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FDA Warns CanaRx Services About Its Illegal Internet Website and Mail Operation Obtaining Unapproved and Potentially Risky Drugs from Canada

The [Food and Drug Administration](#) (FDA) today issued a warning [letter](#) to CanaRx Services, Inc., of

Detroit, Mich., notifying the firm that the agency considers its operations to be illegal and a risk to public health. FDA's warning letter states that

CanaRx runs an Internet website and mail operation that illegally causes the shipment of prescription drugs from a Canadian pharmacy into the U.S., subjecting Americans to risky imported drug products and making misleading assurances to consumers about the safety of its drugs.

"Firms like this should not continue to profit through illegal actions that put the health of the American public at risk," said Mark B. McClellan, M.D., Commissioner of Food and Drugs. "Our investigation has shown that CanaRx operates a drug purchasing arrangement that channels drugs through companies other than licensed pharmacies and does not consistently use shipping practices that ensure its drugs are safe and effective."

FDA has long been concerned that medications purchased by U.S. consumers from foreign, unregulated drug outlets pose a growing potential danger. CanaRx Services and similar companies often state incorrectly to consumers that their prescriptions are "FDA approved" or use similar language, which could lead consumers to conclude mistakenly that the prescription drugs sold by the companies have the same assurance of safety and effectiveness as drugs actually regulated by the FDA.

For example, FDA has evidence demonstrating that CanaRx shipped insulin, a product that should be stored under refrigerated conditions, in a manner that did not ensure adherence with the storage conditions specified in FDA approved labeling - potentially compromising the safety and effectiveness of the insulin.

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State pharmacy boards are responsible for determining whether pharmacies operating within the state are doing so in compliance with state law. In the U.S., state law requires proper licensing for a pharmacy to sell prescription drugs. In this case, it appears that CanaRx is not a licensed Canadian pharmacy subject to regulatory oversight, and so may place patients at additional risk.

Because the medications obtained and shipped by operations such as CanaRx are not subject to

FDA's safety oversight, they could be outdated, contaminated, counterfeit or contain too much or too little of the active ingredient. In this case, these risks are heightened by the fact that many of the products CanaRx sells to U.S. consumers are indicated for serious medical conditions

In addition, foreign dispensers of drugs to American citizens may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications or medications without proper directions for use.

FDA is working closely with its partners in the individual states in support of their efforts to curtail illegal and potentially dangerous operations, especially when they involve misleading claims about drug safety.

The National Association of Boards of Pharmacy, which is urging FDA to assist in acting against these schemes has stated, "Allowing unlicensed practitioners to dispense non-FDA approved medicines without regard for patient health and safety sets a dangerous precedent that puts Americans at risk."

Although many legitimate Internet pharmacies provide safe and possibly more convenient access to prescription services, foreign Internet pharmacies selling to the U.S. operate outside the law. FDA provides guidance to consumers on buying prescription drugs safely over the Internet at <http://www.fda.gov/oc/buyonline>.

Despite continued efforts to identify ways to assure the safety of purchased from foreign sources, the FDA for many years has stated that it cannot assure the safety of prescription drugs that are obtained outside its comprehensive regulatory system.

CanaRx has fifteen working days to respond to FDA's warning letter. FDA will take appropriate action, including collaborative actions with individual states and foreign governments, to stop similar illegal activities by this or other similar firms.

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Warning Letters:

<http://www.fda.gov/cder/warn/2003/RHoward.pdf>
<http://www.fda.gov/cder/warn/2003/Todd.pdf>
<http://www.fda.gov/cder/warn/2003/GAHoward.pdf>

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