

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1051
Rockville, MD 20852

FDA Docket No. 2003D-0570
Request for Comments on a Draft Guidance of the Clinical Evaluation of Weight-
Control Drugs

Dear Sir/Madam:

As leaders in the discovery, development, manufacturing and marketing of prescription medicines, the pharmaceutical business and research organizations in the Johnson & Johnson family of companies are committed to improving health and well being through innovative products and services. I am sending these comments on their behalf.

We fully support the FDA's interest in incorporating the latest scientific advances in the field of obesity and drug development into an amended obesity guidance document. The current epidemic of obesity in the U.S. needs to be addressed and it is encouraging that Tommy Thompson, Secretary of Health and Human Services (HHS) has kicked off a major initiative on obesity to convert opinion that obesity is a medical concern not a life style issue. Acting Commissioner Lester Crawford has stated that obesity-related deaths in the U.S. have increased to 400,000 per year, up from 300,000 two years ago. He predicted the number will exceed 500,000 deaths per year by the end of this decade and at that point will likely overtake tobacco as the leading cause of death in the U.S.

Although not a complete and total answer, pharmacological intervention has an integral role along side other treatments (e.g. bariatric surgery) and lifestyle modifications in curbing the obesity epidemic and reducing the incidence of associated diseases such as diabetes and hypertension that are well recognized as major contributors to the onset of cardiovascular morbidity and premature cardiovascular mortality. The treatment of obesity includes induction of weight loss, maintenance of weight loss and prevention of weight gain. As such, it needs to be recognized that available therapies may provide valuable benefit to one phase of the treatment paradigm.

The guidance should address the recent emergent environment associated with obesity such as metabolic syndrome and childhood obesity. With newer and novel therapeutic approaches to treat obesity and the associated morbidity and mortality, we encourage

FDA to take into account clinically relevant improvements in co-morbid disease biomarkers (HbA_{1c}, blood pressure, lipids etc.) whilst determining the benefit-risk of a new agent. We further encourage the Agency to utilize all resources at their disposal to expedite delivery of new therapeutic options to obese patients.

We believe the obesity guidance revision process will be greatly enhanced by broad consultation with experts in the field and therefore encourage the FDA to take full benefit of the larger scientific and medical community on developing solutions in the field of obesity research. As indicated in FDA's recently issued paper on Innovation Stagnation (US Department of Health and Human Services, March 2004), the FDA is uniquely positioned to help identify the challenges of development with the goal of promoting efficient development of safe and effective new medical treatments.

In closing, we appreciate the opportunity to comment on this very important draft guideline. We look forward to working alongside the FDA with the goal of promoting efficient development of safe and effective new medical treatments for obesity.

Sincerely,

Jacqueline A. Coelln, R.Ph.
Director
Regulatory Affairs