

SMG 1291.12

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF GENERIC DRUGS

OFFICE OF RESEARCH AND STANDARDS

DIVISION OF QUANTITATIVE METHODS AND MODELING

Effective Date: 01/24/2014

1. DIVISION OF QUANTITATIVE METHODS AND MODELING (DKKNUAB).

- A. Uses predictive or physiological models of drug product performance, drug absorption, drug pharmacology, or other quantitative methods to ensure generic drug equivalence and develop new policies.
- B. Develops and implements new computational tools for analysis of in vitro, pharmacokinetic, pharmacodynamic and clinical bioequivalence studies.
- C. Establishes in vitro in vivo correlations (IVIVC) for the use in generic drug review and policy development and provides consults for the review of IVIVC's submitted in ANDAs.
- D. Performs quantitative data-driven risk assessments to prioritize OGD review and post-approval surveillance activities.
- E. Provides OGD's scientific computing expertise and infrastructure including software access and training for effective use of CDER and FDA scientific computing resources.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Secretary of the Department of Health and Human Services and effective on January 24, 2014