T6 LS-313 MF 15 T1-T6 LU-814-T LU-323 T LU-323 TY	
LENTIS M PLUS **MDR- 04651**	LS-313 MF20 LS-313 MF20 Y LS-313 MF 30 LS-313 MF 80 LU-814 MF15	

LENTIS M PLUS X **MDR-04653**	LS- 313 MF 30	
LENTIS M PLUS TORIC **MDR- 04719**	LU-313 MF15 T LU-313 MF 15 TY LU- 313 MF 20 T LU-313 MF 20 TY LU-313 MF 30 T LU-313 MF 30 TY LU- 814 MF 30 T	
LENTIS M PLUS X TORIC **MDR- 04706**	LU-313 MF 30 T LU-313 MF20 T	

Ophthaswissmed received a notice of product recall from the Oculentis BV, the manufacturer of the above-mentioned medical device product. Oculentis received notifications of sporadic late postoperative opacification of Lentis IOL's. Opacification may compromise the optical transparency of the IOL's in time, potentially leading to a slow reduction in the patient's visual acuity. Studies made by the manufacturer have indicated that opacification could possibly be the result of phosphate remnants from a phosphate-containing cleaning agent used in the production. Oculentis assured that all currently produced and all Lentis IOL's products on the market with an expiry date of 2020-06 or later are completely unaffected and may be used safely and effectively.

All concerned healthcare professionals and establishments are advised to discontinue further use, sale and distribution of the said affected medical device product.

For more information and inquiries, please email us at cdrrhr_prsdd@fda.gov.ph or call the Product Research and Standards Development Division of the FDA - Center for Device Regulation, Radiation Health and Research at 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
FDA Director General

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