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DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

PSYCHOPHARMACOLOGICAL DRUGS

ADVISORY COMMITTEE

Friday, September 20, 1991

Conference Rooms D/E
Parklawn Building
Rockville, Maryland

MILLER REPORTING CO., INC.
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Washington, D.C. 20002
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taken as a whole, continues to support the conclusion that Prozac meets the standards of drug product safety and efficacy required for marketing approval under the federal Food, Drug, and Cosmetic Act that is our national drug domestic regulatory law.

I want to emphasize again, to be fair, that this conclusion does not mean that we believe, individually or collectively, that antidepressants, or Prozac, are absolutely risk-free. Neither does this conclusion mean that the agency is going to lessen its vigilance or will cease to review and assess the significance of adverse reports it receives on Prozac now or in the future.

Reports of Prozac, like those received on all marketed drugs, are regularly monitored and evaluated. When a signal of potential concern is identified, as it has been in the case of Prozac, we take additional actions, and urge manufacturers to do so as well. In the present case, for example, the sponsor, Eli Lilly, was asked -- and, I want to mention, expeditiously complied with the request -- to examine data from previously conducted controlled investigations and was also asked to develop plans to conduct new studies, including clinical trials and epidemiological studies, studies that could provide more direct answers to the questions that have been raised in the open session earlier.

Unfortunately, it is very difficult to tell, from