Lou Dallago
Vice President – US Trade Group

Pfizer Inc
235 East 42nd Street, New York, NY 10017

URGENT: DRUG RECALL

March 07, 2017

Quillivant XR®
methylphenidate HCl
for extended-release oral suspension - CII

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
24478-190-10	03215042A	08/17	300 mg	Carton containing 1 bottle of 300 mg powder (to prepare 60 mL suspension), 1 oral dosing dispenser & 1 bottle adapter
24478-210-30	03216025A	01/18	900 mg	Carton containing 1 bottle of 900 mg powder (to prepare 180 mL suspension), 1 oral dosing dispenser & 1 bottle adapter
24478-205-25	03216026A	02/18	750 mg	Carton containing 1 bottle of 750 mg powder (to prepare 150 mL suspension), 1 oral dosing dispenser & 1 bottle adapter

Dear Customer:

Pfizer Inc is voluntarily recalling the above referenced lots of **Quillivant XR® (methylphenidate HCl) for extended-release oral suspension**. Pfizer initiated this recall because product from lot 03215042A does not meet the specification for dissolution. As a precautionary measure, lots 03216025A and 03216026A are also being recalled because product from these lots may not meet the specification for dissolution throughout shelf life. Please note that use of, or exposure to, product from these lots is not likely to cause adverse health consequences. The potential risk to the patient arising from this issue is considered to be negligible.

FEDERAL REGULATION 21 CFR 7.49 (d) RESPONSIBILITY OF RECIPIENT STATES: "CONSIGNEES THAT RECEIVE A RECALL COMMUNICATION SHOULD IMMEDIATELY CARRY OUT THE INSTRUCTIONS SET FORTH BY THE RECALLING FIRM ..." PFIZER INC RECOMMENDS THAT YOU RESPOND TO THIS RECALL, EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED POSTAGE-PAID, BUSINESS REPLY CARD (BRC) AND RETURN IT TO US, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS. If you have any questions about responding to this letter, please contact Stericycle Inc. at 1-800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

The recall of the above referenced lots of **Quillivant XR® (methylphenidate HCl) for extended-release oral suspension** is being conducted to the **Retail level**.

Our records indicate that you may have received shipment of the affected lots, which were distributed from November 2015 to November 2016. Please check your stock immediately against the table above. If you have any of the affected product in your inventory, please stop distribution and quarantine it immediately. Complete a physical count of your affected inventory and record this data on the BRC that is included with this letter. Return the postage paid BRC to Stericycle Inc. even if you do not have the affected product lots.

Upon receipt of your completed BRC by Stericycle Inc., a Product Return Package, including a DEA Form 222, Packing Slip and pre-paid UPS Return Service shipping label, will be forwarded to you by Stericycle Inc. on behalf of Pfizer Inc. A completed DEA Form 222 is required to process your return. Once you receive the Product Return Package, complete the Packing Slip and enclose the completed Packing Slip and DEA Form 222, along with the product returns, in a return carton. Please attach the pre-paid UPS Return Service shipping label to the outside of the carton and return it to Stericycle Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 7170. If you received this notification without the BRC or have questions regarding the return procedure, please contact Stericycle Inc. at 1-800-805-3093.

If you have further distributed any of these lots to other wholesale or retail level accounts, please forward a copy of this letter along with your sub-recall customer notifications to those accounts immediately. Please request that they immediately cease distribution of the affected product and promptly contact Stericycle at 1-800-805-3093 to obtain a BRC to initiate the return process.

Reimbursement for the returned product will be made by credit memorandum. If you have any questions regarding the reimbursement, please contact your Pfizer Customer Service Representative at 1-800-533-4535 (Mon.-Fri. 8 am-5:30 pm ET).

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience this action may cause you. If you have any medical questions regarding the product, please contact Pfizer Medical Information at 1-800-438-1985 (Mon.-Fri. 8 am-7 pm ET).

Sincerely,

Lou Dallago
Vice President U.S. Trade Group