



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



23 OCT 2018

FDA ADVISORY

No. 2018-307

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Voluntary Recall of "Monoclonal Mouse, Anti-Pneumocystis Jiroveci, Clone 3F6 with Product Code M0778"

The Food and Drug Administration (FDA) informs the public and all concerned healthcare professionals that MMJ Biosystem Philippines (MMJ), Inc. has voluntarily recalled the Monoclonal Mouse, Anti-Pneumocystis Jiroveci, Clone 3F6 with product code M0778 with the following lot numbers:

- 20010445
- 20030858
- 20042555



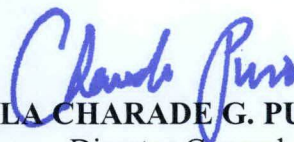
According to MMJ, the primary label of the affected vial was mislabeled with an incorrect concentration. For the product code M0778 the concentration was written to be 30 mg/L when the correct concentration is 75 mg/L.

MMJ further claims that ~2.5-fold higher concentration in the vial will have no consequence on the quality of M0778 and the products are expected to perform as usual.

Lastly MMJ claims that if diluted according to the label, the higher concentration will result in stronger signals than expected and may lead to increased background staining and/or false positive staining. Positive and negative run controls would detect any problems with staining in this case.

In view of the foregoing, distributors, retailers, hospitals and all healthcare professionals / users are advised to discontinue further distribution, sale and use of the said affected medical device product.

For more information and inquiries, please e-mail us at cdrrhr_prsdd@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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