

**ORALLY INHALED AND NASAL DRUG PRODUCTS SUBCOMMITTEE
OF THE ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE**

July 17, 2001

QUESTIONS TO THE COMMITTEE

To establish bioequivalence of suspension formulation nasal aerosols and nasal sprays for allergic rhinitis, the June 1999 draft guidance *Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action* recommends equivalence of formulation, both qualitatively and quantitatively; device; in vitro studies; and systemic exposure or systemic absorption. The in vitro studies, however, do not assure equivalence of particle size of the suspended drug. Because particle size differences between test and reference products have the potential to alter the rate and extent of delivery of drug to local sites of action in the nose, differences in clinical effectiveness could result. For this reason, the draft guidance also recommends the conduct of a clinical study for allergic rhinitis to confirm equivalent local delivery. Providing equivalence of each of the items in the first sentence exists:

1. Does the committee believe that a placebo-controlled traditional two-week rhinitis study conducted at the lowest active dose is sufficient to confirm equivalent local delivery of suspension formulation nasal sprays and nasal aerosols for allergic rhinitis?
2. Does the committee believe that a placebo-controlled park study or an EEU study conducted at the lowest active dose is an acceptable option to confirm equivalent local delivery of suspension formulation nasal sprays and nasal aerosols for allergic rhinitis?