are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: June 9, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–14946 Filed 6–19–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0114]

Medical Devices; Premarket Notification (510(k)) Procedures/Good Manufacturing Practices; Compliance Program; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of revisions to the standard compliance program for good manufacturing practices (GMP's) (Compliance Program 7382.830). These revisions are intended to refine and refocus FDA's compliance program linking GMP requirements with class I and II premarket notification (510(k)) submissions and other relevant applications. The revisions are being made as part of FDA's reinventing Government initiative and have been incorporated into ''Compliance Program 7382.830, Inspection of Medical Device Manufacturers,'' which supersedes the ''Medical Device Reference List'' procedures.

ADDRESSES: Submit written requests for single copies of the revisions to the Division of Small Manufacturers Assistance (DSMA) (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 or 1–800–638–2041. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist the office in processing your requests. The revisions are available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. Copies of a facsimile of the revision are available from CDRH Facts on Demand by requesting the following document numbers and their respective parts: 2702 (compliance program), 3702 (attachment A), 4702 (attachment A–1), 5702 (attachment B through F), 6702 (attachment G), (1–800–899–0281). Copies of the revisions may also be obtained from the Electronic Docket administered by DSMA and available to any one with a video terminal or personal computer (1–800–252–1366).

FOR FURTHER INFORMATION CONTACT: Marje A. Hoban, Center for Devices and Radiological Health (HFZ–306), Food and Drug Administration, 2094 Gaither Rd., MD 20850, 301–594–4695.

SUPPLEMENTARY INFORMATION: In a letter dated April 7, 1995, the Director of the Center for Devices and Radiological Health advised registered medical device companies of changes that FDA was making to its compliance program linking class I and II 510(k) submissions with GMP requirements. These procedural changes became effective May 1, 1995, and have been made part of the standard compliance program for GMP's (Compliance Program 7382.830). FDA is now making the revisions available in conjunction with the April 7, 1995, letter. The general framework of the restructured program incudes: (1) Criteria for linking GMP's with marketing clearance for class I or II (510(k)) devices; (2) procedures for notifying firms that clearance of their class I or II (510(k)) submission may be deferred due to serious, related GMP violations; (3) actions FDA will take to reply promptly to a firm's response to an FDA Form 483 and/or GMP Warning Letter; and (4) timeframes for agency action. The changes noted above also apply to PMA supplements that are not subject to the PMA preapproval inspection program, and to export certificates for legally marketed devices.

These changes are being made as part of FDA's reinventing Government initiative. This compliance program supersedes the ''Medical Device Reference List'' announced in the **Federal Register** of October 26, 1993 (58 FR 57614).

Dated: June 12, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–14947 Filed 6–19–95; 8:45 am]

BILLING CODE 4160–01–F

Public Health Service

Centers for Disease Control and Prevention; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HC (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 60 FR 17792–17795, dated April 7, 1995) is amended to reflect the merger of the Division of Training and Manpower Development and the Division of Standards Development and Technology Transfer, and the establishment of the Education and Information Division, National Institute for Occupational Safety and Health.

Section HC–B, Organization and Functions, is hereby amended as follows:

After the functional statement for the *Health Effects Laboratory Division (HCC3),* insert the following:

Education and Information Division (HCC4). (1) Develops from existing scientific and technical information documents containing (a) criteria for recommended occupational safety and health standards, and (b) technical and scientific information relevant to a variety of occupational safety and health issues; (2) develops recommended health and safety standards under the Occupational Safety and Health Act of 1970 and the Federal Mine Safety and Health Act of 1977; (3) prepares and coordinates with the Office of the Director comments and testimony on regulations proposed by the Department of Labor and other departments or agencies that pertain to occupational diseases or injuries; (4) assists the Institute Director in establishing and operating a priority system for research, surveillance, document development, and recommended standards; (5) prepares and at least annually revises the legislatively mandated toxic substance list; (6) establishes and maintains a library and a clearinghouse for receiving, storing, retrieving, and disseminating technical information on occupational safety and health; (7) provides risk evaluations for NIOSH