

US EPA ARCHIVE DOCUMENT

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6863-5]

Regulatory Reinvention (XL) Pilot Projects

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Availability of the Draft Project XL Final Project Agreement: Ortho-McNeil Pharmaceutical – Laboratory-Scale High-Temperature Catalytic Oxidation Process to Treat Low-Level Mixed Wastes

SUMMARY: The Environmental Protection Agency (EPA) is requesting comments on a Draft Project XL Final Project Agreement (FPA) for the Ortho-McNeil Pharmaceutical, Inc. (hereafter “OMP”) pharmaceutical research and development facility in Spring House, PA. The FPA is a voluntary agreement developed collaboratively by OMP, the Pennsylvania Department of Environmental Protection (PADEP), EPA and interested stakeholders. Project XL, announced in the Federal Register on May 23, 1995 (60 FR 27282), gives regulated entities the opportunity to develop alternative strategies that will replace or modify specific regulatory or procedural requirements on the condition that they produce greater environmental benefits.

As presented in the draft FPA, OMP proposes to determine whether dual regulatory oversight (i.e., EPA’s Resource Conservation and Recovery Act (RCRA) oversight and the Nuclear Regulatory Commission’s (NRC’s) Atomic Energy Act (AEA) oversight) is necessary to ensure protection of human health and the environment concerning the small volumes of low-level mixed wastes (i.e., wastes that meet both the definition of a RCRA hazardous waste and the AEA definition of low-level radioactive waste) that are treated using a bench-scale high temperature catalytic oxidation process in the laboratory where they are generated. Specifically, OMP is

seeking a waiver of all applicable RCRA requirements for the original mixed waste, as well as for the treatment residuals resulting from the catalytic oxidation of the original mixed waste. The original mixed waste and the treatment residuals will continue to be subject to NRC oversight as low-level radioactive wastes.

OMP generates small volumes of mixed wastes (typically less than 50 liters/year) as a result of radiolabeling undertaken to conduct research on a drug's bioabsorption and metabolism in the body. The low-level mixed wastes that are the focus of this XL project are comprised of an organic component (typically a solvent) and a radioactive component (typically tritium or carbon-14, depending on the drug being studied). Data gathered during a treatability study conducted by OMP since 1996 indicate that the high-temperature catalytic oxidation process effectively destroys the organic portion of the mixed waste, resulting in a low-level radioactive residual. When the sample uses tritium as the radioisotope tracer, tritiated water results from the treatment process. When the sample uses carbon-14 as the radioisotope tracer, the residual is a low-level radioactive carbon dioxide which is then converted to low-level radioactive potassium carbonate solution.

To implement this XL project, EPA and PADEP have agreed to provide the regulatory flexibility OMP seeks subject to applicable regulatory procedures. Specifically, in the near future, EPA will propose in a separate **Federal Register** notice a site-specific conditional exclusion from the definition of hazardous waste in 40 CFR 261.4(b) for the small volumes of mixed waste being generated by OMP. PADEP has also agreed to adopt the appropriate legal implementing mechanism to allow for the XL project to proceed.

DATES: The period for submission of comments on the draft FPA ends on [INSERT DATE TWO WEEKS FROM PUBLICATION].

ADDRESSES: All comments on the draft Final Project Agreement should be sent to: Charles Howland, U.S. EPA Region III (3OR00), 1650 Arch Street, Philadelphia, PA 19103-2029. Comments may also be faxed to Mr. Howland at (215) 814-2783. Comments may also be received via electronic mail sent to: howland.charles@epa.gov.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the draft Final Project Agreement, contact: Charles Howland, U.S. EPA Region III (3OR00), 1650 Arch Street, Philadelphia, PA 19103-2029, or Mitch Kidwell, U.S. EPA (1802), 1200 Pennsylvania Ave., NW, Washington, DC 20460. The FPA and related documents are also available via the Internet at the following location: <http://www.epa.gov/ProjectXL>. Questions to EPA regarding the documents can be directed to Charles Howland at (215) 814-2645 or Mitch Kidwell at (202) 260-2515. For information on all other aspects of the XL Program, contact Christopher Knopes at the following address: Office of Policy, Economics and Innovation (1802), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460. Additional information on Project XL, including documents referenced in this notice, other EPA policy documents related to Project XL, regional XL contacts, application information, and descriptions of existing XL projects and proposals, is available via the Internet at <http://www.epa.gov/projectxl>.

Date: August 28, 2000. _____

Signature: _____

Elizabeth A. Shaw

Director

Office of Environmental Policy Innovation