U.S. Food and Drug Admintration
Sunlamp Products; Proposed Amendment to § 1002.1 (Record and Reporting Requirements) and § 1040.20 (Performance Standard)

0910- NEW
RIN 0910-AG30
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Safe Medical Devices Act of 1990 (Pub. L. 101-629), enacted on November 28, 1990, transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602) from Title III of the Public Health Service Act to Chapter V, subchapter C of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360hh *et seq*.). Under these provisions, FDA administers an electronic product radiation control program to protect the public health and safety. This authority provides for developing, amending, and administering radiation safety performance standards for electronic products, including sunlamp products. As electronic products, sunlamp products are subject to the regulations for electronic product radiation control, including 21 CFR parts 1000 through 1010 and § 1040.20.

A sunlamp product is a device that emits ultraviolet (UV) radiation to induce tanning. The device incorporates one or more UV lamps as a radiation source. Examples of sunlamp products are tanning beds, which are used while lying down, and tanning booths, which are used while standing. FDA is concerned about the safety risks from UV radiation. Therefore, FDA is updating our requirements for sunlamp products which allow for indoor exposure to UV radiation. There have been many changes in our understanding of how UV radiation interacts with human skin since the FDA Performance Standard for Sunlamps was last published in 1985. There have also been many changes in the indoor tanning industry which affect the type of equipment on the market and the measurement techniques used by manufacturers. FDA is updating requirements for sunlamp products to bring our regulations up to date with current science. FDA also wants to improve consumers' understanding of the risks related to UV radiation exposure.

Current § 1002.1 requires that sunlamp product manufacturers submit product reports, supplemental reports, and annual reports and requires that test records and distribution records are maintained, used for summary data submitted in the annual report, and made available upon request. In addition, current § 1002.1 requires UV lamp manufacturers to submit product reports. Proposed § 1002.1 would require that manufacturers of UV lamps also submit supplemental reports and annual reports and maintain test records and distribution records.

Proposed § 1002.1 would also require that manufacturers of protective eyewear maintain test records and distribution records as well as submit annual reports, supplemental reports, and product reports. The eyewear must meet certain transmittance limits in the UV and visible wavelength range. Both manufacturers of sunlamp products that include eyewear with their products and manufacturers of protective eyewear that is sold separately would be responsible for maintaining records of the results yielded by the testing and reporting these results to FDA. (See § 1002.1.) There are no operating and maintenance costs associated with testing the eyewear because this requirement reflects current market practices.

Proposed § 1040.20(d)(2)(ii) would require that the UV lamp labeling include a replacement lamp code instead of a list of compatible replacement lamps. Although the single UV lamp manufacturer in the United States is already required to conduct spectral irradiance testing of lamps in order to demonstrate compatibility with other model lamps (whether made by that company or other manufacturers), proposed § 1040.20(d)(2)(ii) would require testing in accordance with test methods as specified in IEC 61228, Ed. 2.0, ''Fluorescent Ultraviolet Lamps Used for Tanning—Measurement and Specification Method.'' The spectral irradiance data obtained is used to calculate the UV code that would be required to be printed on the lamp by proposed § 1040.20(d)(2)(ii). Manufacturers would be responsible for maintaining and reporting records of the results yielded by the testing as well as imprinting the lamp with the replacement lamp code.

Proposed § 1040.20(d)(2)(iii) would require that each UV lamp have a label containing the model identification of the lamp, if applicable. Manufacturers would be responsible for printing the model number on the lamp itself. Proposed § 1040.20(d)(3)(iii) would permit the manufacturer of the sunlamp product or UV lamp to submit a request to the Director, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health for an approval of alternate labeling if the size, configuration, design, or function of the sunlamp product or UV lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective. In these circumstances, manufacturers would be responsible for reporting the request to FDA. The operating and maintenance costs associated with this provision are based on correspondence costs (postage) for non-email communications.

Proposed § 1040.20(d)(3)(iv) would permit manufacturers of UV lamps to permanently affix or inscribe the tags or labels required by §§ 1010.2(b) and 1010.3(a) on the lamp packaging associated with the UV lamps, rather than the UV lamps themselves. The third party disclosure burden of this provision would be the time it takes to inscribe the label or tag on the UV lamp packaging.

Proposed § 1040.20(e)(1)(v) would require instructions for sunlamp ''assembly, operation, and maintenance,'' and would include a schedule of maintenance. This information would also protect those maintaining and assembling sunlamp products from inadvertent exposure to UV radiation by providing adequate instructions to avoid UV exposure during assembly or maintenance. We presume that the maintenance schedules

would be developed from known information about how to properly maintain these devices. The third party disclosure burden of this provision would be the time spent bringing this known information into a user-friendly format and disclosing it to users. We also assume that this information would be identical for all units of a given model of sunlamp products.

Proposed § 1040.20(g) would require that those who change the function or performance characteristics of a sunlamp are manufacturers and would need to recertify and re-identify the device. This requirement applies only if the modification affects any aspect of the product's performance or intended function(s) for which § 1040.20 has an applicable requirement. We believe some sunlamp owners (e.g., tanning facility owners) view such modifications as a less expensive alternative to purchasing a new sunlamp product. We believe some owners, otherwise inclined to alter their sunlamp's performance characteristics, would be deterred from doing so by our proposal because recertification would cost a tanning facility owner more than $30,000 in operating and maintenance costs since tanning facility owners do not typically have the equipment necessary to recertify sunlamp products. However, if a tanning facility owner chooses to recertify the sunlamp product, documentation must be submitted to FDA.

2. Purpose and Use of the Information Collection

   This information will be provided by private sector businesses.

   FDA wants to ensure that all test data necessary to ensure compliance with § 1040.20 and other relevant regulations and standards is collected and maintained.

   A considerable amount of this information collection relates to third-party disclosure. Based on its analysis of the consumer testing, FDA concluded that the previous warning statement could be made more effective by changes to its required language, formatting, and location. FDA believes that the current warning statement most effectively conveys the risks of indoor tanning to users. Similarly, the labeling provisions ensure that respondents present the necessary compatibility codes in order for the electronic products to function properly and safely.

3. Use of Improved Information Technology and Burden Reduction

   FDA expects 22 total reporting submissions. Respondents have the option of submitting all of these filings electronically.

   FDA estimates that 20% of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

   FDA is the only Federal agency responsible for the collection of information associated with sunlamp products. No similar information is currently collected by any other agency and, therefore, no similar information is available that can be used or modified for the purpose described.

5. Impact on Small Businesses or Other Small Entities

100% of the affected businesses are small businesses. FDA does not believe the regulation will have a significant impact on a substantial number of these small entities.

FDA aids small businesses and manufacturers to comply with applicable statutes and regulations by providing guidance and information through the Division of Small Manufacturers, International, and Consumers Assistance (DSMICA) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DISMICA provides workshops, on-site evaluations and other technical and nonfinancial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device labeling information. The Division also maintains a toll-free 800 telephone number and a website which firms may use to obtain regulatory compliance information.

6. Consequences of Collecting the Information Less Frequently

Annual and supplemental reports from UV lamp manufacturers required by 1002.1(b) will be submitted yearly and occasionally, respectively.

Protective eyewear product reports required under 1002.1(b) are submitted occassionally in order for FDA to verify that protective eyewear meets applicable requirements.

Reports required by 1040.20(d)(2)(ii) are submitted occasionally in order for FDA to verify that the requisite spectral irradiance testing has been performed on UV lamps.

Reports required by 1040.20(d)(3)(iii) are submitted occasionally when a manufacturer of a sunlamp product of UV lamp cannot comply with the required label due to size, configuration, design, or function of the sunlamp product or UV lamp.

The reporting requirement under 1040.20(g) would be submitted occasionally if someone makes modifications to the sunlamp product and would like to recertify it.

Subsequent modifications to a product may require a supplemental report, which are only required when the new model has changes that affect the radiation hazard from the product. This would be a one-time submission. Generally, all manufacturers of electronic products subject to the reporting requirements under this clearance must file an Annual report, which is a production summary report.

The statutes and regulations generally require that labeling accompany each shipment of a device. If this were not done, the device user may not have the necessary information for the safe and effective use of the device.

If this information were obtained less frequently, fewer report reviews and evaluations of compliance could be conducted by FDA, which could potentially result in endangering the public health through unnecessary exposure to electronic radiation. In the event that this product information was not provided to FDA in a timely manner, a hazard could go undetected and the risk to the public from unnecessary radiation would be increased significantly. If information was not provided to users, distributors, or assemblers at the

time of possession of the product they may be unable to make rational decisions and take actions relating to safety.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of 12/22/2015 (80 FR 79505).

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information that is made available in labeling is, by its nature, public information. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. All records and other information submitted to FDA are releasable under 21 CFR Part 20. FDA can and does routinely protect company proprietary information, but does not have on-site means of complying with the requirements for material classified in national security interests.

11. Justification for Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Time estimates were based on informal testing in the office and experience with current similar activities.

Table 1. - Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1002.1(b) – Lamp only	1	9	9	2	18
1002.1(b) –	5	4	20	0.5	10

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Protective eyewear					
1040.20(d)(2)(ii)	1	1	1	1	1
1040.20(d)(3)(iii)	1	1	1	.17 (10 minutes)	.17
1040.20(g)	1	1	1	8	8
TOTAL					37

Reporting Burden

For 1002.1(b) – Lamp only, we estimate the single U.S.-based manufacturer of UV lamps will need to submit 2 new reports (supplemental reports and an annual report) for the 75 models. Based on previous submissions, we estimate that 9 supplemental reports will be submitted per year. Annual reports are submitted once per year. We estimate that it takes approximately 2 hours to complete each report for a total of 18 burden hours.

For 1002.1(b) – Protective eyewear, we estimate that the five respondents would need to report the information annually and that each of the manufacturers produces two models of protective eyewear. Manufacturers are not required to produce two types of eyewear, however FDA estimates that each of the five respondents produces two types of eyewear that could be made available for use with sunlamp products. Manufacturers would fill out and submit the annual, supplemental, and product reports demonstrating conformance to the performance standard, and this process is estimated to take 30 minutes per report for a total of 10 hours.

For 1040.20(d)(2)(ii), we estimate that the single U.S.-based manufacturer of UV lamps will test 75 UV lamps and that the time needed to incorporate the data into the product report is 1 hour.

For 1040.20(d)(3)(iii), we estimate that 1 sunlamp product and UV lamp manufacturer will submit a request for alternate labeling approval to FDA. This task is expected to be performed by clerical staff that prepare the request and submit it to FDA. This process is expected to take 10 minutes (.17 hours) to type the request and e-mail it. The request is expected to be submitted electronically and does not involve any operating and maintenance cost.

For 1040.20(g), we estimate that, at most, one respondent per year will decide to re-certify a sunlamp product with the agency, instead of the less expensive alternative of purchasing a new sunlamp product. The $43,000 capital costs for recertifying the sunlamp product includes the required instrumentation and calibration light sources such as a double-grating spectroradiometer with integrating sphere and software. We estimate the time needed to make the necessary spectral measurements and compile them into a report that will be sent to FDA to take 8 hours.

Table 2. - Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1002.1(b) – Lamp only	1	2	2	2.5	5
1002.1(b) – Protective eyewear	5	3	15	7	105
1040.20(d)(2)(ii)	1	75	75	0.8	60
TOTAL					170

Recordkeeping Burden

For 1002.1(b) – Lamp only, we estimate the single U.S.-based manufacturer of UV lamps will need to maintain 2 types of records (test records and distribution records) for each of the 75 models and that it takes approximately 2 minutes per model per record for a total of 300 minutes, or 5 burden hours.

For 1002.1(b) – Protective eyewear, we estimate that there are five U.S. manufacturers of protective eyewear that will be affected by this amendment. However, this number is uncertain and we welcome comment on this issue. We estimate that each of the manufacturers produces two models of protective eyewear and the manufacturer will sample approximately 10 units per model. The time required to perform the necessary testing, including time to verify the instrument, set up the test and prepare and file a report takes approximately seven hours per model. Protective eyewear manufacturers would also be required to maintain distribution records for their products. We estimate that 7 hours per year would be necessary for the manufacturer to log and file the distribution data. We estimate a total of 105 hours for each manufacturer to maintain the single distribution record for both models of pretective eyewear as well as perform the testing for the individual test records that are to be maintained for each model of protective eyewear.

For 1040.20(d)(2)(ii), we expect that the single U.S. based lamp manufacturer does not use IEC UV codes and would have to test and label its models under the proposed rule. The manufacturer has an estimated 30 to 120 models and we chose the mean number of models – 75 – for our calculations. Manufacturers are already performing similar spectral irradiance testing to determine lamp compatibility. We estimate that it will take 0.8 hours per model to modify the test set-up to measure spectral irradiance in order to determine the UV code as well as file the results, for a total of 60 hours. We estimate that the single U.S.-based lamp manufacturer is already maintaining records of these tests, so there should be no additional cost associated with proposed 1002.1 that required lamp manufacturers now also to maintain test records, although FDA is seeking comment on this understanding.

Table 3. - Estimated Annual Third Party Disclosure Burden

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
1040.20(d)(1)(vi)	5	5,200	26,000	.0034	88
1040.20(d)(2)(ii)	1	286,000	286,000	.0017	486
1040.20(d)(2)(iii)	1	286,000	286,000	.0017	486
1040.20(d)(3)(ii)	1	286,000	286,000	.0017	486
1040.20(d)(3)(iv)	1	23,833	23,833	.0017	41
1040.20(e)(1)(v)	5	10	50	12	600
TOTAL					2,187

Third Party Disclosure Burden

For 1040.20(d)(1)(vi), we estimate that the 5 respondents will need to list the code range that can be used in each of the 5,200 sunlamp products produced annually. We estimate 2 minutes to print and affix this label on each of the 26,000 total sunlamp products, for a total of 88 hours.

For 1040.20(d)(2)(ii), the single U.S.-based lamp manufacturer will need to inscribe the UV lamp equivalency code onto each lamp. We estimate it will take 1 minute to ink stamp ten lamps with the new UV lamp equivalency code. The operating and maintenance costs for this information collection are subsumed in the recordkeeping burden estimate for 1040.20(d)(2)(ii). The lamp manufacturer produces 286,000 new lamps per year so this process is expected to take approximately 28,600 minutes per year, or about 486 hours.

For 1040.20(d)(2)(iii), the single U.S.-based lamp manufacturer will need to inscribe the model identification onto each lamp. We estimate it will take 1 minute to ink stamp ten lamps with the model identifier. The lamp manufacturer produces 286,000 new lamps per year so this process is expected to take approximately 28,600 minutes per year, or about 486 hours.

For 1040.20(d)(3)(iv), we estimate that the single U.S.-based lamp manufacturer will permanently affix or inscribe the tags or labels required by 1010.2(b) and 1010.3(a) on the packaging of all the ultraviolet lamps rather than the lamps themselves. Since lamps are typically packaged and sold in cases of 12, this yields 23,833 packages that must bear the third party disclosure required by 1040.20(d)(3)(iv). We estimate it will take 1 minute to ink stamp ten lamp packages with the tags or labels required by 1010.2(b) and 1010.3(a) for a total of 41 hours.

For 1040.20(d)(3)(ii), the single U.S. based lamp manufacturer will need to inscribe or affix the UV lamp equivalency code on the packaging of each lamp. We estimate it will take 1 minute to ink stamp ten lamp packages with the new UV lamp equivalency code. The lamp manufacturer produces 286,000 new lamps per year so this process is expected to take 28,600 minutes per year, or about 486 hours.

For 1040.20(e)(1)(v), we estimate the 5 respondents would need to go through this reporting exercise once for each of their 10 models of sunlamp products. We estimate that 10 hours of a technician's time will be required to collect all the necessary information regarding maintenance and assembly and 2 hours of a manager's time to review this information once it is re-formatted into the user instructions. Thus, we estimate a total of 12 hours per model of tanning bed/booth will be required for a total of 600 hours. This would be a one-time burden.

12b. Annualized Cost Burden Estimate

The annual cost to respondents for submitting and maintaining information relating to the amendment of the sunlamp performance standard is $65,029. This figure was derived by identifying the type of employee that would perform the activity required by the information collection and determining the hourly wage rate for that type of employee from the Bureau of Labor and Statistics. Multiplying the wage rate for that type of employee by the number of hours estimated in tables 1, 2, and 3 above provided the total respondent costs of $65,029.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Technician	2,357	$27	$63,639
Regulatory Affairs Specialist	32	$75	$2,400
Clerical Staff	5	$14	$70
Total			$66,109

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

Proposed section 1040.20(d)(2)(ii) requires that UV lamp manufacturers test the lamps and label them according to the IEC standard. FDA estimates that 75 lamp models would need to be tested and that the mean cost of testing each lamp model is $350 while the cost for an ink stamp is $50 per model. With 75 models, this yields $30,000 in operating and maintenance costs ($350 + $50 = $400 x 75 models = $30,000).

Proposed section 1040.20(d)(2)(iii), requires the lamp manufacturer to inscribe the model identification onto each lamp. The operating and maintenance costs for this information collection are subsumed in the recordkeeping burden estimate for 1040.20(d)(2)(ii).

For proposed § 1040.20(g), we estimate that, at most, one respondent per year will decide to re-certify a sunlamp product with the agency, instead of the less expensive alternative of purchasing a new sunlamp product. The $43,000 capital costs for recertifying the sunlamp product includes the required instrumentation and calibration light sources such as a double-grating spectroradiometer with integrating sphere and software.

14. Annualized Cost to the Federal Government

We estimate that reviewing the data submitted to FDA in the 22 reporting responses pursuant to the amendment to the sunlamp performance standard will take approximately 1 hour per submission or 22 hours. At a fully-loaded rate of $100 per hour for a GS-13 Step 10 FDA employee, this is expected to cost the Federal Government $2,200.

15. Explanation for Program Changes or Adjustments

    This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

    Not applicable.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

    FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.

B. Statistical Methods (used for collection of information employing statistical methods)

There are no statistical methods being employed in this collection of information.