

**SMG 1293.11**

**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 GENERIC DRUG POLICY**

**DIVISION OF LEGAL AND REGULATORY SUPPORT**

Effective Date: 01/24/2014

**1. DIVISION OF LEGAL AND REGULATORY SUPPORT (DKKNUCA).**

- A. Manages the review within OGD of those petitions on which OGD is requested to provide consult; manages the review of ANDA Suitability Petitions.
- B. Functions as liaison and supports the work of the Office of Chief Counsel and CDER's Office of Regulatory Policy with respect to generic drug matters.
- C. Coordinates all work with respect to Hatch-Waxman matters in OGD, including but not limited to the review of approval and tentative approval letters when there is a paragraph IV certification, forfeitures, and 180-day exclusivity.

**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.