SMG 1292.14

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 CLINICAL REVIEW

Effective Date: 01/24/2014

1. DIVISION OF CLINICAL REVIEW (DKKNUBD).

A. Evaluates bioequivalence studies with clinical endpoints and protocols supporting Abbreviated New Drug Applications (ANDAs) and supplements to ANDAs.

B. Recommends approval, disapproval, or new bioequivalence with clinical endpoints and/or protocols.

C. Identifies potential clinical safety or product use issues or bioequivalence problems and provides guidance for resolving the matters.

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