URGENT: DRUG RECALL EXPANSION

September 20, 2021

UPDATE TO NOTIFICATION DATED AUGUST 17, 2021

Chantix® (varenicline) Tablets, 0.5 mg Tablets
Chantix® (varenicline) Tablets, 1 mg Tablets
Chantix® (varenicline) Tablets, 0.5/1 mg Tablets

Multiple NDCs and Lots Affected
All lots of Chantix Tablets, 0.5 mg bottles, Chantix Tablets, 1 mg bottles, 1 mg blister pack cartons and 0.5/1 mg cartons currently within expiry and on the market. Refer to pages 4 and 5 for additional lots added in red font.

Dear Customer,

Pfizer is voluntarily expanding the August 17, 2021 recall to include **all lots of Chantix Tablets, 0.5 mg bottles, Chantix Tablets, 1 mg bottles, 1 mg blister pack cartons and 0.5/1 mg cartons currently within expiry and on the market.** 138 additional lots are being added to the scope and are listed in the table below in red. The recall is due to the presence of N-nitroso-varenicline at or above the interim FDA Acceptable Daily Intake (ADI) level. This action is being taken out of an abundance of caution as alternative suppliers have been approved in the United States.

Long-term ingestion of N-nitroso-varenicline may be associated with a theoretical potential increased cancer risk in humans, but there is no immediate risk to patients taking this medication. The health benefits of stopping smoking outweigh the theoretical potential cancer risk from the nitrosamine impurity in varenicline. Pfizer believes that the benefit/risk profile of Chantix remains positive. Although a theoretical excess lifetime cancer risk from N-nitroso-varenicline may exist, it is considered to be low based on currently available data. Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines.

To date, Pfizer has not received reports of adverse events assessed to be related to this recall.

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 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 BUSINESS REPLY FORM (BRF) AND RETURN IT BY USING THE ENCLOSED PREPAID ENVELOPE, BY FAX AT 800-807-5314 OR BY EMAIL AT PFIZER6503@STERICYCLE.COM, WITHIN FIVE (5) BUSINESS DAYS. If you have any questions about responding to this letter, please contact Stericycle Inc. at 888-276-6166 (Mon.-Fri. 8:00 am – 5:00 pm ET).

The recall of the below referenced lots of Chantix (varenicline) tablets is being conducted to the **Consumer/User Level**.

Instructions for Wholesalers, Retailers, Hospitals and Health Care Providers:
Our records indicate that you may have received shipment of the Chantix Tablets, which were distributed between May 2019 to September 2021. Please check your stock immediately to identify whether you have Chantix bottles/cartons. If you have any of product in your inventory, please stop distribution and quarantine the product immediately. Promptly return it to Stericycle Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 6503 using the enclosed pre-paid UPS label. All returns are requested to be completed within six months of this notice date. If you received this notification without the prepaid UPS label and Business Reply Form (BRF), require additional shipping labels, or have questions regarding the return procedure, please contact Stericycle Inc. at 888-276-6166 (Mon.-Fri. 8:00 am – 5:00 pm ET).

If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request they immediately cease distribution and quarantine the product. Promptly contact Stericycle at 888-276-6166 (Mon.-Fri. 8:00 am – 5:00 pm ET) to obtain a BRF to initiate the return process.

If the product has been dispensed to patients, please notify these customers regarding this recall.

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 800-533-4535 (Mon.-Fri. 8:00 am - 5:30 pm ET).

If you received free product through the Pfizer Patient Assistance Program (PAP) or the Pfizer Institutional Patient Assistance Program (IPAP), please check your stock immediately. If you have any of the product in your inventory, please follow the instructions above for returning the product to Stericycle Inc. Additionally, if you are aware of any patients to whom you dispensed the product and who still may have the product in their possession, please ask them to return the product to you and

then follow the instructions above for returning the product to Stericycle Inc. For any questions related to Pfizer PAP or Pfizer IPAP product, please contact 833-203-2776 (Mon.-Fri. 8 am-6 pm ET).

Instructions for Patients:
Patients who are taking this product should consult with their health care provider about alternative treatment options. Patients with the product should contact Stericycle Inc. at 888-276-6166, [(Mon.-Fri. 8:00 am – 5:00 pm ET) for instructions on how to return their product and obtain reimbursement for their cost.

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 questions regarding this recall, please call the appropriate contact center below.

Contact Center	Contact Information	Area of Support
Pfizer Medical Information	800-438-1985, option 3 (Mon.-Fri. 9 am-5 pm ET) www.pfizermedinfo.com	For medical questions regarding the product
Pfizer Drug Safety	800-438-1985, option 1 (24 hours a day; 7 days a	To report adverse events and product complaints
Stericycle, Inc.	888-276-6166 (Mon.-Fri. 8 am-5 pm ET)	For product returns and reimbursement questions

Adverse events or quality complaints experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: **www.fda.gov/medwatch/report.htm**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Sincerely,

Lou Dallago
Vice President
US Trade Group

Recalled Product List

PRODUCT: Chantix Tablets, 0.5 mg
NDC: 0069-0468-56
SIZE: Bottle of 56 Tablets
EXPIRATION DATE: January 2022 - May 2023
LOT NUMERS:

00019213	DM9007	EC6994	EN8362
CY6861	DM9008	EN5725	EN8467

PRODUCT: Chantix Tablets, 1 mg
NDC: 0069-0469-56
SIZE: Bottle of 56 Tablets
EXPIRATION DATE: September 2021 – December 2023
LOT NUMBERS:

00018777	00021024	CW1572	DF5280	DY7987	EN5694
00019289	00021073	CW1573	DF5281	EA6080	EN5695
00019593	00021074	CW1574	DF5282	EC9841	EP1717
00019682	CW1565	CW1575	DR5086	EC9842	EP1718
00019846	CW1566	CW1578	DR5092	EC9843	EP1719
00019977	CW1567	CW1579	DR5093	EC9847	EW2012
00020295	CW1568	CW1581	DR5094	EC9848	EW3854
00020448	CW1569	DF5277	DT3885	EE1011	EW3865
00020458	CW1570	DF5278	DW4148	EM1069	EX2102
00020480	CW1571	DF5279	DW4152	EM1070	EX2103

Continued on the Next Page

Recalled Product List (Continued)

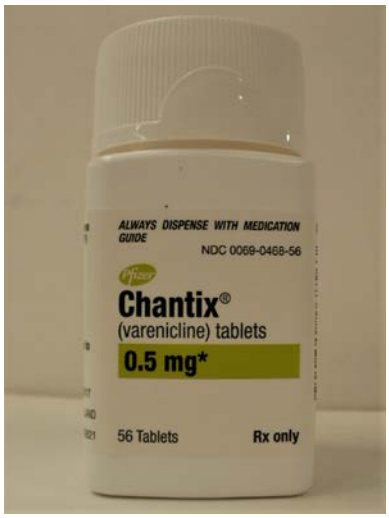
PRODUCT: Chantix Tablets, 1 mg
NDC: 0069-0469-03
SIZE: Carton containing 4 blister packs of 14 tablets each
EXPIRATION DATE: September 2021 – June 2023
LOT NUMBERS:

00019431	00021421	00022765	DR2614	DY7060	EE9391
00019542	00021422	00022766	DX4576	DY9367	EF2346
00019543	00021423	00023134	DX5870	DY9473	EM4805
00019544	00022136	00023135	DX5871	DY9475	EM4807
00020814	00022174	00023747	DX5872	DY9476	EN2005
00020815	00022175	00023748	DX5873	DY9505	ET1601
00020907	00022176	DL3896	DX7805	EC5910	ET1605
00020965	00022177	DL7779	DY6078	EC5913	ET1606

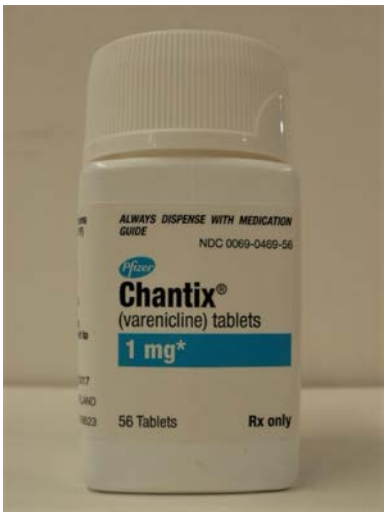
PRODUCT: Chantix Tablets, 0.5/1 mg
NDC: 0069-0471-03
SIZE: Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
EXPIRATION DATE: August 2021 – January 2023
LOT NUMBERS:

00018522	00020358	00021688	00022851	DM0277	ET1607
00018523	00020716	00021788	00023136	DY4470	ET1609
00018739	00020813	00021789	00023137	EC5911	ET1611
00018740	00021288	00021790	00023190	EC5912	
00020231	00021289	00021791	00023448	ED6814	
00020232	00021420	00021792	DM0275	ET1600	
00020357	00021687	00022819	DM0276	ET1603	

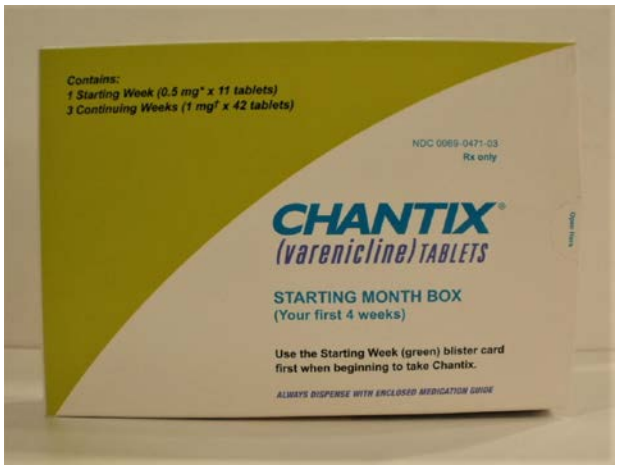
Chantix (varenicline) Tablets, 0.5 mg Tablets



Chantix (varenicline) Tablets, 1 mg Tablets



Chantix (varenicline) Tablets, 0.5/1 mg Tablets



Chantix (varenicline) Tablets, 1 mg Tablets