

SMG 1294.12

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 REGULATORY OPERATIONS

DIVISION OF FILING REVIEW

Effective Date: 01/24/2014

1. DIVISION OF FILING REVIEW (DKKNUDB).

- A. Reviews newly submitted Abbreviated New Drug Applications (ANDAs) to determine if they are “sufficiently complete” to be received.
- B. Monitors and issues Refusal to Receive letters.
- C. Provides evaluation of patent and exclusivity issues.

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.