

2008 Summit: Pharmaceuticals in Water

What We Know, Don't Know, and Should Do

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Pharmaceuticals in Water Regulatory Landscape FDA Perspective

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ABSTRACT

The Food and Drug Administration (FDA) is the primary Federal agency responsible for the regulation of pharmaceuticals and personal care products in the United States. The FDA Center for Drug Evaluation and Research (CDER) regulates the safety and efficacy of pharmaceuticals for human use. Drug companies must submit extensive pre-clinical and human clinical data to CDER regarding the safety and efficacy of a drug product. In addition, the FDA is required under provisions of the National Environmental Policy Act (NEPA) to consider the environmental impacts of approving drug and biologics applications as an integral part of its regulatory process. FDA's regulations at 21 CFR part 25 specify that environmental assessments (EAs) must be submitted as part of certain new drug applications (NDAs), and for various other actions. CDER environmental activities also extend to working closely with sister agencies on the development of Federal guidelines for drug disposal, an interagency research strategy to define and prioritize research and data needs, and towards gaining a better understanding of the potential ecological and human health effects of pharmaceutical residues in the environment as a consequence of drug use and disposal.

KEYWORDS

pharmaceuticals, drugs, environmental assessments, NEPA, FDA, CDER