DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority: Office of the Assistant Secretary for Financial Resources

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is updating a portion of one office, the Office of the Assistant Secretary for Financial Resources (ASFR), which is located within the Office of the Secretary (OS). The update is designed to streamline and clarify the roles and responsibilities with ASFR's Office of Grants and Acquisition Policy and Accountability (OGAPA).

FOR FURTHER INFORMATION CONTACT: Richard Turman, Principal Deputy Assistant Secretary for Financial Resources, 200 Independence Ave., SW., Washington, DC 20201, (202) 690–6061.

Part A, Office of the Secretary, Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (HHS) is being amended at Chapter AMT, ''Office of Grants and Acquisition Policy and Accountability (OGAPA)'' as last amended at 74 FR 57679–82 dated November 09, 2009.

The Changes are as follows:

1. Under Chapter AM, ''Office of the Assistant Secretary for Financial Resources,'' delete Chapter AMT, ''Office of Grants and Acquisition Policy and Accountability,'' in its entirety and replace with the following:

Chapter AMT, Office of Grants and Acquisition Policy and Accountability (AMT)

Section AMT.00 Mission. The Office of Grants and Acquisition Policy and Accountability (OGAPA) provides Department-wide leadership and management in the areas of grants and acquisition management through policy development, data systems operations and analysis, performance measurement, oversight, and workforce training, development, and certification. OGAPA fosters collaboration, innovation, and accountability in the administration and management of the grants and acquisition functions throughout the Department. In addition to facilitating Departmental implementation of and compliance with existing grants and acquisition laws and regulations, OGAPA provides Departmental and government-wide leadership on implementation of the Federal Financial Accountability and Transparency Act (FFATA) for grant and acquisition activities. OGAPA is the organizational location for Grants.gov, which provides a Government-wide electronic portal for citizens to ''Find'' and ''Apply'' for Federal grant opportunities. OGAPA represents the Department in dealing with the Office of Management and Budget (OMB), U.S. Government Accountability Office (GAO), other Federal agencies, and Congress in the area of grants and acquisition policies and management.

Section AMT.10 Organization. OGAPA is headed by a Deputy Assistant Secretary for Grants and Acquisition Policy and Accountability who reports to the Assistant Secretary for Financial Resources. The Deputy Assistant Secretary also serves as the Department's Suspension and Debarment Official. OGAPA consists of the following components:

- Immediate Office of Grants and Acquisition Policy and Accountability (AMT).
- Division of Grants (AMT1).
- Division of Acquisition (AMT2).
- Office of Small & Disadvantaged Business Utilization (AMT3).

Section AMT.20 Functions

1. Immediate Office of Grants and Acquisition Policy and Accountability (AMT). The Immediate Office of Grants and Acquisition Policy and Accountability consists of the Deputy Assistant Secretary and support staff who assist in the management and administration of the Office's functions, and facilitate and coordinate OGAPA-wide initiatives and activities on behalf of the grants, acquisition and small business communities, including Suspension and Debarment related activities.

2. Division of Grants (AMT1). The Division of Grants is headed by an Associate Deputy Assistant Secretary who serves as the Department's Senior Grants Executive and the Division Director. The Division Director provides leadership, guidance, and oversight to constituent organizations, and coordinates long and short-range planning for HHS' grants management policies, practices, systems and workforce. This Division provides technical assistance to the Department's OPDIVs and STAFFDIVs, evaluates effectiveness of the grants programs and processes; develops pertinent HHS-wide regulatory guidance, policies, and performance standards; maintains and reports Departmental grant/financial assistance award information; and conducts special Departmental initiatives related to grants. It also serves as the focal point for coordinating ASFR's response to cross-cutting Freedom of Information Act (FOIA) requests, audits, reports and suspension and debarment activities related to grants. The Division provides input for coordinated Department positions on proposed legislation and Government regulations specific to grant-related matters. The Division also manages activities associated with the training, development, and certification of—and strategic planning for—the Department's grants management workforce. In its role as managing partner of Grants.gov, the Division engages with grant-making agencies within and external to HHS, grantees, and the Office of Management and Budget.

3. Division of Acquisition (AMT2). The Division of Acquisition is headed by an Associate Deputy Assistant Secretary, who serves as the Department's Senior Procurement Executive and the Division Director. The Division Director provides leadership, guidance, and oversight to constituent organizations, and coordinates long and short-range planning for HHS' acquisition practices, systems and workforce. This Division provides technical assistance to the Department's OPDIVs and STAFFDIVs; evaluates effectiveness of the acquisition programs and processes; develops pertinent HHS-wide regulatory guidance, policies, and performance standards; maintains Departmental contract award information; and conducts special Departmental initiatives related to acquisition. It also serves as the focal point for coordinating ASFR's response to cross-cutting Freedom of Information Act (FOIA) requests, audits, reports, and suspension and debarment activities related to acquisition. The Division provides input for coordinated Department positions on proposed legislation and Government regulations specific to acquisition-related matters. The Division also manages activities associated with the training, development, and certification of—and strategic planning for—the Department's acquisition workforce.

4. Office of Small & Disadvantaged Business Utilization (AMT3). The Office of Small & Disadvantaged Business Utilization (OSDBU) is headed by a Director who reports directly to the Deputy Secretary and is administratively supported by OGAPA. The OSDBU fosters the use of small business as Federal contractors pursuant to Public Law 95–507 and has responsibility within the Department for policy, plans, and oversight to execute

the functions under Sections 8 & 15 of the Small Business Act. The OSDBU provides leadership, policy, guidance and supervision, as well as coordinating short- and long-range strategic planning to assure that small business vendors have a fair opportunity to compete for and receive business with the Department. The Office also provides technical assistance to the Department's OPDIVs and STAFFDIVs; reviews and evaluates planned procurements to ensure that small businesses are given thorough consideration; evaluates effectiveness of the small business programs and processes; develops pertinent HHS-wide policies, guidance, and performance standards; maintains Departmental small business reports; and conducts special Departmental initiatives related to small and socio-economic business concerns. The OSDBU manages the development and implementation of appropriate outreach programs aimed at heightening the awareness of the small business community to the contracting opportunities available within HHS. The OSDBU provides input for coordinated Department positions on proposed legislation and Government regulations on matters affecting cognizant small socioeconomic business programs. It also serves as the focal point for coordinating ASFR's response to cross-cutting Freedom of Information Act (FOIA) requests, audits, and activities related to small business related efforts and programs.

Dated: November 2, 2011.

E.J. Holland, Jr.,

Assistant Secretary for Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0797]

Agency Information Collection Activities; Proposed Collection; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing State enforcement notifications.

DATES: Submit either electronic or written comments on the collection of information by January 9, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

State Enforcement Notifications—21 CFR 100.2(d) (OMB Control Number 0910–0275)—Extension

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the FD&C Act in their own names but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2(d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the FD&C Act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.2(d)	1	1	1	10	10

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.