Food and Drug Administration
Center for Drug Evaluation and Research

Pregnancy Labeling Subcommittee
of the
Advisory Committee for Reproductive Health Drugs

Hyatt Regency, One Metro Center, Bethesda, Maryland

Tuesday, September 12, 2000, 10 a.m. – 12 noon

BACKGROUND & QUESTIONS TO THE SUBCOMMITTEE

BACKGROUND

General Implementation Plan to Revise Pregnancy Labeling : The agency is currently in the process of changing the general format of labeling for all prescription drugs. Because of anticipated resource demands on industry to develop revised labeling and on the agency to review and approve revised labeling, the implementation plan will phase in the new format requirement over a period of several years. Under the plan that will be proposed, when drugs have to have revised labeling will be determined based on date of approval. The rule would apply to newer drugs first, starting with those yet to be approved. Fairly old drugs would not have revised labeling for many years, if at all. For the rule to revise pregnancy labeling, the tentative plan is to require that, for most products, revisions to pregnancy labeling occur at the same time as revisions to the general format.

Accelerated Implementation Plan for Products Considered to be High Priority: The agency is also considering an accelerated implementation plan for certain products for which it would be important to have improved pregnancy labeling as soon as possible—products for which it would not be reasonable to wait for many years to have more informative labeling. Our preliminary thinking is that there are two general categories of products (with considerable overlap) that might benefit from an accelerated implementation plan to improve pregnancy labeling: (1) drugs to which women are likely to be inadvertently exposed during pregnancy and (2) drugs for which there is a pressing therapeutic need during pregnancy.

The agency is seeking advisory subcommittee input on whether it is worthwhile to pursue an accelerated implementation for products for which improved pregnancy labeling would seem to be a high priority and, if so, how to identify and rank products that should be high priority.

QUESTIONS

(1) In general, is an accelerated implementation plan for certain high priority products a worthwhile endeavor from a public health perspective?

(2) If so, what criteria should we use to identify priority (or non-priority) products?

(3) How would you suggest identifying specific products that meet these criteria?