

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Children and Families****Statement of Organization, Functions, and Delegations of Authority**

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: Statement of Organizations, Functions, and Delegations of Authority. The Administration for Children and Families (ACF) has added the title Deputy Assistant Secretary for Native American Affairs to Commissioner, Administration for Native Americans position.

FOR FURTHER INFORMATION CONTACT: Jeff Hild, ACF Chief of Staff, 330 C Street SW., Washington, DC 20201, (202) 401-5180.

Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF) is being amended at Chapter K, Administration for Children and Families, as last amended at 81 FR 49223 as follows:

I. Under Chapter K, ACF, delete K.10 Organization in its entirety and replace with the following:

K.10 Organization. The Administration for Children and Families (ACF) is a principal operating division of the Department of Health and Human Services (HHS). The Administration for Children and Families is headed by the Assistant Secretary for Children and Families, who reports directly to the Secretary. The Assistant Secretary also serves as the Director of Child Support Enforcement. In addition to the Assistant Secretary, the Administration consists of the Principal Deputy Assistant Secretary; the Chief of Staff; the Deputy Assistant Secretary for Administration; the Deputy Assistant Secretary for Policy; the Deputy Assistant Secretary for Early Childhood Development; the Deputy Assistant Secretary for Native American Affairs and Commissioner, Administration for Native Americans; the Deputy Assistant Secretary for External Affairs; and Staff and Program Offices. ACF is organized as follows:

Office of the Assistant Secretary for Children and Families (KA)
Administration on Children, Youth and Families (KB)
Administration for Native Americans (KE)

Office of Child Support Enforcement (KF)
Office of Community Services (KG)
Office of Family Assistance (KH)
Office of Regional Operations (KJ)
Office of Planning, Research and Evaluation (KM)
Office of Communications (KN)
Office of the Deputy Assistant Secretary for Administration (KP)
Office of the Chief Information Officer (KQ)
Office of Refugee Resettlement (KR)
Office of Legislative Affairs and Budget (KT)
Office of Head Start (KU)
Office of Child Care (KV)
Office of Human Services Emergency Preparedness and Response (KW)***

II. Under Chapter KA, Office of the Assistant Secretary for Children and Families, delete KA.20 Functions, Paragraph A in its entirety and replace with the following:

KA.20 Functions. A. Office of the Assistant Secretary for Children and Families: The Office of the Assistant Secretary for Children and Families is responsible to the Secretary for carrying out ACF's mission and providing executive supervision of the major components of ACF. These responsibilities include providing executive leadership and direction to plan and coordinate ACF program activities to ensure their effectiveness; approving instructions, policies, publications, and grant awards issued by ACF; and representing ACF in relationships with governmental and nongovernmental organizations. The Principal Deputy Assistant Secretary serves as an alter ego to the Assistant Secretary for Children and Families on program matters and acts in the absence of the Assistant Secretary for Children and Families. The Chief of Staff advises the Assistant Secretary for Children and Families and provides executive leadership and direction to the operations of ACF. The Deputy Assistant Secretary for External Affairs provides executive leadership and direction to the Offices of Regional Operations and Communications. The Deputy Assistant Secretary for Early Childhood Development serves as a key liaison and representative to the Department for early childhood development on behalf of the Assistant Secretary, ACF, and to other agencies across the government on behalf of the Department. The Deputy Assistant Secretary for Native American Affairs and Commissioner of the Administration for Native Americans is responsible for handling a variety of assignments requiring knowledge and

expertise in advising the Assistant Secretary, ACF, in the formulation of policy views, positions, and implementation strategies related to American Indians, Alaska Natives, and Native Americans as delineated in the Native American Programs Act (NAPA). The incumbent will also serve as a key liaison and representative to all ACF program and staff offices on behalf of the Assistant Secretary related to tribal and Native American affairs. The Deputy Assistant Secretary for Policy has responsibility for cross-program coordination of ACF initiatives, including efforts to promote interoperability and program integration.

Dated: November 29, 2016.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2009-D-0095]

Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format." This guidance is one of a series of guidance documents intended to assist applicants in complying with FDA regulations on the content and form of labeling for human prescription drug and biological products. The guidance describes the recommended information to include in the CLINICAL PHARMACOLOGY section of labeling that pertains to the safe and effective use of human prescription drug and biological products. This guidance finalizes the 2014 revised draft guidance entitled "Clinical Pharmacology Labeling for Human Prescription Drug and Biological Products—Considerations, Content, and Format."