January 22, 2016

Dr. Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: FDA Recommendations to Flush Certain Medications and Harmonize Federal Agency Messaging on Safe Medicine Disposal

Dear Commissioner Ostroff:

To protect public health and environmental quality, the signatories to this letter urge the FDA to work with the EPA, the DEA, and the White House Office of National Drug Control Policy to develop clear and consistent guidance to consumers on safe disposal of leftover household medications. **We call on the FDA to end its recommendation that certain medications be disposed by flushing, and to clarify that secure medicine take-back programs provide the best disposal method for leftover household medications.**

We appreciate the FDA’s efforts to protect people from leftover medications that can be particularly harmful, even fatal, if abused or mistakenly consumed. However, the time has come for FDA to align its medicine disposal guidance with that of federal, state and local agencies who seek to protect both the public’s health and our water quality.

Disposal of leftover medications by flushing contributes to pharmaceutical pollution that is harming aquatic ecosystems and entering our food web. Wastewater treatment plants are designed to remove human waste and easily degraded organics, and cannot effectively remove pharmaceuticals and other complex, synthetic chemicals. Because of this, some wastewater agencies have established laws, regulations, or guidance prohibiting flushing as a disposal method for pharmaceuticals. In these areas, FDA’s recommendations infringe on wastewater districts’ jurisdictional authority to protect public health.

While pharmaceuticals also enter wastewater through excretion, flushing of unwanted medication is a source that we have the ability and technology to control. The amount of leftover and expired medications in American homes is significant – estimated at 30-40% of all medications sold. It is critical to keep these pharmaceuticals from polluting our waterways by recommending secure and environmentally sound disposal through medicine take-back programs. Preventing pollution is always the most effective and least expensive option to protect public health and environmental health.

Many communities across the country now have medicine collection programs and the DEA’s regulation to implement the Secure & Responsible Drug Disposal Act allows new options for take-back of prescription drugs that are controlled substances. We need clear and harmonized direction to the public and health practitioners on using medicine take-back programs, as well as ongoing efforts to increase access to secure medicine take-back programs in all communities.

Messages on medicine disposal are inconsistent between federal agencies and often in conflict with state and local regulations or guidance against flushing or trash disposal of leftover medications. This is confusing and frustrating for the public. Furthermore, some in the pharmaceutical industry take advantage of inconsistencies in federal agency messaging to undermine efforts to establish local medicine take-back programs and regulations.
We therefore urge the FDA to end its “flush list” recommendation, and work to create a single disposal guidance that is endorsed by all federal agencies and consistently used on all federal websites and materials. The public should be directed to store medications securely in locked containers or cupboards, to use secure medicine take-back programs where available, never to flush medications, and to dispose of medications in the trash only as a last resort where allowed by local ordinances. We encourage adoption of the following, clear messages on safe medicine disposal:

1. To protect water quality, never flush unwanted medicine down any drain.
2. Use a community medicine take-back program for secure and safe medicine disposal. Check with local household hazardous waste, wastewater, or police departments for locations. Use the medicine manufacturer’s mail-back program if available.
3. Take leftover medicines to the Drug Enforcement Administration’s twice a year National Prescription Drug Take-back Days. Look for a site in your community at http://www.deadiversion.usdoj.gov/drug_disposal/takeback/ or contact your police department.
4. As a last resort, if there are no medicine take-back options in your community: put medicines in a sealed container in the trash after mixing the medicines with an undesirable substance, such as cat litter or used coffee grounds. Make sure the trash cannot be accessed by children, pets, or others who might be looking in garbage. Check with your local government or garbage service first, because local laws may not allow disposing of any pharmaceuticals in the trash.

We look forward to your response to our letter and to your actions to address our concerns.

Sincerely,

Individual signers, affiliation stated for purposes of identification only.

Barbara J. Bickford, Madison, Wisconsin
Nancy Busen, Bentonville, Arkansas
Jennifer Caldwell, CalRecycle
Audrey L. Comeaux, Director- West County Wastewater District
Gary Goldbaum, Health Officer, Snohomish County, Washington
Sarah Hellekson, Solid Waste Manager, City of Plymouth, Minnesota
Veora M. Little, Certified Registered Nurse Anesthetist, Napes, Florida
Heidi Mayer, Marin, California
Chris McFaul, Spokane, Washington
Nate Miley, Oakland, California
Karin North, City of Palo Alto, Watershed Protection Manager,
Carol Scienza, City of Winters, Environmental Services Manager
Ruth W. Shearer, Ph.D., Retired Toxicologist
Margaret Shield, Ph.D., Seattle, Washington
MaryAnne Sullivan, Aging in Place Facilitator, Sibert & Sullivan, LLC
Susan Strand, Environmental Specialist, City of West Sacramento
Mark Nystrom, Energy, Environment and Land Use Policy Manager for the Association of Oregon Counties
Angela Goldberg, Member of the San Diego Drug Abuse Task Force
Carol Bailey, Concerned Consumer and Member of California Alliance for Retired Americans
Cc: Administrator Gina McCarthy, U.S. Environmental Protection Agency
    Director Dan Ashe, U.S. Fish & Wildlife Service
    Acting Administrator Chuck Rosenberg, Drug Enforcement Administration
    Director Michael Botticelli, White House Office of National Drug Control Policy
Patricia Danielson, Vice-President
Alameda County Special District Association

Nate Miley
Alameda County Supervisor
District 4

Gail Magsaysay MSN, RN, Owner
Alternatives in Wellness

Steve Via
American Water Works Association

John F. Birrer, President/CEO
Asepsis Bio Group, Inc.

Diane VanDe Hei, Executive Director
Association of Metropolitan Water Agencies

Jim Taft, Executive Director
Association of State Drinking Water Administrators

Sherry Hull, Assistant Executive Director
Bay Area Clean Water Agencies

Bobbi Larson, Executive Director
California Association of Sanitation Agencies

Heidi Sanborn, MPA, Executive Director
California Product Stewardship Council

John H. Dane, Executive Director
California Resource Recovery Association

Executive Board
California Water Environment Association

California State Assemblymember David Chiu
California State Senator Hannah-Beth Jackson  
Melody LaBella, Pollution Prevention Program Coordinator  
Central Contra Costa Sanitary District

Robert Cole, Environmental Services Manager  
Central Marin Sanitation Agency

Comm. Mike Robinson, Chair  
Chisago County Minnesota Board of Commissioners

Robbin Finch, Water Quality Environmental Program Manager  
City of Boise Public Works

Craig M. Locke, Director of Public Works  
City of Chowchilla, California

Brian R. Stahl, Deputy Director, Department of Environmental Services  
City of Gresham, Oregon

Frankie Riddle, Director of Special Programs  
City of Palm Desert

Phil Bobel, Assistant Director Public Works  
City of Palo Alto Regional Water Quality Control Plant

Paulina Benner, Environmental Services Manager  
City of West Sacramento
Greg Meyer, Public Works Director
City of Woodland

Greg Geist, Director
Clackamas County Water Environment Services

Andria Ventura, Toxics Program Manager
Clean Water Action

Curt McCormick, Owner
Clean Water Act Consulting Services

Della Lisi Kerr, Alcohol Drug Education & Prevention Team
County of Orange Health Care Agency

Beverly Hanstrom, President
Colorado Medical Waste, Inc.

Larry Krolikowski, Volunteer Organizer
Common Ground of Southeastern Wisconsin Watershed Team

Delta Diablo Sanitation District
Gary W. Darling, General Manager

Carly Gibb, Development Assistant
Drug Free Collier

John Archer, Interim General Manager
Dublin San Ramon Services District
Food & Drug Administration
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Jacqueline T. Zipkin, Manager of Environmental Services
East Bay Municipal Utility District

Colin Bailey, Executive Director
The Environmental Justice Coalition for Water

Violette Brown, President
FillAbox Corporation

David Stitzhal, MRP, President
Full Circle Environmental, Inc.

Daniel Parshley, Project Manager
Glynn Environmental Coalition

Stuart Moody, Board President
Green Sangha

Rachel Gibson, Director, Safer Chemicals
Health Care Without Harm

John Mohoff, General Manager
Healthwise Services

Sherrie Rubin, Founder/Director
Hope2gether Foundation

Rodney Larson, Founding Dean
Husson University School of Pharmacy
Sharon Ehrhardt, Solid Waste/Clean Sweep Specialist
Jefferson County Solid Waste/Air Quality Committee

Mike Mohajer, Representative
Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force

Amy Ziff, Founder & Executive Director
MADE SAFE & NONTOXIC CERTIFIED

Aglia Panos Pharm D, President
Marin County Pharmacists Association

Patty Garbarino, President
Marin Sanitary Service

Paul Sanftner
MEDS Coalition, Alameda County

David W. Pedersen, P.E., General Manager / Administering Agent
Las Virgenes – Triunfo Joint Powers Authority

David St. Pierre, Executive Director
Metropolitan Water Reclamation District of Greater Chicago

Paul Koretz, Los Angeles City Councilmember
Kerrin O’Brien, Executive Director
Michigan Recycling Coalition

Doug Kobold, President
National Stewardship Action Council

Jennifer Volkman, Household Hazardous Waste Program Coordinator, MPCA
Minnesota Pollution Control Agency

Tiffany C Ingram, JD, Midwest Advocacy Director
Natural Resources Defense Council

Timothy Healy, General Manager
Napa Sanitation District

Kristen Anderson, Project Coordinator
Nebraska MEDS Coalition

Adam Krantz, Chief Executive Officer
National Association of Clean Water Agencies

Victoria Hodge, President
North American Hazardous Materials Management Association

April Rovero, Executive Director
National Coalition Against Prescription Drug Abuse

Janet Gillaspie, Executive Director
Oregon Association of Clean Water Agencies
Marti Martz, Senior Coastal Outreach Specialist
Pennsylvania Sea Grant

Frederick S. Mayer, R.Ph., MPH, CEO
Pharmacists Planning Service, Inc. (PPSI)

Thomas P. Jacobus, Chairman
Potomac River Basin Drinking Water Source Protection Partnership - Metro Area Water Utility Committee

Greg Knell, Community Co-Chair Community Based Prevention
RxSafe Marin

Terrie Mitchell, Manager, Legislative & Regulatory Affairs
Sacramento Regional County Sanitation District

Victoria O. Conway, Head Wastewater Management
Sanitation Districts of Los Angeles County

Katherine O’Dea, Executive Director
Save Our Shores

Leslie Tamminen, Ocean Program Director
Seventh Generation Advisors

Deborah Raphael, Director
San Francisco Department of the Environment
Cynthia Stark-Wickman, Executive Coordinator
San Juan Island Prevention Coalition

Stiv J. Wilson, Campaigns Director
The Story of Stuff Project

Angela T. Howe, Esq. | Legal Director
Surfrider Foundation, Representing 84 domestic chapters

Tina Segura, Chair
Surfrider Foundation West LA/Malibu Chapter

Debbie Branch, Chair
Texas Product Stewardship Council

Doug Dattawalker, Environmental Outreach Representative
Union Sanitary District

Dan Tafolla, Director of Environmental Services
Vallejo Sanitation & Flood Control District

Melissa Meeker, Executive Director
WateReuse

Angie Rosser, Executive Director
West Virginia Rivers Coalition

Nancy A. Eggleston, R.S.
Environmental Health and Communicable Disease Supervisor
Wood County Health Department
Food & Drug Administration
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Steve Devine, Program Manager
Zero Waste Marin