FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Antiviral Drugs Advisory Committee
and the
Nonprescription Drugs Advisory Committee

HILTON WASHINGTON, DC/ROCKVILLE
QUESTIONS TO THE COMMITTEES

OCTOBER 29, 2008

1. Please comment on the concept of a prescription influenza antiviral MedKit intended for use during a pandemic. Specifically address potential risks and benefits, for individual consumers and the U.S. population, if prescription MedKits were approved with the intention of home stockpiling.

2. Will the phase 3 clinical trials that supported approvals and favorable results from the proposed "consumer use" studies (e.g., label comprehension, simulated use, etc.) allow for safe and effective use of the MedKits by individuals who may not be under direct medical supervision at the time of antiviral drug use? [voting question]. Yes/No

   If no, what additional studies are needed?

3. Please comment on the use of a MedKit for treatment versus prophylaxis of influenza during a pandemic. Specifically, taking into account the characteristics of the drugs included in the proposed MedKits:

   - Are both treatment and prophylaxis indications appropriate for MedKits for both of the proposed products?
   - If both indications are appropriate, is it acceptable for the same MedKit to be used for both indications?

4. The Tamiflu MedKit proposal includes instructions for dosing children using the contents of the 75 mg adult capsules although Tamiflu is also available commercially as 30 mg and 45 mg capsules as well as an oral suspension. What is the most appropriate formulation to be used for pediatric dosing in this setting?

5. Comment on specific elements of labeling, packaging, or instructions that are critical for safe and effective use of a MedKit.

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6. Please comment on additions or modifications to the proposed studies (e.g., label comprehension, simulated use, or additional studies) that would help to assess risks and benefits. For example:

   a. What is a reasonable percentage of study subjects who should understand various components of the labeling and/or be able to refrain from using the product for seasonal influenza?
   b. What types of additional studies would be helpful to assess how users would behave in a real-life situation?

7. Please comment on the type of availability that would best be suited to provide MedKits to the American public and state your reasons for your comments. If availability without a prescription is considered an option, please describe any additional studies that would be needed to support a switch from prescription to nonprescription availability.