

For Immediate Release

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**DAIICHI SANKYO Subsidiary Files for Additional Pediatric Indication for
Fentanyl Injection**

Tokyo, October 2, 2006 – DAIICHI SANKYO COMPANY, LIMITED announced today that wholly owned subsidiary Sankyo Co., Ltd. (President: Yasuhiro Ikegami) filed on September 28 for approval of an additional indication for Fentanyl Injection 0.1 mg (Sankyo) and Fentanyl Injection 0.25 mg (Sankyo) (generic name: fentanyl citrate) for pain relief during anesthesia.

Fentanyl Injection is widely used in analgesia and sedation, as well as in anesthesia and as an anesthetic adjunct, but its use has been contraindicated in Japan for pediatric patients aged two and under because its safety in this group had not been established. However, because of the urgent clinical needs in this area, a physician-led Phase III trial (see note) was conducted in pediatric patients. The trial generated extremely valuable results in this patient group—including newborns and infants—where surgical clinical studies are extremely difficult to perform. On the basis of the results, Sankyo filed for the additional indication in pediatric patients, including infants aged two and under.

The approval of this additional indication would represent a major step towards satisfying the clinical needs in pediatric medicine.

Note: Amendments to the Pharmaceutical Affairs Law in July 2003 enabled investigators (physicians) to lead the implementation of clinical studies, based

on the Ministerial Ordinance for Good Clinical Practice (GCP).