DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 10-8-04
Publication Date 10-12-04
Certifier R. TEDESMA

[Docket No. 2004N–0034]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Devices; Current Good Manufacturing Practices Quality System Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Medical Devices; Current Good Manufacturing Practices Quality System Regulation" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 14, 2004 (69 FR 33035), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0073. The approval expires on September 30, 2007.

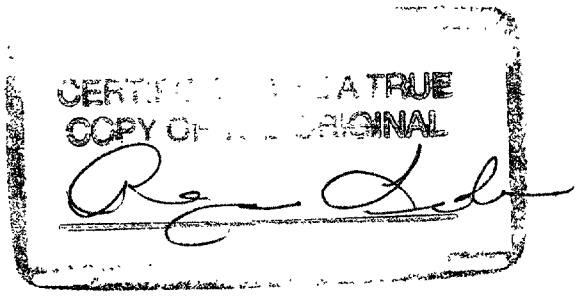
A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: 10/4/04
October 4, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S



PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

1. Agency/Subagency originating request
FDA/CDRH/OC

2. OMB control number
a. 0910 -0073 b. [ ] None

3 Type of information collection (*check one*)

a. [ ] New Collection

b. [ ] Revision of a currently approved collection

c [X] Extension of a currently approved collection

d. [ ] Reinstatement, without change, of a previously approved collection for which approval has expired

e [ ] Reinstatement, with change, of a previously approved collection for which approval has expired

f. [ ] Existing collection in use without an OMB control number
For b-f, note Item A2 of Supporting Statement instructions

4. Type of review requested (*check one*)
a. [x] Regular submission
b. [ ] Emergency - Approval requested by ___/___/___
c. [ ] Delegated

5. Small entities
Will this information collection have a significant economic impact on a substantial number of small entities? [ ] Yes [x] No

6. Requested expiration date
a. [x] Three years from approval date b. [ ] Other Specify: ___/

7. Title Medical Devices: Current Good Manufacturing Practice (CGMP), Quality System (Q/S) Regulation; 21 CFR Part 820; OMB No. 0910-0073

8 . Agency form number(s) (*if applicable*) None

9. Keywords GGP, CGMP, QS, Manufacturing, Quality Systems, 21 CFR Part 820

10. Abstract Section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)) states 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.

21 CFR part 820 sets forth basic CGMP requirements governing the design, manufacture, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use. It contains design and purchasing controls; modifies previous critical device requirements; revises previous validation and other requirements; and harmonizes device CGMP requirements with quality system specifications in the international standard, ISO (International Organization for Standardization) 9001:1994 ``Quality Systems-Model for Quality Assurance in Design, Development Production, Installation and Servicing."

The rule imposes burdens upon finished device manufacturer firms, which are subject to all recordkeeping requirements, and upon finished device contract manufacturer, specification developer, repacker and relabeler, and contract sterilizer firms, which are subject only to requirements applicable to their activities. Re-manufacturers of hospital single use devices are now treated as manufacturers in regard to this regulation. The establishment, maintenance and/or documentation of procedures, records and data required by this final regulation assist FDA in determining whether firms are in compliance with CGMP requirements, and ensures that devices meet their design, production, labeling, installation, and servicing specifications. This validates the devices' safety, effectiveness and suitability for their intended purpose, and should decrease the number of design-related device failures that have resulted in deaths and serious injuries.

11 Affected public (*Mark primary with "P" and all others that apply with "x"*)
a. ___ Individuals or households d. ___ Farms
b. P Business or other for-profit e. ___ Federal Government
c. ___ Not-for-profit institutions f. ___ State, Local or Tribal Government

12. Obligation to respond (*check one*)
a. [ ] Voluntary
b. [ ] Required to obtain or retain benefits
c. [x]Mandatory

13. Annual recordkeeping and reporting burden
a. Number of respondents 8,254
b. Total annual responses 1
1. Percentage of these responses collected electronically 0 %
c. Total annual hours requested 2,833,020
d. Current OMB inventory 3,167,670
e. Difference - 334,650
f. Explanation of difference
1. Program change
2. Adjustment X

14. Annual reporting and recordkeeping cost burden (*in thousands of dollars*)
a. Total annualized capital/startup costs 0
b. Total annual costs (O&M) 1,181,925
c Total annualized cost requested 1,181,925
d. Current OMB inventory 1,181,925
e. Difference 0
f. Explanation of difference
1. Program change
2. Adjustment X

15. Purpose of information collection (*Mark primary with "P" and all others that apply with "X"*)
a. __ Application for benefits e.__ Program planning or management
b X Program evaluation f.__ Research
c. __ General purpose statistics g. P Regulatory or compliance
d. __ Audit

16. Frequency of recordkeeping or reporting (*check all that apply*)
a. [x] Recordkeeping b. [ ] Third party disclosure
c. [ ] Reporting
1. [x] On occasion 2. [ ] Weekly 3. [ ] Monthly
4. [ ] Quarterly 5. [ ] Semi-annually 6. [ ] Annually
7. [ ] Biennially 8. [ ] Other (describe)

17. Statistical methods
Does this information collection employ statistical methods
[ ] Yes [x] No

18. Agency Contact (person who can best answer questions regarding the content of this submission)
Name: Colin Figueroa
Phone: (301) 594-4654 x 119

OMB 83-I 10/95

2004N-0034

551

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal Agency, I certify that the collection if information encompassed by this request complies with 5 CFR 1320.9

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

(a) It is necessary for the proper performance of agency functions;

(b) It avoids unnecessary duplication;

(c) It reduces burden on small entities;

(d) It used plain, coherent, and unambiguous terminology that is understandable to respondents;

(e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;

(f) It indicates the retention period for recordkeeping requirements;

(g) It informs respondents of the information called for under 5 CFR 1320.8(b)(3):

(i) Why the information is being collected;

(ii) Use of information;

(iii) Burden estimate;

(iv) Nature of response (voluntary, required for a benefit, mandatory);

(v) Nature and extent of confidentiality; and

(vi) Need to display currently valid OMB control number;

(h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of instructions);

(i) It uses effective and efficient statistical survey methodology; and

(j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of the provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Senior Official or designee	Date