

Dated: February 20, 2002.

Bob Sargis,

Reports Clearance, Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of the Assistant Secretary; Compassion Capital Fund

AGENCY: Administration for Children and Families (ACF), Department of Health and Human Services.

ACTION: Solicitation of public comments.

SUMMARY: ACF is preparing guidelines to award funds in fiscal year 2002, as allowed by the newly funded Compassion Capital Fund. In order to obtain a wide range of views and comments, ACF is soliciting comments from the public and other Federal agencies on the important issues that ACF should consider in developing such guidelines.

DATES: In order to be considered, comments must be received by ACF on or before March 29, 2002.

ADDRESSES: Comments sent by mail should be addressed to: Mr. Bobby Polito, Administration for Children and Families, 6th Floor—West, 370 L'Enfant Promenade, SW., Washington, DC 20447. Comments may be sent by email to: ccf@acf.dhhs.gov, or faxed to Bobby Polito at 202-401-5770.

FOR FURTHER INFORMATION CONTACT: Mr. Bobby Polito, Administration for Children and Families, 6th Floor—West, 370 L'Enfant Promenade, SW., Washington, DC 20447 or phone: 202-690-6241.

SUPPLEMENTARY INFORMATION: In fiscal year 2002, the Congress funded the establishment of a Compassion Capital Fund. This new program is part of the Administration's Faith-Based Initiative. Funds will be used to support public/private partnerships to help small faith- and community-based organizations replicate or expand model social service programs and conduct evaluations of "best practices" among charitable organizations so that successful models can be emulated and expanded by others.

The Administration for Children and Families (ACF) within the Department of Health and Human Services has been given administrative responsibility for implementing this program. ACF is inviting public comment to help make informed deliberations about the

parameters for this new program, as well as ways to support and promote rigorous evaluations on the "best practices" among charitable organizations.

Request for Comments

ACF is seeking public comment on the following topics and other topics that responders choose to address. Among things we are considering are: (1) Providing technical assistance for faith- and community-based organizations, such as—(A) grant writing and grant management assistance, which may include assistance provided through workshops and other guidance; (B) legal assistance with incorporation and with obtaining tax-exempt status; and (C) information on, and referrals to, other non-governmental organizations that provide expertise in accounting, legal issues, tax issues, program development, and on a variety of other organizational topics; (2) providing information and assistance for faith- and community-based organizations on capacity building; (3) providing for faith- and community-based organizations information on and assistance in identifying and using best practices for delivering assistance to persons, families, and communities in need; (4) providing information on, and assistance in, utilizing regional intermediary organizations to increase and strengthen the capabilities of nonprofit faith- and community-based organizations; (5) assisting faith- and community-based organizations in replicating social programs of demonstrated effectiveness; and (6) encouraging research on the best practices of social service organizations.

Dated: February 20, 2002.

Robert J. Polito,

*Special Assistant for Faith-Based Initiatives
Office of the Assistant Secretary.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (DHHS), Administration for Children and Families (ACF) as follows: Chapter KB, the Administration on Children, Youth and Families (ACYF)

(67 FR 4453), as last amended January 30, 2002; Chapter KF, the Office of Child Support Enforcement (OCSE) (66 FR 13934), as last amended March 8, 2001; and Chapter KP, the Office of the Deputy Assistant Secretary for Administration (ODASA) (66 FR 52627), as last amended, October 16, 2001. This notice reflects the realignment of the discretionary, formula, entitlement and block grant functions within ACF.

These Chapters are amended as follows:

I. Chapter KB, Administration on Children, Youth and Families

A. Delete KB.10 Organization in its entirety and replace with the following:

KB.10 Organization. The Administration on Children, Youth and Families is headed by a Commissioner, who reports directly to the Assistant Secretary for Children and Families and consists of:

- Office of the Commissioner (KBA)
- Office of Management Services (KBA1)
- Head Start Bureau (KBC)
- Program Operations Division (KBC1)
- Program Support Division (KBC2)
- Program Management Division (KBC3)
- Children's Bureau (KBD)
- Office of Child Abuse and Neglect (KBD1)
- Division of Policy (KBD2)
- Division of Program Implementation (KBD3)
- Division of Data, Research and Innovation (KBD4)
- Division of Child Welfare Capacity Building (KBD5)
- Division of State Systems (KBD6)
- Family and Youth Services Bureau (KBE)
- Child Care Bureau (KBG)
- Immediate Office/Administration (KBG1)
- Program Operations Division (KBG2)
- Policy Division (KBG3)
- Technical Assistance Division (KBG4)

Delete KB.20 Functions, Paragraph A, in its entirety and replace with the following:

KB.20 Functions. A. The Office of the Commissioner serves as principal advisor to the Assistant Secretary for Children and Families, the Secretary, and other officials of the Department on the sound development of children, youth, and families. It provides executive direction and management strategy to ACYF components. The Deputy Commissioner assists the Commissioner in carrying out the responsibilities of the Office. In addition to the Immediate Office, the Office of the Commissioner contains the Office of Management Services. In support of the Commissioner and Deputy

Commissioner and in consultation with ACYF programs the:

Office of Management Services manages the formulation and execution of the budgets for ACYF programs and for federal administration; serves as the central control point for operational and long range planning; functions as Executive Secretariat for ACYF; including managing correspondence, correspondence systems, and electronic mail requests; reviews and manages clearance for program announcements for ACYF, the Administration for Native Americans (ANA), and the Administration on Developmental Disabilities (ADD); plans for/coordinates the provision of staff development and training; provides support for ACYF's personnel administration, including staffing, employee and labor relations, performance management and employee recognition; manages procurement planning and provides technical assistance regarding procurement; plans for/oversees the discretionary grant paneling process; manages ACYF-controlled space and facilities; performs manpower planning and administration; plans for, acquires, distributes and controls ACYF supplies; provides mail and messenger services; maintains duplicating, fax, and computer computer peripheral equipment; supports and manages automation within ACYF; provides for health and safety; and oversees travel, time and attendance, and other administrative functions for ACYF.

II. Chapter KF, Office of Child Support Enforcement

A. Delete KF.10 Organization in its entirety and replace with the following: KF.10 Organization. The Office of Child Support Enforcement is headed by a Director and consists of:

- Office of the Director/Deputy Director/Commissioner (KFA)
- Office of Audit (KFAA)
- Office of the Deputy Commissioner (KFB)
- Office of Automation and Program Operations (KFB1)
- Division of Federal Systems (KFB11)
- Division of State and Tribal Systems (KFB12)
- Division of Management Services (KFB2)
- Division of Consumer Services (KFB3)
- Division of Planning, Research, and Evaluation (KFB4)
- Division of Policy (KFB5)
- Division of Special Staffs (KFB6)
- Division of State, Tribal and Local Assistance (KFB7)

B. Delete KF.20 Functions. Paragraph KFA, in its entirety and replace with the following:

KF.20 Functions. KFA. The Office of the Director and Deputy Director/Commissioner. The Director is also the Assistant Secretary for Children and Families and is directly responsible to the Secretary for carrying out OCSE's mission. The Deputy Director/Commissioner has day-to-day operational responsibility for Child Support Enforcement programs. The Deputy Director/Commissioner assists the Director in carrying out responsibilities of the Office and provides direction and leadership to the Office of the Deputy Commissioner, the Office of Automation and Program Operations, and the Office of Audit.

The Office is responsible for developing regulations, guidance and standards for States/Tribes to observe in locating absent parents; establishing paternity and support obligations and enforcing support obligations; maintaining relationships with Department officials, other federal departments, State and tribal and local officials, and private organizations and individuals interested in the CSE program; coordinating and planning child support enforcement activities to maximize program effectiveness; outreach to the communities of faith and service, as well as access/visitation programs and advocacy interests and approving all instructions, policies and publications issued by OCSE staff. The Office is responsible for Child Support Enforcement financial analysis and strategy development; internal OCSE compliance operations; and the management of large-scale or high profile assistance activities involving multiple OCSE areas of responsibility.

C. Delete KF.20 Functions, Paragraph KFB2 Division of Management Services, in its entirety and replace with the following:

KFB2. The Division of Management Services manages the formulation and execution of the budgets for OCSE operated programs and for federal administration of the CSE program; serves as the central control point for operational and long-range planning of the needs of the OCSE; plans for and coordinates the provision of staff development and training; provides support for OCSE's personnel administration, including staffing, employee and labor relations, performance management, and employee recognition; manages procurement planning and provides technical assistance regarding procurement; manages OCSE-controlled space and facilities; performs manpower planning and administration; plans for, acquires, distributes, and controls OCSE supplies; provides mail and messenger

services; maintains duplicating, fax, computer and computer peripheral equipment; supports and manages automation acquisition within OCSE; provides for health and safety; and overseas travel. In addition, the Division reviews and manages clearance of Federal Register Notices and program announcements for OCSE, the Office of Refugee Resettlement, the Office of Community Services, and the Office of Research and Evaluation.

D. Delete KF.20 Functions, Paragraph KFAB Office of Grants Management, in its entirety.

E. Delete KF.20 Functions, Paragraph KFAC Office of Mandatory Grants, in its entirety.

III. Chapter KP, Office of the Deputy Assistant Secretary for Administration

A. Delete KP.10 Organization in its entirety and replace with the following: KP.10 Organization. The Office of the Deputy Assistant Secretary for Administration is headed by the Deputy Assistant Secretary who reports to the Assistant Secretary for Children and Families. The Office is organized as follows:

- Office of the Deputy Assistant Secretary for Administration (KPA)
- Office of Information Services (KPB)
- Office of Financial Services (KPC)
- Office of Organizational Development Services (KPD)
- Office of Customer Service and Administration (KPE)
- Office of Grants Management (KPG)
- Equal Employment Opportunity and Civil Rights Staff (KPH)
- Office of Administrative Services and Facilities Management (KPL)

B. Amend KP.20 Functions to add the following new paragraph:

G. The Office of Grants Management is headed by a Director who reports to the Deputy Assistant Secretary for Administration and provides management and technical administration of ACF discretionary, formula, entitlement and block grants; assures that all grants awarded by ACF conform with applicable statutes, regulations, and policies; computes grantee allocations, prepares grant awards, ensures incorporation of necessary grant terms and conditions, and monitors grantee expenditures; analyzes financial needs under grant programs; provides data in support of apportionment requests; prepares reports and analyses on the grantee's use of funds; maintains liaison and coordination with appropriate ACF and HHS organizations to ensure consistency between ACF grant systems and the Department's grant payment

systems; and provides technical assistance to ACF program and regional components on grant operations and technical grants management issues; and performs audit resolution activities for ACF grant programs. The Office serves as the lead for ACF in coordination and liaison with the Department and other federal agencies on grants management.

Dated: February 19, 2002.

Wade F. Horn,

Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0398]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by March 28, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling (OMB Control No. 0910-0340)

In the *Federal Register* of March 17, 1999 (64 FR 13254), FDA amended its regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products. The rule requires OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. The rule is intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products. FDA concludes that the labeling statements required under this rule are not subject to review by OMB because they are "originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)) and therefore do not constitute a "collection of information" under the PRA (44 U.S.C. 3501 *et seq.*).

Section 201.66 (21 CFR 201.66) of the labeling requirements requires all OTC drug manufacturers to format labeling as set forth in paragraphs (c) and (d) of that section. FDA has learned from the industry that OTC drug product manufacturers routinely redesign the labeling of their products as part of their usual and customary business practice. The rule provides varied timeframes for implementing the labeling requirements. Therefore, the majority of respondents will be able to format OTC drug product labeling in accordance with § 201.66 as part of their routine redesign practice, creating no additional paperwork or economic burden.

In discussing the collection of information under the PRA in the final rule (64 FR 13254 at 13274 to 13276), the agency stated that of the 39,310 stockkeeping units (SKUs) (individual products, packages, and sizes) currently marketed under a final monograph, approximately 32 percent, or 12,573 products, may necessitate labeling changes sooner than provided under their usual and customary practice of label design. FDA estimated that of the 400 respondents who produce OTC drug products, including the 12,573 products described above, each may be required to respond approximately 31.4 times to this rule outside of their usual and customary practice. Each response was estimated to take, on the average of, 4 hours, for a total of 50,292 hours per

year. The burden was expected to be a one-time burden.

The agency stated that although the usual and customary practice of label redesign would minimize the burden for the remaining 68 percent of SKUs currently marketed, or 26,737 products, additional time may be necessary for each company to make the format changes under this rule. FDA estimated that of the 400 respondents, who produce OTC drug products, each may be required to respond approximately 66.8 times to bring the 26,737 products into compliance with this rule. FDA estimated that for this group, each response will take an average of 2.5 hours for a total of 66,842 hours. The burden was expected to be a one-time burden.

Finally, the agency estimated that approximately 61 respondents hold new drug applications (NDAs) and abbreviated new drug applications (ANDAs) (41 NDA holders and 20 ANDA holders) for which supplements and amendments will be required. FDA expected that 522 submissions (350 to NDAs and 172 to ANDAs) will be required for labeling changes under 21 CFR 201.66(c) and (d), which averages to 8.5 submissions per respondent. The agency estimated that each submission will take an average of 2 hours to prepare for a total of 1,040 hours annually. The burden was also expected to be a one-time burden.

Since the final rule was issued on March 17, 1999, the agency has extended the April 16, 2001, compliance date by 1 year to April 16, 2002 (with a corresponding extension of the April 16, 2002, compliance date for products with annual sales of less than \$25,000 to April 16, 2003) (65 FR 38191, June 20, 2000). During this time, the agency has published only one major final rule (which has had its effective date extended from May 21, 2001, to December 31, 2002) (65 FR 36319, June 8, 2000) and several minor amendments to existing final rules. These monograph amendments have an effective date of May 16, 2002, so that the relabeling required by the amendments may be coordinated with the relabeling required by the OTC drug product labeling final rule. For these reasons, the agency believes that the numbers of affected products in the different categories discussed in the collection of information in the final rule are little changed. Accordingly, the agency is listing the same number of respondents, annual frequency per response, and total annual responses in this notice.

The agency believes the hours per response and total hours may be less than the numbers stated in the final rule