

NOTICE OF VIOLATION

SmithKline Beecham Pharmaceuticals Co.
Guayama, Puerto Rico

Docket No. 030-20183
License No. 52-23021-01

During an NRC inspection conducted September 30, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

- A. Condition 14 of NRC License No. 52-23021-01 requires, in part, that relocation and removal from service of devices containing licensed material be performed only by persons specifically licensed by the Commission or an Agreement State to perform such services.

Contrary to the above, during August 1993, the licensee relocated within the licensee's facility, one device containing approximately 5 millicuries (mCi) of Cesium 137 without being specifically licensed by the NRC or an Agreement State to perform such services.

This is a Severity Level IV violation (Supplement VI).

- B. Condition 13 of License No. 52-23021-01 requires, in part, that the licensee test for leakage and/or contamination sealed sources at intervals not to exceed six months or at such other intervals specified by the certificate of registration referred to in 10 CFR 32.210. The certificate of registration specifies that the devices used by the licensee be leak and/or contamination tested at intervals not to exceed three years.

Contrary to the above, between July 31, 1990 and September 30, 1994, an interval which exceeds three years, the licensee did not test for leakage and/or contamination three sealed sources of Cesium 137 with an activity range of 200 to 500 mCi.

This is a Severity Level IV violation (Supplement VI).

- C. Condition 19 of License No. 52-23021-01 requires, in part, that the licensee conduct a physical inventory at intervals not to exceed six months to account for all sealed sources and/or devices received and possessed under their license.

Contrary to the above, between August 18, 1993, and September 30, 1994, an interval which exceeds six months, the licensee did not perform a physical inventory of all sealed sources and/or devices possessed under their license.

This is a Severity Level IV violation (Supplement VI).

Enclosure

- D. Condition 16 of License No. 52-23021-01 requires, in part, that the licensee test each gauge for the proper operation of the on-off mechanism and indicator, at intervals no longer than six months.

Contrary to the above, between August 18, 1993, and September 30, 1994, an interval which exceeds six months, the licensee did not test the on-off mechanism and indicator of each gauge for proper operation.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, SmithKline Beecham Pharmaceuticals Co. is hereby required to submit a written statement or explanation to the Regional Administrator, Region II, with a copy to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Atlanta, Georgia
This 24 day of October 1994

Enclosure