From the FDA

Commissioner proposes 'user fees'

In an effort to speed up the drug approval process, FDA Commissioner David Kessler, MD, has proposed a series of user fees charged to pharmaceutical companies. The largest federal budget deficit in history makes any additional monetary allocations unlikely. Yet, without additional reviewers, the current backlog of drug approval applications will only worsen, and promising new drugs will be buried in a backlog, warns the commissioner.

Currently, it takes approximately 20 months before a drug receives approval; drugs for life-threatening diseases, however, are approved in about 12 months. Dr Kessler estimated that the approval time would be enhanced by 8 and 6 months, respectively.

Although the exact fee schedules had not been set as of press time, Dr Kessler estimated that drug companies with a drug on the market would be charged an annual $50,000 fee; an application fee of $150,000 would be charged for each drug seeking approval; and a $5000 fee for each drug that reaches the marketplace. The fee schedule would be commensurate with the size of the drug company.

All fees would be earmarked exclusively for the drug approval process and would not be used to supplement any federal budget cuts.

Dr Kessler emphasized that standards would not be lowered nor would objectivity be sacrificed in this new system.

At press time, Reps Henry Waxman (D-Calif) and John Dingell (D-Mich) had planned to introduce this proposed user-fee bill to Congress before it adjourns this month.

Common 'medications' banned from OTC preparations

Manufacturers of over-the-counter products with ingredients that have not been proved to be effective or that are making false claims will be banned or forced to change their labels. Under the new regulations, which at press time were scheduled to take effect this month, common ingredients such as calamine could not be sold as an "external analgesic." It could, however, be sold as a "skin protectant."

"We are taking this action because no proof has been submitted to the FDA that shows the ingredients are effective for the conditions claimed," said FDA Commissioner David Kessler, MD, in a press conference held in late August.

Likewise, alfalfa leaves, blessed thistle, dog grass extract, and Venice turpentine cannot be advertised as active ingredients. Similarly, peppermint spirit, catnip, or chamomile flowers can no longer be touted as aiding digestion, nor can common ingredients found in diaper rash products claim to fight fungus or ease pain.

Although 415 ingredients have been targeted, thousands of products will be affected, noted pharmacist William Gilbertson, who is in charge of this FDA review process. None of the ingredients themselves are unsafe. As long as such ingredients are classified as inactive, they can remain as part of the preparations.

From NIH

Office for Study of Unconventional Medical Practices established

In response to a Congressional directive to foster research among "alternative" healing practices, the National Institutes of Health (NIH) has established the Office for the Study of Unconventional Medical Practices. According to the agency, unconventional medical practices are defined as being outside the realm of established scientific proof. The Congressional directive is intended to bring these so-called unconventional practices into mainstream research.

Six panels convened in mid-September to discuss alternative intervention methods, including mind/body control, electromagnetic and pharmacologic/biologic intervention, and physical manipulation. This was the second meeting held since the Office for the Study of Unconventional Medical Practices was established.

Stephen C. Groft, PharmD, who heads this office, said that the goal of these meetings is to provide assistance in developing study protocols as well as to enhance the peer review process. One of the complaints that persons working in alternative healthcare practices have, said Dr Groft, is that peers do not actually review their research. Thus, Dr Groft's office is trying to establish a true peer review process.