# CENTER FOR DRUG EVALUATION AND RESEARCH

## ADVISORY COMMITTEE: ANESTHETIC and LIFE SUPPORT DRUGS ADVISORY COMMITTEE

## DATE OF MEETING: 09/17/97

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# AGENDA

# Food and Drug Administration
Center for Drug Evaluation and Research
## Anesthetic and Life Support Drugs Advisory Committee

Gaithersburg Hilton
620 Perry Parkway
Gaithersburg, MD

## Proposed Agenda

**Wednesday, September 17, 1997** **Open Session**

| | | |
|---|---|---|
| 8:00 AM | Greetings and Call to Order | John B. Downs, M.D., Chairman |
| 8:05 AM | Conflict of Interest Statement | Karen M. Templeton-Somers, Ph.D.<br>Executive Secretary |
| | Open Public Hearing<br>One-half hour allocated unless public participation does not last that long. | |
| | **NDA 20-747 Actiq™, Anesta Corp.**<br>- for the management of chronic pain, particularly breakthrough pain, in patients who are already receiving and are tolerant to opioid therapy. | |
| 8:35 AM | FDA Opening Remarks and Introduction | Cynthia McCormick, M.D. |
| 8:45 AM | Sponsor's Presentation | |
| 10:15 AM | Break | |
| 10:30 AM | Committee Discussion | |
| 11:00 AM | FDA Presentations | |
| | Clinical Review | Roberta Kahn, M.D. |
| | Pharmacokinetics | Suresh Doddapaneni, Ph.D. |
| | Abuse Liability | Michael Klein, Ph.D. |
| | Risk Management Plan | Curtis Wright, M.D. |
| | Chemistry | Abi D'Sa, Ph.D. |
| 12:00 N | Committee Discussion | |
| 12:30 PM | Lunch | |
| 1:30 PM | Committee Discussion | |
| 3:00 PM | Open Public Hearing<br>One-half hour allocated unless public participation does not last that long. | |
| 3:30 PM | Break | |
| 3:45 PM | Committee Discussion and Vote | |
| 5:00 PM | Adjourn | |

# Anesthetic and Life Support Drugs Advisory Committee

The following people will also be participating and voting at this meeting:

**Drug Abuse Advisory Committee:**

Harriet de Wit, Ph.D.
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Eric Strain, M.D.
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**Oncologic Drugs Advisory Committee:**

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ANESTHETIC AND LIFE SUPPORT DRUGS ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH

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**July 29, 1997**

# CENTER FOR DRUG EVALUATION AND RESEARCH

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# QUESTIONS

## Questions for the Committee

1. Do adequate and well controlled studies support the Sponsor's claim that this product is effective in the treatment of recurrent breakthrough cancer pain at the doses proposed and in the manner of use proposed?

2. Do adequate and well controlled studies support a broader claim for pain control?

   If so, for what dose and in which population?

3. Has the sponsor adequately identified and supported with data the limits of safe dosing for this product?

   How should recommendations on the maximum recommended dose be addressed in the product label?

4. Has the Sponsor adequately assessed the potential for accidental misuse and diversion or abuse? In your deliberations, please consider these issues:
   - the effect of dose on opiate-naive individuals.
   - packaging and identification.
   - accessibility and disposal.

5. Does the sponsor's risk management plan adequately provide for administration of this product in the environment proposed?

   Based on the risk management plans, should there be specific restriction on its dispensation (for example, should this be marketed for at home use)?

   In what manner should this be addressed in the product label?