



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103

December 28, 1999

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2/9/2000*

Michael Esposito
Acting Manager of Environmental Engineering
Ortho-McNeil Pharmaceutical, Inc.
Welsh & McKean Rds
Spring House, PA 19477-0000

Re: EPA Acceptance of Ortho-McNeil Pharmaceutical Project XL Proposal (On-Site Treatment of Low-Level Mixed Wastes) for Final Project Agreement Negotiation

Dear Mr. Esposito:

EPA is pleased to inform you that the U. S. Environmental Protection Agency ("EPA") has selected Ortho-McNeil Pharmaceutical's ("OMP's") XL proposal as a potential Project XL pilot. EPA congratulates you on your selection and thanks you and the rest of the OMP staff for your hard work on getting the proposal approved.

EPA invites you now to work with EPA staff, members of the Pennsylvania Department of Environmental Protection ("PADEP"), and appropriate stakeholders on the next stage of your XL project - developing a draft Final Project Agreement ("FPA"). While this letter does not represent final EPA approval of the project, Agency staff both at headquarters and at Region III believe your proposal has significant merit and look forward to working with you to develop your project further.

Your proposal requested relief from certain RCRA permitting requirements for an on-site bench scale catalytic oxidation unit that treats relatively small quantities of low-level mixed wastes (i.e., a waste that includes both radioactive material and RCRA hazardous waste). EPA understands that in treatability studies conducted in compliance with the RCRA regulations, the catalytic oxidation process demonstrated greater than 99.999% efficiency in the destruction of the organic component and yielded a low-level radioactive waste stream that can be solidified and landfilled at an NRC-licensed low-level waste facility.

EPA's interest in your proposal stems from its conclusion that this XL proposal has the potential to result in superior environmental performance in several respects. First, it appears that OMP's continued deployment of its catalytic oxidation process will make it easier to create a uniform low level radioactive waste stream whose radioactivity would be amenable to recycling

and reuse. Second, under this proposed project OMP would be allowed to continue operating its catalytic oxidation device, instead of having to send the LLMW to an off-site commercial treatment facility. This would enable OMP to fully contain the radioactive component of the mixed wastes generated at the Spring House facility and facilitate recovery of radioactivity. Although the amount of radioactivity involved is relatively small, a net environmental benefit would result, since full containment and recovery of the radioactive materials is generally not achieved at off-site treatment facilities.

To fulfill all the stakeholders' goals, EPA anticipates discussing with OMP the following items during FPA negotiations:

1. Regulatory Flexibility

OMP proposes that EPA provide it a conditional exemption from the RCRA regulations that would otherwise require it to obtain a RCRA permit to operate its catalytic oxidation unit. OMP also desires that the residues from its catalytic oxidation unit be "delisted" such that the "derived-from" rule would no longer apply to the residues.

EPA staff has identified several possible approaches to achieve the regulatory flexibility OMP is seeking, including a conditional exemption or exclusion from the definition of solid waste or hazardous waste for the mixed wastes. EPA anticipates that both the FPA and the implementing legal mechanism will contain certain conditions, including volumetric limits on the amount of low level mixed waste which may be treated each year, and limiting the regulatory relief to wastes generated at OMP's Spring House facility. EPA looks forward to working with OMP to develop the most appropriate approach to providing the regulatory flexibility OMP is seeking as part of the FPA. As you know, the regulatory flexibility will need to be specifically described in OMP's FPA, as well as incorporated into a legal implementing mechanism in order to implement the final project.

2. Superior Environmental Performance

All XL projects must result in better environmental performance than would be achieved absent Project XL. As noted above, acceptance of OMP's proposal is expected to facilitate the improved containment and potential recycling of the radioactive materials. EPA believes that this project should achieve additional superior environmental performance, which OMP, PADEP, EPA, and other relevant stakeholders can develop during FPA negotiations.

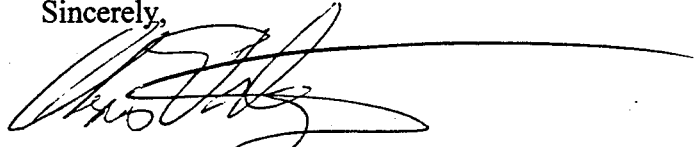
3. Monitoring and Reporting

Specific monitoring and reporting requirements for this XL project will also need to be developed during FPA negotiations with EPA, the Commonwealth of Pennsylvania, and relevant stakeholders. These requirements will serve to verify that the XL project is being conducted in compliance with the parameters detailed in the FPA and the legal implementing mechanisms.

Again, EPA thanks you for your participation in Project XL and looks forward to working with your team to develop the FPA and implement this project. EPA has assembled an Agency-wide team to work with you and your stakeholders in the next phase of the project. This team will be led by Charles Howland in Region III (215-814-2645) and Mitch Kidwell at EPA Headquarters (202-260-2515). Please feel free to contact them if you have any questions.

Once the FPA is signed the Ortho-McNeil XL Project will become an official XL pilot. The Agency appreciates OMP's commitment to innovative projects that improve our system of environmental protection. If you have any questions or need any assistance in expediting the development and review of your Final Project Agreement, please do not hesitate to call.

Sincerely,

A handwritten signature in black ink, appearing to read 'Thomas Voltaggio', with a long horizontal line extending to the right.

Thomas Voltaggio
Deputy Regional Administrator

cc: Rick Shipman, PADEP
Betsy Ullrich, NRC