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For program technical assistance for the Congressional Glaucoma Caucus Foundation, contact: Joseph B. Smith, National Center on Birth Defects and Developmental Disabilities, 4770 Buford Highway, NE, MS F-35, Atlanta, Georgia 30341, Telephone: (770) 488-7082, Email Address: jos4@cdc.gov.

For program technical assistance for the Children's Hospital of Buffalo, contact: William A. Paradies, National Center on Birth Defects and Developmental Disabilities, 4770 Buford Highway, NE, MS F-45, Atlanta, Georgia 30341, Telephone: (770) 488-4704, Email Address: wep2@cdc.gov.

Dated: May 24, 2001.

**Henry S. Cassell III**

*Acting Director, Procurement and Grant Office, Centers for Disease Control and Prevention (CDC).*

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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 66 FR 20148-20149, dated April 12, 2001) is amended to retitle and revise the functional statement of the Division of Quarantine (DQ), National Center for Infectious Diseases (NCID).

Section C-B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and functional statement for the Division of Quarantine (CR2) and insert the following:

*Division of Global Migration and Quarantine (CR2).* (1) Administers a national quarantine program to protect the United States against the introduction of diseases from foreign countries; (2) administers an overseas program for the medical examination of immigrants and others with inadmissible health conditions that would pose a threat to public health and impose a burden on public health and hospital facilities; (3) maintains liaison with and provides information on quarantine matters to other Federal agencies, State and local

health departments, and interested industries; (4) provides liaison with international health organizations, such as the Pan American Health Organization and the World Health Organization, and participates in the development of international agreements affecting quarantine; (5) conducts studies to provide new information about health hazards abroad, measures for their prevention, and the potential threat of disease introduction into the United States; and (6) provides logistic support to other programs of the Centers for Disease Control and Prevention in the distribution of requested biologicals and movement of biological specimens through U.S. ports of entry.

*Office of the Director (CR21).* (1) Manages directs, and coordinates the activities of the Division; (2) provides leadership in development of Division policy, program planning, implementation, and evaluation; (2) identifies needs and resources for new initiatives and assigns responsibilities for their development; (4) coordinates liaison with other Federal agencies, State and local health departments, and interested industries; (5) coordinates liaison with international health organizations; (6) provides administrative services, including procurement, property and supply management, travel arrangements, space and facilities maintenance, and timekeeper coordination; (7) provides budgeting and fiscal management for the Division; (8) provides personnel support to the Division, both for Civil Service and Commissioned Corps employees, and assures that Division is in compliance with HRMO regulations for all personnel matters; (9) reviews and evaluates all administrative services for both headquarters and Quarantine Stations and provides policy procedures and guidance on such matters; (10) provides statistical and information systems consultation for study design and protocol development; (11) provides user and technical support for Local Area Network (LAN) and other designated software and hardware, and maintains LAN and other information systems in accordance with CDC guidelines; (12) designs and implements database management systems in support of Division projects; (13) provides data analysis and statistical consultation in support of Division projects; (14) assists in production of and provides graphics support for presentations and publications related to Division objectives; and (15) evaluates new software and hardware for statistical analysis, database management, graphics production, geographic information systems, and other functions related to Division objectives.

Dated: May 18, 2001.

**Jeffrey P. Koplan,**

*Director.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 01N-0063]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Current Good Manufacturing Practice Quality System Regulation**

**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.

**DATES:** Submit written comments on the collection of information by July 2, 2001.

**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: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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.

**Medical Devices; Current Good Manufacturing Practice (CGMP) Quality System (QS) Regulation—21 CFR Part 820 (OMB Control No. 0910-0073)—Extension**

Under section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)), the Secretary of the Department of Health and Human Services has the authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a device but not including an evaluation of the safety and effectiveness of a device), packing, storage, and installation of a device conform to CGMP, as described in such regulations, to assure that the device