D Sylvia

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality
Sterile Drugs Branch, HFD-322
7520 Standish Place
Rockville, Maryland 20855-2737

TELEPHONE: (301) 594-0095
FAX: (301) 594-2202

July 26, 1995

[redacted]

Dear [redacted]

This is in confirmation to our May 8, 1995, telephone conversation regarding the Food and Drug Administration's (FDA) requirements for the testing of liquid nitrogen filled into large mouth, non-pressurized dewars which in turn are supplied to doctors for use in cryosurgery.

We acknowledge the difficulty in obtaining a sample for analysis from a large mouth, non-pressurized container of liquid nitrogen. Therefore, as long as a firm assures that the incoming drug product meets all established specifications, then the testing of the finished product would not be required. Further, a firm filling these dewars would be required to comply with the following good manufacturing practices: 1) the supplier of the incoming nitrogen should be registered with FDA, 2) a valid certificate of analysis should be received with each delivery, 3) a test for oxygen should be taken directly from the storage tank, immediately after each delivery. This analysis may be accomplished with a properly calibrated paramagnetic oxygen analyzer, and 4) the filling system should have dedicated supply lines, and these supply lines should be traceable from the bulk source to the filling manifold. However, if there exists a possibility that another gas, whether it be industrial or medical could contaminate the finished product, then full United States Pharmacopeia testing would be required.

If you should have any further questions, please feel free to me at the above number.

Sincerely yours,

Duane S. Sylvia

Duane S. Sylvia
Consumer Safety Office