information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the ''INTRODUCTION'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

A copy of American Society for Testing and Materials (ASTM) Number 1292 may be obtained from ASTM, Customer Services, 1916 Race Street, Philadelphia, PA 19103–1187, telephone (215) 299–5585.

Dated: June 9, 1998.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–15805 Filed 6–12–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0378]

Agency Information Collection Activities: Proposed Collection; Comment Request; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of May 19, 1998 (63 FR 27581). The document announced an opportunity for public comment on the proposed collection of certain information by the agency. The document published with the incorrect docket number. This document corrects that error.

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

In FR Doc. No. 98–13228, appearing on page 27581 in the **Federal Register** of Tuesday, May 19, 1998, the following correction is made:

1. On page 27581, in the first column, ''[Docket No. 98N–0194]'' is corrected to read ''[Docket No. 98N–0378]''.

Dated: June 5, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15770 Filed 6–12–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0357]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

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 July 15, 1998.

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: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. 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 section 3507 of the PRA (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) (21 CFR Part 820)—(OMB Control Number 0910–0073—Reinstatement)

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 (the Secretary) has the authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production 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 will be safe and effective and otherwise in compliance with the act.

The CGMP/QS regulation implementing the authority provided by this statutory provision is found in part 820 of the Code of Federal Regulations (21 CFR part 820) and sets forth basic CGMP requirements governing the design, manufacture, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use. Section 820.20(a) through (e) requires management with executive responsibility to establish, maintain, and/or review: The quality policy; the organizational structure; the quality plan; and the quality system procedures of the organization. Section 820.22 requires the conduct and documentation of quality system audits and reaudits. Section 820.25(b) requires the establishment of procedures to identify training needs and documentation of such training.

Section 820.30(a)(1) and (b) through (j) requires, in the following respective order, the establishment, maintenance, and/or documentation of: Procedures to control design of class III and class II devices, and certain class I devices as listed therein; plans for design and development activities and updates; procedures identifying, documenting, and approving design input requirements; procedures defining design output, including acceptance criteria, and documentation of approved records; procedures for formal review of design results and documentation of results in the design history file (DHF); procedures for verifying device design and documentation of results and approvals in the DHF; procedures for validating device design, including documentation of results in the DHF; procedures for translating device design into production specifications; procedures for documenting, verifying validating approved design changes before implementation of changes; and the records and references constituting the DHF for each type of device.

Section 820.40 requires the establishment and maintenance of procedures for the review, approval, issuance and documentation of required records (documents) and changes to those records.

Section 820.50 requires the establishment and maintenance of procedures and requirements to ensure service and product quality, records of acceptable suppliers and purchasing