

NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

Date 07/17/2017

Department of Health and Human Services
Food and Drug Administration

FOR CERTIFYING OFFICIAL: Beth Killoran

FOR CLEARANCE OFFICER: Darius Taylor

In accordance with the Paperwork Reduction Act, OMB has taken action on your request received 06/15/2017

ACTION REQUESTED: Reinstatement without change of a previously approved collection

TYPE OF REVIEW REQUESTED: Regular

ICR REFERENCE NUMBER: 201706-0910-005

AGENCY ICR TRACKING NUMBER: CDRH

TITLE: Reporting and Recordkeeping for Electronic Products - General Requirements

LIST OF INFORMATION COLLECTIONS: See next page

OMB ACTION: Approved without change

OMB CONTROL NUMBER: 0910-0025

The agency is required to display the OMB Control Number and inform respondents of its legal significance in accordance with 5 CFR 1320.5(b).

EXPIRATION DATE: 07/31/2020

DISCONTINUE DATE:

BURDEN:	RESPONSES	HOURS	COSTS
Previous	0	0	0
New	22,995	471,994	0
Difference			
Change due to New Statute	0	0	0
Change due to Agency Discretion	0	0	0
Change due to Agency Adjustment	22,995	471,994	0
Change due to PRA Violation	0	0	0

TERMS OF CLEARANCE:

OMB Authorizing Official: Dominic J. Mancini
Deputy and Acting Administrator,
Office Of Information And Regulatory Affairs

List of ICs

IC Title	Form No.	Form Name	CFR Citation
Reporting for Electronic Products: General Requirements	FDA 3626, FDA 3626, FDA 3631, FDA 3627, FDA 3627, FDA 3639, FDA 3632, FDA 3632, FDA 3640, FDA 3640, FDA 3640, FDA 3630, FDA 3630, FDAS 3646, FDA 3644, FDA 3659, FDA 3660, FDA 3801, FDA 3629, FDA 3661, FDA 3662, FDA 3663, FDA 3628, FDA 3634, FDA 3638, FDA 3641, FDA 3643, FDA 3636	Diagnostic X-Ray, Diagnostic X-Ray (esubmitter), Sunlamp annual report (esubmitter), CT X-Ray, CT X-Ray (esubmitter), Cabinet X-Ray (esubmitter), Laser, Laser (esubmitter), Laser Light Show, Laser Light Show (esubmitter), Sunlamp, Sunlamp (esubmitter), Mercury vapor lamp (esubmitter), Ultrasonic therapy (esubmitter), TV (esubmitter), Microwave oven (esubmitter), UV lamps (esubmitter), General abbreviated report (esubmitter), X-ray tables, etc (esubmitter), Cephalometric device (esubmitter), Microwave products (non-oven) (esubmitter), General Med X-ray annual report (esubmitter), TV annual report (esubmitter), Diagnostic X-ray annual report (esubmitter), Cabinet x-ray annual report (esubmitter), Microwave oven annual report, Laser annual report (esubmitter)	21 CFR 1002.10, 21 CFR 1002.11, 21 CFR 1002.12, 21 CFR 1002.20, 21 CFR 1002.50, 21 CFR 1002.51, 21 CFR 1002.13, 21 CFR 1005.10, 21 CFR 1005.25, 21 CFR 1010.2, 21 CFR 1010.4, 21 CFR 1010.5, 21 CFR 1010.13, 21 CFR 1020.30, 21 CFR 1030.10, 21 CFR 1040.10
Recordkeeping for Electronic Products: General Requirements			21 CFR 1020.30, 21 CFR 1040.10, 21 CFR 1002.30, 21 CFR 1002.31, 21 CFR 1002.40, 21 CFR 1002.41
Third party disclosure for Electronic Products: General Requirements			21 CFR 1002.41, 21 CFR 1040.30, 21 CFR 1050.10, 21 CFR 1002.3, 21 CFR 1002.40, 21 CFR 1002.40, 21 CFR 1020.10, 21 CFR 1020.20, 21 CFR 1020.30, 21 CFR 1020.32, 21 CFR 1020.33, 21 CFR 1020.40, 21 CFR 1030.10, 21 CFR 1040.10, 21 CFR 1040.11, 21 CFR 1040.20