

SMG 1294.13

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 REGULATORY OPERATIONS

DIVISION OF PROJECT MANAGEMENT

Effective Date: 01/24/2014

1. DIVISION OF PROJECT MANAGEMENT (DKKNUDC).

- A. Provides for the management of the review processes associated with the Abbreviated New Drug Applications (ANDAs) across all review disciplines, by planning, organizing, prioritizing, and assigning ANDA review work.
- B. Monitors and controls review resources and outcomes to assure achievement of individual, team, discipline and Office review goals.
- C. Monitors the compliance evaluation processes for all facilities associated with an ANDA.
- D. Continuously optimizes the allocation of review resources to improve review efficiency.

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.