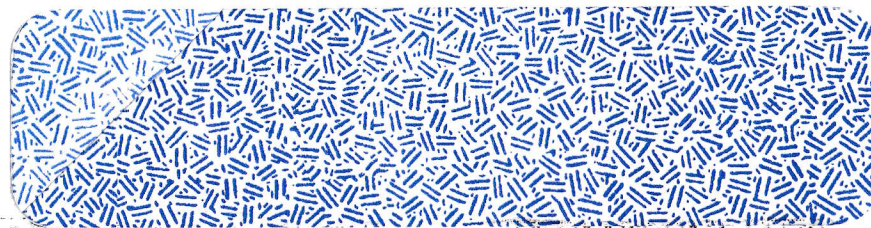
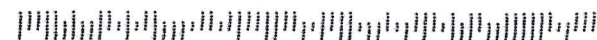


U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993



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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

Ms. Heidi Sanborn
Executive Director
National Stewardship Action Council
1822 21st Street, Suite 200
Sacramento, CA 95811

042816

Dear Ms. Sanborn:

Thank you for your letter of January 22, 2016 to Dr. Stephen Ostroff, Acting Commissioner of Food and Drugs, and your letter of April 19, 2016 to Dr. Robert Califf, Commissioner of Food and Drugs, regarding safe disposal of unused drugs. Your letter was forwarded to me for response.

As reflected in the language on our website¹, we agree with the majority of your suggested messaging on safe medicine disposal. For example, the U.S. Food and Drug Administration (FDA or the Agency) is very supportive of medicine take-back programs which are a good way to safely dispose of unneeded medicines. However, FDA continues to recommend that, when other recommended disposal options are not available, a small number of medicines that can be particularly harmful or even fatal with just one dose be flushed down the sink or toilet as soon as they are no longer needed.

FDA supports the proper disposal of unused or unwanted prescription drugs through drug take-back programs and continues to include this as the first recommendation in our information to the public. We note that the 2010 enactment of the Secure and Responsible Drug Disposal Act helped ensure that controlled substances could also be returned through local medicine take-back programs. Neighborhood pharmacies and other local authorities have the option of setting up disposal locations, and may also administer mail-back programs. We are encouraged by recent reports indicating nation-wide chain pharmacies are establishing take-back programs as a result of this legislation.

FDA has strongly supported work to expand the availability of take-back programs for several years, including providing take-back locations on its campus during National Drug Take-Back Days sponsored by the U.S. Drug Enforcement Agency. FDA continues to work with manufacturers to develop new formulations with reduced risk for accidental harm and with its federal partners to develop alternative, safe disposal systems. We look forward to a time when effective disposal alternatives are more widely available.

However, FDA also recognizes that there may be situations whereby consumers may not be able to access a take-back program, perhaps due to a lack of program availability or lack of transportation to a take-back location. These alternative disposal options include disposal in the

¹<http://www.fda.gov/drugssafedisposal>

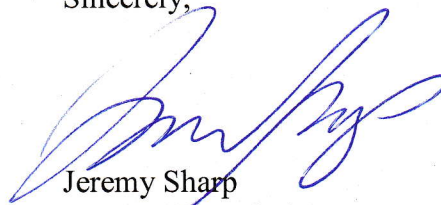
household trash and, for a small number of drug products, flushing down the sink or toilet as soon as they are no longer needed.

FDA is aware of public concerns regarding the potential environmental impact of flushing medicines and we are working with other agencies, including the U.S. Environmental Protection Agency (EPA) to better understand the human health and ecological risks from medicines in our water. We agree with the goal of reducing overall medicine levels in our water. However, available data indicate that the vast majority of drug product residues in water is a consequence of patient drug use and enters the environment through normal excretion and elimination. Considering the available data, we believe that the known risk of severe, even fatal, harm to humans from accidental exposure to a small number of drug products far outweighs the undetermined risks to the environment from flushing them. Again, please note that this recommendation is secondary to the preferred method of disposal for these drugs via a drug take-back program when available.

FDA will continue to evaluate its disposal website to ensure that our messages are clear, including the preferred use of drug take-back programs, and will continue to work with other federal authorities and stakeholders to protect the public health.

Thank you again for contacting FDA concerning this matter. Please let us know if you have any further questions.

Sincerely,



Jeremy Sharp
Deputy Commissioner
Policy, Planning, Legislation & Analysis
