GUID INVESTIGATIONAL DEVICE EXEMPTION POLICY

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Public Health Service

Memorandum

Date May 10 1995

From Director, Office of Device Evaluation (ODE)

Subject Investigational Device Exemption (IDE) Policy Which Permits Continued Access to Investigational Devices While a Marketing Application is Being Prepared or Reviewed

To ODE Review Staff

It has recently been brought to my attention that the Office policy regarding continued availability of investigational devices during the period between completion of the clinical study and approval of the marketing application required clarification. In the near future, a blue book memorandum will be developed which will provide specific guidance on this topic. In the mean time, however, ODE's reviewing divisions should use the general principles presented below as a guideline for developing appropriate criteria for their own use.

ODE has traditionally permitted sponsors of clinical investigations to continue to enroll subjects at a pre-determined rate while a marketing application is being prepared by the sponsor or reviewed by the Office if there is: (1) a public health need for the device or (2) if there is preliminary evidence that the device is likely to be effective and no significant safety concerns have been identified for the proposed indication. Such a policy is scientifically sound as it allows the sponsors to collect additional safety and effectiveness data in support of the marketing application or to address new questions regarding the investigational device during this intervening period. This approach is also administratively appropriate as the preparation and review times for a marketing application can be lengthy; and thus, it could be contrary to the public health to prevent access to these potentially safe