

SMG 1294.11

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 REGULATORY OPERATIONS

DIVISION OF LABELING REVIEW

Effective Date: 01/24/2014

1. DIVISION OF LABELING REVIEW (DKKNUDA).

- A. Reviews and approves all aspects of labeling submissions for Abbreviated New Drug Applications (ANDAs), coordinating and consulting with the new drug divisions when necessary.
- B. Monitors New Drug Applications (NDA) labeling, including patent and exclusivity status, to advise generic drug applicants of correct model labeling and to prepare and update labeling guidance's.

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.