NDAC Sept 19 and 20, 2002

Draft Agenda

8:00	Call to order and conflict of interest statement
8:15	Open Public Hearing
9:00	Questions from the Chair to Open Public Hearing Presenters
9:15	FDA presentations
10:15	Questions from the Committee to the Presenters
10:30	Break
11:00	FDA Presentations to the Committee
12:00	Questions from the Committee to the Presenters
12:30	Lunch
1:30	Charge to Committee
2:00	Committee Discussion

Where and When: The Nonprescription Drugs Advisory Committee with consultants from other CDER advisory committees will meet on September 19 and 20, 2002, from 8 a.m. to 5:00 p.m. The entire meeting is open to the public and you do not need to register to attend. The meeting will be at the Silver Spring Hilton, Maryland Ballroom**,** 8727 Colesville Road, Silver Spring, MD. The hotel phone number is 301-589-5200. **LISTEN TO OUR HOT LINE FOR NEW INFORMATION: 1-800-741-8138 (301-443-0572 in the Washington, DC area) code 2541.**

The purpose of the meeting: On September 19, the committee will discuss safety issues related to the use of acetaminophen. The primary area for discussion will focus on potential hepatotoxicity related to the use of acetaminophen in both OTC and prescription (RX) products. On September 20, the committee will discuss safety issues related to the use of aspirin and other over-the-counter non-steroidal anti-inflammatory drugs (NSAIDS). The primary areas for discussion will focus on potential gastrointestinal bleeding and renal insufficiency related to the use of these products.

In rulemaking, the agency has proposed aspirin and acetaminophen as Category I ingredients for safety and effectiveness. Other NSAIDS and combination products are marketed under New Drug Applications. The agency continues to believe that these ingredients are safe and effective for OTC use. The advisory committee will discuss whether labeling or other measures are warranted to reduce the risk of occurrence or the severity of these adverse reactions.

B**ackground Material:** Background material will be posted no later than 24 hours before the meeting. However, as background material becomes available from the FDA and from interested parties, it will be posted. (http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.)

Open Public Hearing: Those interested in addressing issues related to the purpose of the meeting should contact Sandra Titus,Ph.D at 301-827-7001 or at tituss@cder.fda.gov. The open public hearing is scheduled from 8:15-9:00 am both days. Those interested in making a presentation to the committee should contact Sandra Titus by September 4, 2002. In addition to presenting to the committee, one may submit written material for the committee to review. This material must be received by August 26. All written submission will also be posted on this docket site.