SMG 1292.11

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 BIOEQUIVALENCE

DIVISION OF BIOEQUIVALENCE I

Effective Date: 01/24/2014

1. DIVISION OF BIOEQUIVALENCE I (DKKNUBA).

A. Evaluates in vivo and in vitro bioequivalence data and protocols in Abbreviated New Drug Applications (ANDAs) and their supplements and amendments.

B. Recommends approval, disapproval, or new bioequivalence studies and/or protocols.

C. Identifies potential bioequivalence problems and provides guidance for conducting bioequivalence studies for all dosage forms.

D. Reviews and evaluates drug disposition data and specialized drug delivery systems to assure bioequivalence of drug products.

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.