COOK®

Cook Group Incorporated

September 21, 1998
2251 '98 SEP 22 P1:35

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 98N-0339

Dear Sir or Madam:

This comment is filed on behalf of the Cook Group, Inc. ("Cook"), a holding company of international corporations engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gastroenterology, emergency medicine and surgery. Cook pioneered the development of products used in the Seldinger technique of angiography, and in techniques for interventional radiology and cardiology. Cook products benefit patients by providing doctors with a means of diagnosis and intervention without the necessity of invasive surgery. Cook sells over 15,000 different products which can be purchased in 130,000 combinations.

We welcome the opportunity to offer written comments for FDA's consideration as it develops and publishes a plan under Section 406(b) of FDAMA, and we commend the Agency for its outreach to all stakeholders. In this letter, we would like to express views on the approval process and quality control. While our ideas are not new, we believe these concepts are very important and should provide important guideposts for FDA, as it implements FDAMA and regulates the medical device industry.

Approval Process

In implementing the approval process as set out be FDAMA, it is critical that FDA not lose sight of the fact that devices are distinct from drugs. Approval of a new drug deals with a new chemical compound, a new product that will be ingested into the body. The development of devices, on the other hand, is very incremental. One generation is very similar to the next. The lifespan of a device is very short and there are thousands and thousands of products. Further, most devices are not implanted. They are used for a purpose by a physician in a procedure. Generally, devices either perform then or they do not. The key to safety and effectiveness for most devices lies not in pre-market reviews but in proper design and manufacturing processes.

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FDA has learned that its involvement in pre-market review of every minor change to devices would consume all of its resources. It must continue to organize its priorities to focus only on approval activities which are of value in ensuring safe and effective products. Rather than pre-market activities, it should rely on a sound system of quality control and inspections as much as possible to protect the public. The Agency has made significant steps in improving the process. We believe that the following areas continue to need attention.

- Exemption from 510(k). Under the Act, the majority of Class I products was exempted from 510(k) requirements with the exclusion of specified categories. The Agency has offered its opinion as to which Class I devices are exempt and which are not. Further, under FDAMA, FDA has exempted a number of Class II products. We believe in executing its mission, the Agency should revisit its opinion on Class I devices that are not exempt from pre-market notification and also take the initiative to exempt additional Class II devices from 510(k). Cook strongly urges FDA to review these matters at least twice a year in order to reduce the burdens of pre-market review.

- Use of Information. FDAMA permits the FDA to use information from PMA applications six years after product is approved. This information can be used in reclassifying devices or in approving new products. We believe that FDAMA is clear on its face and permits FDA to begin using such information for any devices which were approved over six years ago. FDA should do so. It makes absolutely no sense for the Agency to require manufacturers to reprove matters which are well established. This is a waste of FDA and sponsor resources.

- Flexibility. The FDA should implement provisions in FDAMA that provide for changes in devices based upon the knowledge gained in the development process. Such changes should be permitted wherever possible. The goal is to get safe and effective products to patients as early as possible. If the IDE process must be restarted each time a lesson is learned, it can add months or even years to product development. This should be avoided when changes are not fundamental to the operating principles of a product. FDA has taken steps to implement the flexibility permitted by FDAMA. When the regulation becomes final, the Agency should periodically review it to ensure the product development benefits envisioned by Congress are realized and not consumed by even more extensive review of IDE supplements than currently exists.

- Collaboration. As Dr. Henny noted in her confirmation hearings, the underlying philosophy in FDAMA is one of collaboration -- industry and FDA working together to achieve the development of safe and effective products for American patients. Its important that the FDA truly implement this philosophy. If this culture can be established at the Agency, all aspects of the process will work better.

- User Fees. While the Agency is strapped for resources and understandably looking at all options, we believe that user fees simply are not practical in the context of medical devices. There are so very many medical devices on the market. Thousands of them are aimed at small patient populations. They are made by thousands of small companies. As mentioned

earlier, devices have very limited lifespans. The number of submissions required of each company is far greater than those required in the pharmaceutical industry. It is simply unworkable to require a manufacturer to pay fees each time it makes a minor change in a product which is meant for a small patient population and which will be obsolete in a very short period of time. If such fees are required, development of important products that are not aimed at mass markets will be drastically reduced.

Quality Control

We believe that the most important aspect of FDA regulation is in requiring quality controls. It is essential that products be properly designed, manufactured, and marketed. It is also essential that there be prompt, appropriate follow-up by a manufacturer if unforeseen problems arise with a product. This is what the quality control system and GMPs are designed to govern.

We believe that a strong quality control system and a constructive Agency inspection program will provide significant benefits to the American public. Constructive inspections should be instructive with the Agency carefully examining all important processes of the manufacturer and sharing its knowledge based upon its broad experience with other manufacturers.

We are fearful that less and less emphasis is being placed in the Agency upon inspections. We hope this trend will be reversed. Indeed, we believe that more resources should be invested in training specialized inspectors in medical technology for the sole purpose of inspecting medical device manufacturers and that inspections should take place at least every two years. We urge the Agency to give this element of its program the highest priority. This is the area where regulation is most effective.

We should note that the European union has made great strides in developing quality control systems. This is an area where there should be significant opportunities for harmonization of inspection requirements in order to take advantage of CE mark certification inspections of U.S. facilities when FDA inspection resources are thinning.

We thank you very much for the opportunity to make these comments. We again express our appreciation for the Agency's outreach to all interested parties.

Respectfully,

Stephen L. Ferguson

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