# GUID G89-1: TOXICOLOGY RISK ASSESSMENT COMMITTEE

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General Program Memorandum G 89-1 August 9, 1989

Please read the attached memorandum, endorsed by the Center Director, that proposed the establishment of a Center-wide Toxicology Risk Assessment Committee.

The primary purpose of this Committee will be to provide assessments of the potential toxic risks posed by products that are the subjects of marketing applications. The Committee will be a key element in our review process for some of the applications that present difficult toxicology questions. It will review the applications that are potentially problematic, that present sensitive, highly visible issues, or that may result in precedent-setting toxicology decisions. The Committee will also review toxicology-related product approval guidance documents.

The attached memorandum describes the operating procedures to the extent that they have been developed. Clearly, there remain some unanswered questions on selection criteria and policy issues, and the specific operating procedures are yet to be formulated. However, because of the need to expedite the formation and operation of the Committee as a working body, it is our plan to actually begin and resolve many of the open procedural questions as the Committee proceeds. The members of the initial Committee will formulate and propose specific procedures.

Listed below are the members of the initial Committee.

Jerome Donlon, OD, ODE (Co-chair)
Raju Kammula, DOED, ODE (Co-chair)
William D. Galloway, DLS, OST
Hoan-My Do Luu, DSRD, ODE
Nirmal K. Mishra, DSRD, ODE
Phyllis M. Silverman, DBS, OST
Pei Sung, DMMS, OST