DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date JUL 17 2000

From

Deputy Director for Science and Regulatory Policy

Subject

A Systems Approach to Premarket Review

To All ODE Personnel

Medical technology in the United States is developing at an unprecedented rate with breakthrough technologies occurring throughout all areas of medicine. Devices have become increasingly sophisticated, with many incorporating drug, biologic, and cell therapies. At the other end of this spectrum, are those devices that are unlike any others in the marketplace but present relatively low risk to the patient. Yet still, there are the "me-too" technologies which remain the mainstay of patient care.

Congress, in recognizing the changes occurring in the device industry and healthcare community, recently provided for the most sweeping of legislative changes since the Medical Device Amendments of 1976. In the Food and Drug Administration Modernization Act of 1997 (FDAMA), the legislators provided for more efficient device development and review processes, while still ensuring that the public health is well protected. For example, in Section 207 of FDAMA, a more appropriate path to market for novel, but well-characterized devices has been defined than was previously available through the PMA process. Section 210 provides for a much-expanded Third Party Review Program. FDAMA encourages FDA and Industry staff to engage in early collaboration meetings so that clinical protocol issues may be resolved before a clinical trial is initiated. Perhaps most important are the Least Burdensome provisions of FDAMA. This section of the law directs FDA to concentrate its efforts on the information, which is critical to the statutory decision of substantial equivalence for 510(k)s and reasonable assurance of effectiveness for PMAs.

Over the years, the distinction between the various premarket review programs (IDE, HDE, PMA, PDP, and 510(k)) has become increasingly blurred. The numerous provisions of FDAMA (some of which were discussed above), combined with our reengineering initiatives, blur the line even further. For example, although the early collaboration meetings occur during the IDE phase of device development, their importance comes in to play during the review of the PMA. The HDE regulation allows marketing approval for humanitarian devices, has many of the same regulatory requirements as IDEs, but may be an option to either a 510(k) or PMA. Similarly, the path to market for a device without a predicate has generally been a PMA. Now, however, we have other options, such as the *de novo* process and PDPs. Finally, the PDP process is a hybridization of the IDE and PMA processes. The attached diagram symbolizes some of the major factors that influence our core ODE program activities and depicts how complicated the premarket review environment has become.

I believe it is time to capitalize on the regulatory tools which we have been provided through our reengineering efforts and FDAMA and to eliminate the artificial distinctions we have been maintaining between the premarket review programs. By fully integrating the programs, the resulting processes will be more in-tune with Agency needs, the demands of a fast paced industry, and Congress' intent. To help meet this objective, I have asked Mr. Robert Gatling to make this a high priority initiative beginning with the Program Operations Staff. Ms. Heather Rosecrans will lead this effort for the Class I/II device issues, while Dr. Joanne Less will have this responsibility for the Class III devices/programs. Under this initiative, Heather and Joanne will be integrating our new statutory provisions and reengineering tools into the device development and review processes. This will involve in-depth cross-training within POS on the various policies, regulations, and laws to promote a systems approach. In addition, Heather will be working to ensure Third Party Review preparedness and better use of standards and special controls in the review and classification processes. She will also be developing guidance for the handling of Section 513(g) requests and the appeals process for classification decisions. As a key member of the Least Burdensome implementation team, Joanne will be responsible for ensuring that the Least Burdensome concept and principles, as well as the associated guidances and procedures, are incorporated into our work products. She will also be developing new policy in areas such as adverse event reporting and PMA postapproval study requirements and as well as bringing closure to draft documents, including the PDP guidance.

While the initial focus for this initiative will begin in POS, the ultimate responsibility for insuring that we are applying an appropriate level of regulation to medical devices rests with each and every one of us. By consciously identifying the regulatory alternatives and applying the most appropriate ones to the review processes, we will best insure that our efforts capture the letter and the spirit of FDAMA, while optimizing ODE's contribution to public health. Bob Gatling will be conducting outreach to the review divisions to encourage the active participation of everyone in ODE and to help ensure that we meet your needs. I hope that you will share any ideas that you may have with Bob regarding how we can best advance our premarket programs. Your participation in this process will be the key to success both inside and outside the agency.

Philip J. Phillips

Premarket Review Environment