

Medication Disposal to Improve Public Safety

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Introduction

- FDA welcomes the Secure and Responsible Drug Disposal Act as enabling legislation that opens up new possibilities to help prevent prescription drug abuse, misuse, and accidental poisonings
- FDA recognizes the challenge of developing implementing regulations that find the right balance – and offer our full support



Topics

- FDA roles regarding medication disposal
 - Public educational efforts
 - Patient disposal directions in prescription product labeling
- FDA concerns and issues to consider in developing parameters for take-back programs for disposal



Medication Disposal

- FDA Public Education Efforts
 - Goal is to educate consumers about the risks of leaving certain unused medicines in the home
 - Provide information to consumers on how to dispose of certain unused medicines.
 - Explain the agency's recommendations for medicine disposal



FDA Consumer Information Drug Disposal Website





Proper Disposal of Prescription Drugs

of National Drug Control Policy October 20

Federal Guidelines:

- Do not flush prescription drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so. For information on drugs that should be flushed visit the <u>FDA's website</u>.
- To dispose of prescription drugs not labeled to be flushed, you may be able to take advantage of community drug take-back programs or other programs, such as household hazardous waste collection events, that collect drugs at a central location for proper disposal. Call your city or county government's household trash and recycling service and ask if a drug take-back program is available in your

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FDA Disposal Instructions in Prescription Product Labeling

- Disposal directions are recommendations-not a regulatory requirement
- Disposal directions not routinely included for most products
- Included with certain medicines to improve medicines safety profile
 - Package insert, Practitioner to Patient, Med Guides



U.S. Food and Drug Administration Protecting and Promoting Public Health

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Prescription opiates and kids: One pill can kill

Glut of drugs fuels reports of poisonings among very young children

By Jo Nel Aleccia

Health writer msnbc.com wpdated 7:33 a.m. ET, Mon., Oct. 20, 2008



FDA Recommended Disposal

- Federal Disposal Guidelines and FDA recommend that consumers do not flush most unused and expired medicines.
- FDA recommends to flush only certain higher risk medicines, as an interim measure, until better options of disposing these medicines are legal and available
 - Includes, take-backs, mail-backs, impenetrable drug containers, others



Secure and Responsible Drug Disposal Act – Concerns

- Security of drug collections for disposal
 - Secure the drug supply chain from resale and reuse
 - Ensure that medicines intended for disposal are destroyed
 - Prescription Drug Marketing Act prohibition on drug samples in retail pharmacies
 - Security requirements apply to all prescription drugs



Secure and Responsible Drug Disposal Act - Considerations

- Segregation of controlled medicines and non-controlled medicines
 - Difficult to accurately identify medicines
 - Consumers may be unreliable for this task
 - Security concerns are similar between controlled and non-controlled medicines



Secure and Responsible Drug Disposal Act - Considerations

- Extent of availability and access to take back program for disposal
 - Affects ability to take timely action for safety
 - Important consideration when medicine disposal used as a risk mitigation strategy for medicines



Secure and Responsible Drug Disposal Act - Considerations

- FDA promotes the development of safer and more effective disposal methods and systems
 - Flexibility allows for new innovative methods
 - Encourage drug sponsors to develop new disposal systems to mitigate risks, improve medicine safety



Summary

- FDA strongly supports DEA developing procedures to allow individuals to dispose of expired, unused, and unneeded prescription medicines through takeback programs.
- These procedures will empower and encourage citizen's to take timely, safe, and environmentally responsible action to make their homes and communities safer.
- Effective security provisions that assure the ultimate destruction of all returned medicines are critical to protect the public.