

Distributor/Hospital Facility – International – EU

Sage Products LLC

Date: August 24, 2017

URGENT: FIELD SAFETY NOTICE

Specific Lots of Oral Care Products

RE: FSCA Identifier: 20170824

Type of Action: Field Safety Corrective Action (FSCA)

Dear Distributor Partner/Healthcare Facility,

This Field Safety Notice (FSN) is to inform you of a voluntary worldwide product recall involving specific lots of Oral Care products manufactured by Sage Products (“Sage”). The recalled products were distributed between July 2015 and August 2017. Please refer to the enclosed FSN response form for affected products and their corresponding lot numbers.

This recall is being initiated due to the potential for cross-contamination of oral care solutions manufactured by a third party supplier on equipment shared with non-pharmaceutical products. The recall affects all Oral Care products containing solutions manufactured by the third party supplier.

All relevant National Competent Authorities have been advised of this FSCA.

ACTIONS TO BE TAKEN BY THE DISTRIBUTOR/PARTNER/CUSTOMER:

If you have any of the affected product, please do not use or distribute. Please ensure that this notice will be given to all those who need to be aware of it within your organization, and/or other organizations you may have given this product to.

- Check your inventory for the affected lot numbers. Lot numbers are located on the outside of the product case (over shipper) and package. Discontinue use and/or further distribution of the affected lots. Quarantine all identified lots.
- If you are a distributor, and have distributed this product to facilities or consumers, please initiate your sub-recall process down to the facility or consumer level.
- If you are a healthcare facility or consumer, stop use of the affected lots of product immediately.
- Please complete the enclosed Field Safety Notice (FSN) Acknowledgement Response form and return it to Sage Products no later than September 22, 2017. **This form must be completed even if you no longer have affected product.**
- After the FSN Acknowledgment Response form is received by Sage, you will be contacted regarding how to proceed with the return/destruction of the affected lots.

Please maintain awareness of this Notice and resulting action for an appropriate period of time to ensure effectiveness of the corrective action.

CONTACT INFORMATION:

Contact Sage Customer Service at 1+ 847- 516-7603, Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m., Central Time for credit.

Field Safety Notice (FSN) Acknowledgement Response form must be returned to Sage Products.

Sage Products LLC
Attn: Customer Service Department – OC Recall - International
3909 Three Oaks Road
Cary, IL 60013

By email to oralcarerecall.intl@sageproducts.com or by fax + 1 – 224 - 387-2130.

We regret any inconvenience this action may cause you or your firm. The Sage Products Customer Service team is standing by to assist you immediately.

Sincerely,
Sage Products LLC
Customer Service Department