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| **Laboratory Information** |
| Development of Assays of Defined Sensitivity for the Regulatory Management of Novel Cell Substrates |
| Andrew Lewis is a Principal Investigator in the Laboratory of DNA Viruses. He received his M.D. degree from Duke University in 1961 and worked as a scientist at the National Institute of Allergy and Infectious Diseases from 1963 to 1994. His work at the NIH focused on virology, the discovery of non-defective adenovirus-SV40 hybrids, and the ability of DNA viruses such as SV40 to induce neoplastic transformation of cells in tissue culture and cause tumors in rodents. Due to the concerns over the possible risks associated with the non-defective adeno-SV40 hybrid viruses, he was an active participant in the Asilomar Conference in 1975 that focused on the possible risks posed by laboratory experimentation involving recombinant DNA. He joined CBER, FDA in the Division of Viral Products in 1995 to focus on safety issues associated with the use of neoplastically transformed cells as cell substrates for vaccine manufacture. At CBER, Dr. Lewis first worked on the possible association between SV40 contamination of early polio vaccines and subsequent tumor development in humans, which had implications for the safety of continuous cell lines for viral vaccine manufacture. He became Chief of the Laboratory or DNA Viruses in the late 1990s. He and others initiated a program to study the tumorigenic potential of transformed cells used during the production of new vaccines. These data were presented at the FDA advisory committee meeting in 2000. This committee encouraged Dr. Lewis and his lab to pursue this project further to identify and characterize the basic biological processes that allow VERO cells to develop the capacity to form tumors. The lab has continued these studies for the past 20 years and has developed what may provide a hypothetical model of neoplasia in tissue culture.  |