FOOD AND DRUG ADMINISTRATION

FDA upgrade proposed

Washington

THE US Food and Drug Administration (FDA) is so "overextended, underfunded, and shackled by bureaucratic restraints" that it should be taken out of the huge Department of Health and Human Services (HHS) in which it is submerged and given new status as an independent agency, perhaps along the lines of the National Science Foundation. This is the chief recommendation of an *ad hoc* FDA review committee that was appointed a year ago by HHS Secretary Louis Sullivan and which reported back to him last week.

Sullivan was not pleased. The committee, headed by former FDA commissioner Charles C. Edwards, now head of the Scripps Clinic and Research Foundation in California, was blunt in saying that FDA should be freed from HHS. Giving the commissioner real authority to issue regulations, recruit senior staff and manage the FDA's internal affairs without interference from HHS officials who have other things on their minds "would do more than any other single measure available to HHS to restore the commissioner's prestige, enhance the agency's effectiveness, and improve employee morale," the 15-member committee concluded.

FDA advisory committee seeks more clout for new FDA commissioner, David A. Kessler.

Midway through the committee's deliberations, David A. Kessler stepped down as a committee member when he was appointed FDA commissioner by Sullivan.

Sullivan countered the committee's recommendations, predictably, by saying that it would be a serious mistake to separate FDA from his department in view of the need for close coordination between FDA and other HHS agencies, particularly the Centers for Disease Control and the National Institutes of Health.

However, Senator Edward M. Kennedy (Democrat, Massachusetts) is siding with the Edwards committee on this. He said that the committee put forward a "compelling case" and that he is prepared to introduce legislation to free the FDA if the Administration refuses to budge.

A strong FDA is vital to many segments of the US scientific enterprise — the biotechnology industry in particular. During the past four years, the length of time it takes overworked FDA staff to complete the review and approval process for new drugs has increased from two years to 34 months. With the exception of AIDS-related therapies, the increase in the number of new drugs awaiting final review has not been accompanied by a material increase in the number of scientists in the FDA's Center for Biologics Evaluation and Review, which handles 80 per cent of all biotechnology products. This, the committee argues, could have serious implications for the international competitiveness of US industry. The analogous review process in the European Committee for Proprietary Medicinal Products takes about a year.

The committee urged the FDA to adopt new and more flexible standards for approving drugs, particularly those for life-threatening diseases and diseases for which no therapeutic alternative to a new drug exists. This, it believes, could be best accomplished if the FDA commissioner had real decision-making authority and could act more independently.

Although the Edwards group sees independence and authority as the key issue for FDA, more money is needed too. In the current climate, with large increases of federal funds unlikely, the idea of charging companies 'user fees' to deal with FDA is being revived. In fact, the Administration's proposed budget of $770 million for fiscal year 1992 assumes that users will pay fees of $197 million — money that could be used to recruit new scientific staff. **Diane Gershon**

SUPERCONDUCTING SUPER COLLIDER

New detector sought

Washington

IT'S back to the drawing board — literally — for a particle detector to be used on the Superconducting Super Collider (SSC).

Last week, Roy Schwitters, director of the SSC, announced that he will not pursue the so-called L* (pronounced 'L-star') detector and invited physicists from around the world to help with the development of a detector to take its place.

The consortium proposing the L* contained groups from 13 countries' and its downfall threatens to spoil the international flavour of the SSC. But Schwitters says the lessons learned from the L* fiasco should make it easier to foster a new international collaboration.

Two major detectors, each costing $500 million or more, are planned for the SSC, whose projected cost is itself $8,250 million and rising. A group headed by George Trilling of Lawrence Berkeley Laboratory in Berkeley, California, received the go-ahead in January to develop a full design proposal for the primary detector. At the same time, the SSC Laboratory narrowed its choices for a second detector to one proposal, which had been submitted by a consortium of 90 institutions headed by Samuel Ting of the Massachusetts Institute of Technology. Ting's group was invited to submit an amended proposal; in particular, the SSC Laboratory wanted Ting to allay its concerns about L* 's cost, its management structure and the strength of the US constituents of the consortium.

An independent cost estimate completed in March concluded that L* would cost more than the consortium estimated, but not enough in excess to cancel the proposal. Ting, however, never adequately addressed the questions about L* 's management, Schwitters says, and after Germany, Switzerland and the Soviet Union withdrew from the consortium in March and April, the loss of their combined $200 million commitment made the cost of the L* an issue once again.

The four-month debate over L* has left some hurt feelings, especially in Europe. Particularly galling to many was the SSC Laboratory's conclusion that L* needed more and stronger US participation. Schwitters says this reflected concern over the number of US universities in the consortium that were not traditionally strong in high-energy physics and was not meant to denigrate the European members of the consortium. But some of the European collaborators took it this way, and Schwitters now admits that the wording was 'insensitive'.

From 11 to 13 June, the SSC Laboratory will host an open workshop to discuss the development of another detector, and Schwitters says he will work to regain the trust of the international physics community which has been damaged by the laboratory's handling of L* .

Switzerland, home of CERN, the European particle accelerator, may not participate this time around, Schwitters says — Swiss officials were angry with the handling of the L* consortium, and CERN would prefer that Swiss institutes spend their money inside the country. But Schwitters has high hopes for Germany and the Soviet Union, insisting that the L* experience has 'solidified' ties with Soviet scientists in particular.

"Assuming some interest develops at the meeting, we'll pick up the pieces" and go on, Schwitters says. With luck, the whole experience will set back the timetable for detector development less than a year, and both detectors will be ready when the SSC comes on line, now scheduled for 1999. **Robert Pool**