

Dated: July 3, 2012.

**Sherri A. Berger,**

*Chief Operating Officer, Centers for Disease Control and Prevention.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

#### **Statement of Organization, Functions, and Delegations of Authority**

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 77 FR 27070-27071, dated May 8, 2012) is amended to reflect the reorganization of the Procurement and Grants Office, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows: Delete in its entirety the title and functional statements for the Procurements and Grants Office (CAJH) and insert the following:

*Procurement and Grants Office (CAJH).* (1) Advises the Director, Centers for Disease Control and Prevention (CDC), the Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), and their staff, and provides leadership and direction for CDC acquisition, assistance, and materiel management activities to improve the public's health; (2) plans and develops CDC-wide policies, procedures, and practices in acquisition, assistance, and materiel management areas to support public health science and programs; (3) obtains research and development, services, equipment, supplies, and construction in support of CDC's public health mission through acquisition processes; (4) maintains functions relating to personal property, transportation, and warehousing operations; (5) awards, administers, and terminates contracts, purchase orders, grants, and cooperative agreements essential to improve public health; (6) maintains a continuing program of reviews, evaluations, inquiries, and oversight activities of CDC-wide acquisitions, assistance, and materiel management operations to ensure adherence to laws, policies, procedures, regulations, and alignment to CDC's

public health goals; and (7) maintains liaison with the Department of Health and Human Services (DHHS), General Services Administration (GSA), General Accounting Office (GAO), and other federal agencies on acquisition, assistance, and materiel management policies, procedures, and operating matters.

*Office of the Director (CAJH1).* (1) Provides overall leadership, guidance and coordination in all areas of the Procurement and Grants Office (PGO) activities; (2) ensures PGO's policies, processes, and procedures adhere to all rules and regulations and are in alignment with CDC's public health goals; (3) develops and implements organizational strategic planning goals and objectives that support CDC's public health goals; (4) provides overall budgetary and human resource management, and administrative support; (5) directs and coordinates activities in support of the Department's Equal Employment Opportunity Program and employee development; (6) conducts continuing studies and analysis of branch activities; (7) provides technical and managerial direction for the development, implementation, and maintenance of the Integrated Contracts Expert System on a CDC-wide basis; (8) operates CDC's Small and Disadvantaged Business Program, and provides direction and support to various other socioeconomic programs encompassing acquisition and assistance activities; and (9) develops technical requirements for support business practices through technology.

*Office of Policy, Oversight and Evaluation (CAJHK).* (1) Provides technical and managerial direction for the development of CDC-wide policies, procedures, and practices in the acquisition, assistance, and materiel management areas to support CDC's public health science and programs; (2) participates with senior management in program planning, policy determinations, evaluations, and decisions concerning acquisition, assistance, and materiel management; (3) provides direction for award, administration, measures of effectiveness and termination of contracts, purchase orders, grants, and cooperative agreements; (4) maintains a continuing program of reviews, evaluations, inquiries, and oversight activities of CDC-wide acquisitions, assistance, and materiel management operations to ensure adherence to laws, policies, procedures, and regulations and alignment with CDC's public health goals; (5) maintains liaison with DHHS, GSA, GAO, and other federal agencies on acquisition, assistance, and materiel

management policy, procedures, and operating matters; (6) serves as central CDC receipt and referral point for all applications for assistance funds, including interfacing with the automated grants systems and relevant DHHS line of business agencies and distributing draft public health program announcements for review; and (7) provides cost advisory support to acquisition and assistance activities with responsibility for initiating requests for audits and evaluations, and providing recommendations to contracting officer or grants management officer, as required; participates in negotiations with potential contractors and grantees, develops overhead rates for profit and nonprofit organizations, and provides professional advice on accounting and cost principles in resolving audit exceptions as they relate to the acquisition and assistance processes.

*Buildings and Facilities Contracts Branch (CAJHL).* (1) Directs and controls acquisition planning activities to assure total program needs are addressed and procurements are conducted in a logical, appropriate, and timely sequence; (2) plans, directs, and conducts the acquisition of non-personal services, institutional support services, architect-engineering services, construction of new buildings, alterations, renovations, commodities, and equipment in support of CDC/ATSDR facilities, utilizing a wide variety of contract types and pricing arrangements; (3) provides leadership, direction, procurement options, and approaches in developing specification/statements of work and contract awards; (4) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (5) performs simplified acquisition activities in support of CDC/ATSDR program offices; (6) assures that contractor performance is in accordance with contractual commitments; (7) provides leadership and guidance to CDC/ATSDR project officers and program officials; (8) participates with senior program management in program planning, policy determination, evaluation, and directions concerning acquisition strategies and execution; (9) plans, directs, and coordinates activities of the branch; (10) maintains branch's official contracts files; (11) maintains a close working relationship with facilities management and other CDC components in carrying out their

missions; and (12) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with overall objectives of PGO.

*Acquisition and Assistance Branch I (CAJHM).* This branch supports the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention by performing the following: (1) Plans, directs, and conducts the acquisition of non-personal services, supplies, equipment, research and development, studies, and data collection for CDC through a variety of contractual mechanisms (competitive and non-competitive) to support CDC's public health goals; (2) plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive) across the public health system; (3) reviews statements of work and assistance applications from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and negotiates and issues contract, grant, and cooperative agreement awards; (4) provides continuing surveillance of financial and administrative aspects of acquisition and assistance-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (5) gives technical assistance, where indicated, to improve the management of acquisition and assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC offices and the public; (6) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (7) provides for the collection and reporting of business management and public health programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (8) assures that contractor and grantee performance is in accordance with contractual and assistance commitments; (9) provides leadership and guidance to CDC project officers and public health program officials; (10) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (11) plans, directs, coordinates, and conducts the grants management functions and processes in

support of public health assistance awards, including cooperative agreements, discretionary grants, block grants, and formula grants, to state and local governmental public health entities, universities, colleges, research institutions, hospitals, public and private organizations, small businesses, and minority and/or women-owned businesses for CDC; (12) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (13) maintains branch's official contract and assistance files; (14) maintains a close working relationship with CDC program office components in carrying out their public health missions; and (15) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC.

*Acquisition and Assistance Branch II (CAJHN).* This branch supports the National Center for Emerging and Zoonotic Infectious Diseases and the National Center for Immunization and Respiratory Diseases by performing the following: (1) Plans, directs, and conducts the acquisition of non-personal services, supplies, equipment, research and development, studies, and data collection for CDC through a variety of contractual mechanisms (competitive and non-competitive) to support CDC's public health goals; (2) plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and noncompetitive) across the public health system; (3) reviews statements of work and assistance applications from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals; and negotiates and issues contract, grant, and cooperative agreement awards; (4) provides continuing surveillance of financial and administrative aspects of acquisition and assistance-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (5) gives technical assistance, where indicated, to improve the management of acquisition and assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (6) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving

contractor billings, resolving audit findings, and performing close-out/termination activities; (7) provides for the collection and reporting of business management and public health programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (8) assures that contractor and grantee performance is in accordance with contractual and assistance commitments; (9) provides leadership and guidance to CDC project officers and public health program officials; (10) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (11) plans, directs, coordinates, and conducts the grants management functions and processes in support of public health assistance awards, including cooperative agreements, discretionary grants, block grants, and formula grants, to state and local governmental public health entities, universities, colleges, research institutions, hospitals, public and private organizations, small businesses, and minority and/or women-owned businesses for CDC; (12) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (13) maintains branch's official contract and assistance files; (14) maintains a close working relationship with CDC program office in carrying out their public health missions; and (15) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC.

*Acquisition and Assistance Branch III (CAJHP).* This branch supports the National Center for Birth Defects and Developmental Disabilities and the National Center for Chronic Disease Prevention and Health Promotion by performing the following: (1) Plans, directs, and conducts the acquisition of non-personal services, supplies, equipment, research and development, studies, and data collection for CDC through a variety of contractual mechanisms (competitive and non-competitive) to support CDC's public health goals; (2) plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive) across the public health system; (3) reviews statements of work and assistance applications from a management point of view for conformity to laws, regulations, and

policies and alignment to CDC's public health goals, and negotiates and issues contract, grant, and cooperative agreement awards; (4) provides continuing surveillance of financial and administrative aspects of acquisition and assistance supported activities to assure compliance with appropriate DHHS and CDC policies, and application to public health activities; (5) gives technical assistance, where indicated, to improve the management of acquisition and assistance supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (6) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (7) provides for the collection and reporting of business management and public health programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (8) assures that contractor and grantee performance is in accordance with contractual and assistance commitments; (9) provides leadership and guidance to CDC project officers and public health program officials; (10) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (11) plans, directs, coordinates, and conducts the grants management functions and processes in support of public health assistance awards, including cooperative agreements, discretionary grants, block grants, and formula grants, to state and local governmental public health entities, universities, colleges, research institutions, hospitals, public and private organizations, small businesses, and minority and/or women-owned businesses for CDC; (12) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (13) maintains branch's official contract and assistance files; (14) maintains a close working relationship with CDC program office components in carrying out their public health missions; and (15) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC.

*Acquisition and Assistance Branch IV (CAJHR)*. This branch supports the National Center for Environmental

Health, the National Center for Injury Prevention and Control, and ATSDR by performing the following: (1) Plans, directs, and conducts the acquisition of non-personal services, supplies, equipment, research and development, studies, and data collection for CDC through a variety of contractual mechanisms (competitive and non-competitive) to support CDC's public health goals; (2) plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive) across the public health system; (3) reviews statements of work and assistance applications from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and negotiates and issues contract, grant, and cooperative agreement awards; (4) provides continuing surveillance of financial and administrative aspects of acquisition and assistance-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (5) gives technical assistance, where indicated, to improve the management of acquisition and assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (6) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing closeout/termination activities; (7) provides for the collection and reporting of business management and public health programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (8) assures that contractor and grantee performance is in accordance with contractual and assistance commitments; (9) provides leadership and guidance to CDC project officers and public health program officials; (10) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (11) plans, directs, coordinates, and conducts the grants management functions and processes in support of public health assistance awards, including cooperative agreements, discretionary grants, block grants, and formula grants, to state and local governmental public health entities, universities, colleges, research institutions, hospitals, public

and private organizations, small businesses, and minority- and/or women-owned businesses for CDC; (12) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (13) maintains branch's official contract and assistance files; (14) maintains a close working relationship with CDC program office components in carrying out their public health missions; and (15) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC.

*Acquisition and Assistance Branch V (Field) (CAJHS)*. This branch supports the National Institute for Occupational Safety and Health (NIOSH) by performing the following: (1) Plans, directs, and conducts the acquisition of non-personal services, supplies, equipment, research and development, studies, and data collection for CDC through a variety of contractual mechanisms (competitive and non-competitive) to support CDC's public health goals; (2) plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive) across the public health system; (3) reviews statements of work and assistance applications from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and negotiates and issues contract, grant, and cooperative agreement awards; (4) provides continuing surveillance of financial and administrative aspects of acquisition and assistance-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (5) gives technical assistance, where indicated, to improve the management of acquisition and assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, and the public; (6) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (7) provides for the collection and reporting of business management and public health programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (8) assures that contractor and grantee

performance is in accordance with contractual and assistance commitments; (9) provides leadership and guidance to CDC project officers and public health program officials; (10) provides leadership, direction, procurement options, and approaches in developing specification/statements of work and contract awards; (11) plans, directs, coordinates, and conducts the grants management functions and processes in support of public health assistance awards, including cooperative agreements, discretionary grants, block grants, and formula grants, to state and local governmental public health entities, universities, colleges, research institutions, hospitals, public and private organizations, small businesses, and minority- and/or women-owned businesses for CDC; (12) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (13) maintains branch's official contract and assistance files; (14) maintains a close working relationship with CDC components in carrying out their public health missions; (15) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC; and (16) acquisition and public health assistance functions in support of NIOSH are accomplished with field office locations located in Pittsburgh, PA; Morgantown, WV; Cincinnati, OH; and Spokane, WA.

*Acquisition and Assistance Branch VI (CAJHT).* This branch supports the Office of Surveillance, Epidemiology, and Laboratory Services, the Office of Public Health Preparedness and Response and the Office for State, Tribal, Local, and Territorial Support by performing the following: (1) Plans, directs, and conducts the acquisition of non-personal services, supplies, equipment, research and development, studies, and data collection for CDC through a variety of contractual mechanisms (competitive and noncompetitive) to support CDC's public health goals; (2) plans, directs, and conducts assistance management activities for CDC through the awards of grants and cooperative agreements (competitive and non-competitive) across the public health system; (3) reviews statements of work and assistance applications from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and negotiates and issues contract, grant, and cooperative

agreement awards; (4) provides continuing surveillance of financial and administrative aspects of acquisition and assistance-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (5) gives technical assistance, where indicated, to improve the management of acquisition and assistance-supported activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (6) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (7) provides for the collection and reporting of business management and public health programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (8) assures that contractor and grantee performance is in accordance with contractual and assistance commitments; (9) provides leadership and guidance to CDC project officers and public health program officials; (10) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (11) plans, directs coordinates, and conducts the grants management functions and processes in support of assistance awards, including cooperative agreements, discretionary grants, block grants, and, formula grants, to state and local governmental public health entities, universities, colleges, research institutions, hospitals, public and private organizations, small businesses, and minority- and/or women-owned businesses for CDC; (12) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (13) maintains branch's official contract and assistance files; (14) maintains a close working relationship with CDC program office components in carrying out their public health missions; and (15) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC.

*Acquisition and Assistance Branch VII (Global) (CAJHU).* This branch supports the Center for Global Health and CDC's global acquisition and assistance needs by performing the following: (1) Plans, directs and

conducts the acquisition of a wide variety of services, research and development, studies, data collection, equipment, materials, and personal and non-personal services in support of CDC's international public health operations, utilizing a wide variety of contract types and pricing arrangements; (2) plans, directs, and conducts assistance management activities for CDC's international public health programs; (3) provides leadership, direction, acquisition options, and approaches in developing specifications/statements of work and grants announcements; (4) participates with top public health program management in program planning, policy determination, evaluation, and directions concerning acquisition and grants strategies and execution; (5) provides innovative problem-solving methods in the coordination of international procurement and grants for a wide range plan with public health partners in virtually all major domestic and international health agencies dealing with the United Nations Foundation health priorities/issues, to include resolution of matters with the Department of State; (6) executes contracts and grants in support of international activities; (7) provides business management oversight for contracts and public health assistance awards; (8) participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition and assistance strategies and execution; (9) maintains branch's official contract and assistance files; (10) maintains a close working relationship with CDC public health program office components in carrying out their missions; and (11) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC.

*Acquisition and Assistance Branch VIII (CAJHV).* This branch supports the CDC Office of the Director acquisition requirements by performing the following: (1) Plans, directs, and conducts the acquisition of non-personal services, supplies, equipment, research and development, studies, and data collection for CDC through a variety of contractual mechanisms (competitive and non-competitive); (2) reviews statements of work from a management point of view for conformity to laws, regulations, and policies and alignment to CDC's public health goals, and negotiates and issues contracts; (3) provides continuing surveillance of financial and

administrative aspects of acquisition-supported activities to assure compliance with appropriate DHHS and CDC policies and application to public health activities; (4) gives technical assistance, where indicated, to improve the management of acquisition activities, and responds to requests for management information from the Office of the Director, headquarters, regional staffs, CDC program offices and the public; (5) performs contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities; (6) provides for the collection and reporting of business management and public health programmatic data, and analyzes and monitors business management data on grants and cooperative agreements; (7) assures that contractor performance is in accordance with contractual commitments; (8) provides leadership and guidance to CDC project officers and program officials; (9) provides leadership, direction, procurement options, and approaches in developing specifications/statements of work and contract awards; (10) participates with top program management in public health program planning, policy determination, evaluation, and directions concerning acquisition strategies and execution; (11) maintains branch's official contract files; (12) maintains a close working relationship with CDC program office components in carrying out their missions; and (13) establishes branch goals, objectives, and priorities, and assures their consistency and coordination with the overall objectives of PGO and CDC.

Logistics Management Branch (CAJHW). (1) Develops and implements CDC-wide policies, procedures, and criteria necessary to comply with federal and departmental regulations governing personal property, transportation, shipping, and fleet management; (2) determines, recommends, and implements procedural changes needed to maintain effective management of CDC property including but not limited to: Inventory control; property records; receipt, delivery, tracking, shipping and return of CDC materiel; property reutilization and disposal; transportation of freight; and CDC's vehicle fleet; (3) provides audits, training and technical assistance to CDC Centers/Institute/Offices on property, transportation, shipping, and fleet management; (4) determines the requirement for and serves as the functional proponent for the design,

test, and implementation of logistics management systems; (5) represents CDC on inter- and intra-departmental committees relevant to logistical functions; (6) serves as the CDC liaison to HHS and other federal agencies on logistical matters such as property, transportation and traffic management; and (7) establishes branch goals, objectives and priorities, and assures consistency and coordination with overall Procurement and Grants Office logistical goals and objectives.

Dated: July 3, 2012.

**Sherri A. Berger,**  
Chief Operating Officer, Centers for Disease Control and Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0454]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. **DATES:** Fax written comments on the collection of information by August 27, 2012.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0640. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Juanmanuel Vilela, Office of

Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, [juanmanuel.vilela@fda.hhs.gov](mailto:juanmanuel.vilela@fda.hhs.gov).

**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.

#### Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act—(OMB Control Number 0910-0640)—Extension

On December 22, 2006, the President signed into law the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109-462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application.

Section 502(x) of the FD&C Act (21 U.S.C. 352(x)), which was added by Public Law 109-462, requires the label of a nonprescription drug product marketed without an approved application in the United States to include a domestic address or domestic telephone number through which a responsible person may receive a report of a serious adverse event associated with the product. The guidance document contains questions and answers relating to this labeling requirement and provides guidance to industry on the following topics: (1) The meaning of "domestic address" for purposes of the labeling requirements of section 502(x) of the FD&C Act; (2) FDA's recommendation for the use of an introductory statement before the domestic address or phone number that is required to appear on the product label under section 502(x) of the FD&C Act; and (3) FDA's intent regarding enforcing the labeling requirements of section 502(x) of the FD&C Act. Separate guidance, issued by the Center for Food Safety and Applied Nutrition on reporting for dietary supplements, is announced elsewhere in the **Federal Register**.

*Title:* Guidance for Industry on Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.