

**DEPARTMENT OF HEALTH & HUMAN SERVICES**Food and Drug Administration
Rockville MD 20857

January 4, 2007

Stevan E. Gressitt, M.D.
Acting Secretary
Maine Unused Drug Disposal Group
314 Clark Road
Unity, Maine 04988

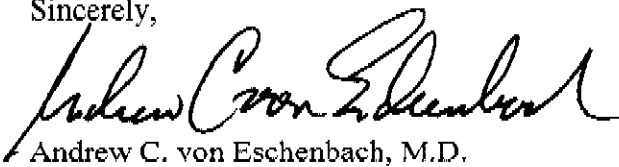
Dear Dr. Gressitt:

Thank you for your letter of November 22 regarding a proposal for a National Unused Drug Disposal Program.

The Food and Drug Administration (FDA) recognizes that safe disposal by the consumer of unused and unneeded drug products are important for public safety. The agency supports efforts to increase drug use safety by encouraging patients to dispose of unused and unneeded controlled drug products, therefore making them unavailable to unintended persons and pets. In fact, FDA-approved labeling for certain higher-risk prescription-only products containing controlled substances, such as Oxycontin (oxycodone), Fentanyl patches, Fentora (Fentanyl buccal tablet), Actiq (Fentanyl citrate), Percodan (hydrocodone), and Xyrem (GHB) include directions that instruct patients to flush unused drug, as part of a more comprehensive risk management plan. Additionally, FDA is currently working with national healthcare professional organizations as well as other Federal agencies on educational efforts promoting safe disposal of unused medications.

FDA supports efforts to initiate pilot programs with measurable outcomes that are useful to the Federal, state, and local efforts to help patients make informed decisions about best ways for them to dispose of unused medicines in a safe and environmentally responsible manner. However, FDA has not evaluated the patient safety consequences of any disposal methods other than flushing unused drugs, such as take-back programs, but encourages the development and testing of alternative disposal mechanisms that are environmentally sound and can be shown to increase patient safety.

Thank you again for taking the time to express your views on this issue. A similar letter is being sent to Dr. Lenard W. Kaye.

Sincerely,

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs