UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 6, 2005

Docket No. 03005986 License No. 37-00282-04
Control No. 135908

Gail E. Martin
Radiation Safety Manager
SmithKline Beecham Pharmaceutical
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King of Prussia, PA 19406-0939

SUBJECT: SMITHKLINE BEECHAM PHARMACEUTICAL, REQUEST FOR ADDITIONAL INFORMATION CONCERNING FINANCIAL ASSURANCE DOCUMENTS, CONTROL NO. 135908

Dear Ms. Martin:

This is in reference to your letter dated October 26, 2004, providing a revised decommissioning funding plan (DFP) for Nuclear Regulatory Commission License No. 37-00282-04. In order to continue our review, we need the following additional information:

1. Please note that, at the time of actual decommissioning of the laboratory room in which calcium-45 was used, the contamination limits for that laboratory must meet the screening level for calcium-45 of 2,810,000 disintegrations per minute (dpm) per 100 square-centimeters area (cm^2), which is more restrictive than the screening level for carbon-14 of 3,700,000 dpm/cm^2. If multiple radionuclides were used in that laboratory, either the unity rule may be used or the more restrictive limit may be used. In addition, the use of 10% of the screening levels may not be considered ALARA if reasonable remediation efforts can greatly reduce these levels.

2. The table on page 4 of the DFP lists the number of rooms that have ever been authorized for use of radioactivity. It lists 249 rooms in Upper Merion and 71 rooms in Collegeville.

   a. In your 1991 DFP, the number of rooms listed as used in Upper Merion was 283, and in 1995, the number of rooms used was stated to be 312. Explain the change from 312 to 249 rooms ever authorized for use in Upper Merion. Provide any adjustments to the DFP based on your response.

   b. In the 1995 DFP, the number of rooms projected for use in Collegeville was 123. Confirm if the 71 rooms in which radionuclides were actually authorized for use does, or does not, include the Building 12 facility discussed on page 5. Provide any adjustments to the DFP based on your response.

3. Current contamination levels listed on pages 5 and 6 of the DFP are based on routine surveys of laboratories. At the time of facility closure and/or license termination, we expect that surveys include surfaces and equipment that may not be checked during routine surveys, such as drain lines, ducts, hoods, vacuum lines, sink traps, and horizontal surfaces near the ceiling such as light fixtures, pipes and ducts where re-suspended contamination might have settled. It is not clear if such surveys are included in this DFP. If these costs are not included, please revise your DFP.

4. Current NRC guidance for determining at a cost estimate for the DFP is found in NUREG-1757 "Consolidated NMSS Decommissioning Guidance", Volume 3, Appendix A.3 (enclosed). Section A.3.5 lists features of typical facilities that should be considered in the cost estimate. Except for the former synthesis laboratory and the waste facilities, it is not clear if facility components such as glove boxes, fume hoods, lab benches, sinks, drains, hot cells, storage tanks, or other specialized facilities were included as facility components to be considered in your cost estimate. You also did not discuss large equipment typically used in laboratories such as freezers, refrigerators, incubators, centrifuges, etcetera. If such facility components were not included, please revise your DFP. Given the size of your facility and your current knowledge of the facility, it is acceptable to assume that only some fraction of the equipment may be contaminated. If a fraction is assumed, state the basis for that fraction in your response.

5. It does not appear that the costs are included for the activities associated with the decontamination for release, or the disposal as radioactive waste, of equipment such as water baths and cell harvesters on page 7, or large items such as freezers, refrigerators, etcetera. These activities include dismantling potentially contaminated equipment, performing surveys of such items, decontaminating items if appropriate, and waste disposal activities. If these costs are not included, please revise your DFP.

6. Your Final Status Survey described on page 8 of the DFP does not include performing static surveys for total contamination, in accordance with the Multi-Agency Radiological Survey and Site Investigation Manual (MARSSIM) guidance. If you believe that all laboratories (survey units) can be surveyed in accordance with the NUREG-1757, Volume 2, Appendix B, "Simplified Approaches for Conducting Final Radiological Surveys", the surveys as described may be acceptable. Excerpts for NUREG-1757 "Consolidated NMSS Decommissioning Guidance" Volumes 1 and 2, are enclosed. The complete guidance documents may be viewed at the NRC website. Review the guidance, and revise the DFP if required.

Current NRC regulations and guidance are available at the NRC web site at http://www.nrc.gov/materials/miau/mat-toolkits.html and http://www.nrc.gov/who-we-are/governing-laws.html or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 135908. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

enclosures:
1. NUREG-1757 “Consolidated NMSS Decommissioning Guidance”, Volume 3, Appendix A.3.
2. Excerpts from NUREG-1757 “Consolidated NMSS Decommissioning Guidance” Volumes 1 and 2.

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