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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

Office of Medical Products and Tobacco

Center for Drug Evaluation and Research

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Medical Policy has modified its structure. This new organizational structure was approved by the Secretary of Health and Human Services on December 15, 2016, and effective on April 17, 2016.

FOR FURTHER INFORMATION CONTACT: Melanie Keller, Office of Management, Center for Drug Evaluation and Research, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301-796-3291.

I. Summary

This organization will expand current activities in the Office of Medical Policy and foster efficient oversight of clinical trials conducted through policy initiatives that build quality upfront and science-based inspectional approaches. This will

provide an oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas, including initiatives to improve science and efficiency trials.

The Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Medical Policy has been restructured as follows:

DKKNF. ORGANIZATION. The Office of Medical Policy is headed by the Director, Office of Medical Policy and includes the following organizational units:

Office of Medical Policy

Office of Prescription Drug Promotion

Division of Advertising and Promotion Review I

Division of Advertising and Promotion Review II

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guides (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's

website at:

http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm

(Authority: 44 U.S.C. § 3101)

Dated: ___April 19, 2016_____

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Sylvia M. Burwell

Secretary of Health and Human Services

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