Mark McClellan said, "We have continued to meet or exceed our goals for reviewing applications for drugs and biologics."

Compared with 2002, median approval times for the nine priority NMEs approved decreased from 16.3 months to 6.7 months, but increased from 15.9 months to 23.1 months for the 12 standard NMEs approved. But it is difficult to fully interpret the data, which, being from such a small pool of applicants, is sensitive to fluctuations from particularly long or short regulatory pathways, and from an approval process that is such a stop–start affair overall. (By contrast, the EMEA refers to approvals both as "total review time" and "active review time", and its mean active review time has been consistently around 6 months during 2000–2003.)

Nevertheless, the approval of bortezomib has shown how successfully companies and the FDA can interact to bring a much-needed drug through to market in the minimal time. If more drugs and biologics can be brought through this process without compromising safety, this will be good news for both the industry and consumers. The FDA argues that there's more to low numbers than just approval times. The agency has approved a higher percentage of submitted NME applications in the years following the enactment of the Prescription Drug Users Fee Act (for more about the act see BOX 1). Approval rates during 1993–2000 were in the range 65–85%, which is up from approval rates of 40–60% observed during 1987–1992.

A more significant factor contributing to the low numbers seems to be slowly drying pharmaceutical pipelines. The number of NME applications filed for approval to the FDA has been dropping in recent years (FIG. 3). Although there are several exciting NMEs filed for approval, such as the thrombin inhibitor ximelegatran (Exanta; AstraZeneca) and the antibiotic telithromycin (Ketek; Aventis), levels will need to rise above the low twenties seen in 2001 and 2002 to make an impact on numbers of NMEs approved.

The trends seen in 2003 have generally been encouraging, but 2004 will be an important year in determining whether the industry has truly escaped from the approval doldrums.

NEWS IN BRIEF

Bayer wins parallel trading case

In a setback to the European Commission's (EC) wish for a single market for drugs, Europe's highest court ruled that the EC was wrong to fine Bayer for restricting parallel trading. In 1996, the EC ruled that Bayer was guilty of making agreements with Spanish and French wholesalers persuading them not to export the calcium channel blocker nifedipine (Adalat) to the United Kingdom, where it is 40% more expensive. The European Union (EU) allows state-regulated drug prices but, being a single market, it also demands free movement of goods between member states, a practice that pharmaceutical companies say costs the industry US $5.6 billion in annual sales. But the European Court of Justice ruled that the EC failed to show that Bayer had intended to impose an export ban because the EC couldn't prove that Bayer had entered any agreements with the wholesalers. The EC maintains that parallel drug trading is perfectly legal within the EU and says it will continue to monitor the practices of pharmaceutical companies.

NIH deals with accusations of conflict of interest

An article in the *Los Angeles Times* has claimed that consulting fees received by US National Institutes of Health (NIH) scientists from drug companies have influenced research decisions involving the companies' products. As a result, the House Committee on Energy and Commerce, which oversees the NIH, demanded complete records of all consulting deals made by in-house NIH scientists since 1999, and a response from the NIH's director, Elias Zerhouni. Zerhouni outlined a four-point action plan to address the concerns: the NIH will review all external payments received by its employees since 1999; an internal ethics advisory committee will be set up, as well as an outside panel of experts to advise the NIH on its ethics policies and practices; and there will be a review of policies that dictate when and how NIH employees disclose their consulting relationships to the public.

Pfizer to buy Esperion

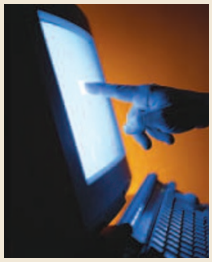
Pfizer has agreed to buy the Ann-Arbor-based biopharmaceutical company Esperion Therapeutics for US $1.3 billion, a move that puts it ahead in the race to design treatments that target high-density lipoprotein (HDL) for cardiovascular disease. This treatment class is one of the most eagerly anticipated in cardiovascular medicine, as HDL targets cholesterol in a complementary way to statins by mobilizing and clearing cholesterol, and thereby reduces atherosclerotic plaques. In buying Esperion, Pfizer has acquired ETC-216, a synthetic variant of HDL, which in an early trial in 47 patients with acute coronary syndromes reduced atheroma volume by 4.2%, the first time any drug has appreciably reversed atherosclerosis. ETC-216 will join Pfizer's own HDL-targeting drug in development, atorvastatin (Lipitor)–torcepatrib. This combines the LDL-lowering effects of the statin with an agent that inhibits cholesteryl ester transfer protein, which raises HDL levels by blocking natural transformation into LDL. The acquisition also welcomes Esperion's CEO Roger Newton back to the fold — Newton led the research team at Warner-Lambert that championed atorvastatin.

European clinical trials directive could harm research

More than 2,000 European scientists have signed an online petition to scrap or amend the proposed European Union clinical trials directive, saying that bureaucratic demands will smother independent medical research. The directive, due to become law in May 2004, requires researchers to conform to the EU's Good Manufacturing and Good Clinical Practice guidelines. It was set up to harmonize industry trials but has since developed to encompass all patient trials. But the scientists say that the administrative requirements — such as filling out mountains of forms, following and reporting of patients' well-being to a central database, and the acceptance of full liability for trials — mean that academics will not have the time or the resources to comply with the directive's demands, and therefore trials that companies do not wish to run could be endangered.

www.saveeuropeanresearch.org

FDA demands electronic drug label submissions



For the first time, the US FDA has issued a mandatory requirement for electronic submissions. It will now require electronic submission of drug labelling for review with New Drug Applications, certain Biologic License Applications and Abbreviated New Drug Applications. Until now, the FDA has offered applicants the choice of submitting required regulatory documents in electronic format, so the move is seen as a step towards the compulsory electronic submission of all regulatory information.