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September 10, 1998

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

The College of American Pathologists (CAP) appreciates this opportunity to comment on the FDA's implementation of the FDA Modernization Act of 1997 (FDAMA). The CAP is a national medical specialty society representing more than 15,000 physicians who are board certified in clinical and/or anatomic pathology. College members practice their specialty in community hospitals, independent clinical laboratories, academic medical centers, and federal and state health facilities. For several years, the CAP has interfaced with the FDA on clinical laboratory issues. Most recently, the CAP actively participated with the agency in the development of an appropriate regulatory scheme for monoclonal antibodies.

In today's health care environment, marked by rapid technological developments, the FDA's ability to ensure that the appropriate processes are in place for the agency to make available safe and effective medical devices, biologics, food and other products in a timely manner is crucial for patient care. For this reason, the CAP supports FDAMA's goal of affirming the FDA's role as protector and promoter of the public health.

The CAP recognizes the daunting task that lies ahead of the FDA in fulfilling the FDAMA mandates. The FDA faces the challenging task of self-evaluation, eventually evolving into an agency that maximizes all available resources and minimizes inefficient practices within the confines of limited agency resources. However, the CAP believes that the benefits to the long term public health will far outweigh the costs, time and resources associated with the agency's implementation of FDAMA.

Based upon our interaction with the FDA, we submit the following recommendations for your consideration as you develop the FDAMA implementation plan.

- *The CAP recommends greater communication with and inclusion of stakeholders in all FDA activities including development of policies, regulations and participation on advisory committees.*

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Stakeholders, such as the CAP, have broad experience, expertise and resources often deficient within the FDA. Appropriate inclusion of external stakeholders can alleviate some of the agency's resource constraints by allowing the FDA staff to more efficiently utilize limited resources.

- ***The CAP recommends better communication between internal FDA offices working on different aspects of a single issue.***

On several occasions within the past six years, CAP members have been impacted by the apparent disconnect and lack of communication between the Center for Devices and Radiological Health's (CDRH) Office of Device Evaluation and Office of Compliance. While the Office of Device Evaluation continued to work towards developing and finalizing policies to appropriately regulate monoclonal antibodies, simultaneously the Office of Compliance continued to draft guidance documents and send out notices to manufacturers threatening to impose sanctions and remove unapproved in vitro diagnostic products from the market. Initially, neither office was aware of the activities of the other. This problem could have been alleviated if the two offices had worked together in a collaborative manner.

- ***The CAP recommends better communication between FDA Centers.***

Due to multifaceted issues and the need to develop new approaches to regulating products, there is a tremendous need for collaboration and regular communication between the FDA Centers. For example, for the first time the Center for Biologics Evaluation and Research (CBER) is considering regulation of blood establishment computer software as class II medical devices. Since CBER staff are not experienced in regulation of medical devices, there will need to be close collaboration and involvement of CDRH staff in this process.

- ***The CAP recommends development of a clearly defined policy on the use of guidance documents.***

The FDA regularly uses guidance documents to provide assistance to industry in compliance with FDA regulations and policies. Issues have often arisen regarding the legal authority of FDA guidance documents. Although efforts have been made by the agency to do so, there still lacks clear understanding of the use of guidance documents as binding FDA policy. Complicating this issue is the fact that guidance documents are often in draft form for extended periods of time.

- ***The CAP recommends more efficient use of the FDA's web site for providing information to the public.***

The FDA's web site contains a wealth of information on FDA regulatory activities. The CAP would like to commend the FDA on its use of the internet as a means of providing

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information to the public. However, there are still improvements to be made to the web site, such as timely updating of information and the availability of detailed information on premarket approval decisions.

In closing, the CAP stands ready and willing to serve as a resource to the FDA. Please feel to refer to Deidra Abbott as a contact person on this issue (202-371-6617, extension 110).

Sincerely,

A handwritten signature in black ink that reads "Thomas P. Wood MD". The signature is written in a cursive style with a large initial 'T'.

Thomas P. Wood, MD  
President

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Attach the Airborne Express Shippers Label within the dotted lines.

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