TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Record-keeping | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| 101.13(q)(5) | 300,000 | 1.5 | 450,000 | 0.75 | 337,500 |
| 101.14(d)(2) | 300,000 | 1.5 | 450,000 | 0.75 | 337,500 |
| 101.22(i)(4) | 25 | 1 | 25 | 1 | 25 |
| 101.100(d)(2) | 1,000 | 1 | 1,000 | 1 | 1,000 |
| 101.105(t) | 100 | 1 | 100 | 1 | 100 |
| Total | | | | | 676,150 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated annual reporting and recordkeeping burdens are based on agency communications with industry and FDA's knowledge of and experience with food labeling and the submission of petitions and requests to the agency. Where an agency regulation implements an information collection requirement in the act or the FPLA, only any additional burden attributable to the regulation has been included in FDA's burden estimate.

No burden has been estimated for those requirements where the information to be disclosed is information that has been supplied by FDA. Also, no burden has been estimated for information that is disclosed to third parties as a usual and customary part of a food producer's normal business activities. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: February 20, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7–3257 Filed 2–26–07; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2006N–0427]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information 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:** Fax written comments on the collection of information by March 29, 2007.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

### Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products (OMB Control Number 0910–0025)—Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ii through 360ss), FDA has the responsibility to protect the public from unnecessary exposure of radiation from electronic products. The regulations issued under these authorities are listed in the Code of Federal Regulations, title 21, chapter I, subpart J. Specifically, 1410.10 of the FDA Staff Manual Guide delegates administrative authorities to FDA.

Section 532 of the act directs the Secretary of Health and Human Services (the Secretary), to establish and carry out an electronic product radiation control program, including the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. The program is designed to protect the public health and safety from electronic radiation, and the act authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products.

Section 534(g) of the act directs the Secretary to review and evaluate industry testing programs on a continuing basis; and section 535(e) and (f) of the act directs the Secretary to immediately notify manufacturers of, and ensure correction of, radiation defects or noncompliances with performance standards.

Section 537(b) of the act contains the authority to require manufacturers of electronic products to establish and maintain records (including testing records), make reports, and provide

information to determine whether the manufacturer has acted in compliance.

Parts 1002 through 1010 (21 CFR parts 1002 through 1010) specify reports to be provided by manufacturers and distributors to FDA and records to be maintained in the event of an investigation of a safety concern or a product recall.

FDA conducts laboratory compliance testing of products covered by regulations for product standards in parts 1020, 1030, 1040, and 1050 (21 CFR parts 1020, 1030, 1040, and 1050).

FDA details product-specific performance standards that specify information to be supplied with the product or require specific reports. The information collections are either specifically called for in the act or were developed to aid the agency in performing its obligations under the act. The data reported to FDA and the records maintained are used by FDA and the industry to make decisions and take actions that protect the public from radiation hazards presented by electronic products. This information refers to the identification of, location of, operational characteristics of, quality assurance programs for, and problem identification and correction of electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

FDA uses the following forms to aid respondents in the submission of information for this information collection:

FDA Form 2579 ''Report of Assembly of a Diagnostic X-ray System''

FDA Form 2767 ''Notice of Availability of Sample Electronic Product''

FDA Form 2877 ''Declaration for Imported Electronic Products Subject To Radiation Control Standards''

FDA Form 3649 ''Accidental Radiation Occurrence''

FDA Form 3626 ''A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components''

FDA Form 3627 ''Diagnostic X-ray CT Products Radiation Safety Report''

FDA Form 3628 ''General Annual Report (Includes Medical, Analytical, and Industrial X-ray Products Annual Report)''

FDA Form 3629 ''Abbreviated Report''

FDA Form 3630 ''Guide for Preparing Product Reports on Sunlamps and Sunlamp Products''

FDA Form 3631 ''Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products''

FDA Form 3632 ''Guide for Preparing Product Reports on Lasers and Products Containing Lasers''

FDA Form 3633 ''General Variance Request''

FDA Form 3634 ''Television Products Annual Report''

FDA Form 3635 ''Laser Light Show Notification''

FDA Form 3636 ''Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products''

FDA Form 3637 ''Laser Original Equipment Manufacturer (OEM) Report''

FDA Form 3638 ''Guide for Filing Annual Reports for X-ray Components and Systems''

FDA Form 3639 ''Guidance for the Submission of Cabinet X-ray System Reports Pursuant to 21 CFR 1020.40''

FDA Form 3640 ''Reporting Guide for Laser Light Shows and Displays''

FDA Form 3147 ''Application for a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device''

FDA Form 3641 ''Cabinet X-ray Annual Report''

FDA Form 3642 ''General Correspondence''

FDA Form 3643 ''Microwave Oven Products Annual Report''

FDA Form 3644 ''Guide for Preparing Product Reports for Ultrasonic Therapy Products''

FDA Form 3645 ''Guide for Preparing Annual Reports for Ultrasonic Therapy Products''

FDA Form 3646 ''Mercury Vapor Lamp Products Radiation Safety Report''

FDA Form 3647 ''Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps''

In the **Federal Register** of November 3, 2006 (71 FR 64714), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

The most likely respondents to this information collection will be electronic product and X-ray manufacturers, importers, and assemblers.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | FDA Form Number | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|---|
| 1002.3 | | 10 | 1 | 10 | 12 | 120 |
| 1002.10 | 3626—Diagnostic X-ray<br>3627—CT X-ray<br>3639—Cabinet X-ray<br>3632—Laser<br>3640—Laser Light Show<br>3630—Sunlamp<br>3646—Mercury Vapor Lamp<br>3644—Ultrasonic Therapy | 540 | 1.6 | 850 | 24 | 20,400 |
| 1002.11 | | 1,000 | 1.5 | 1,500 | 0.5 | 750 |
| 1002.12 | 3629—Abbreviated Report | 150 | 1 | 150 | 5 | 750 |
| 1002.13 | 3628—General<br>3634—TV<br>3638—Diagnostic X-ray | 900 | 1 | 900 | 26 | 23,400 |

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

| 21 CFR Section | FDA Form Number | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|---|
| | 3641—Cabinet X-ray<br>3643—Microwave Oven<br>3636—Laser<br>3631—Sunlamp<br>3647—Mercury Vapor Lamp<br>3645—Ultrasonic Therapy | | | | | |
| 1002.13 | | 250 | 2.4 | 600 | 0.5 | 300 |
| 1002.20 | 3649—ARO | 40 | 1 | 40 | 2 | 80 |
| 1002.41(a) | | 1 | 1 | 1 | 1 | 1 |
| 1002.50(a) and 1002.51 | 3642—General Correspondence | 10 | 1.5 | 15 | 1 | 15 |
| 1005.10 | 2767—Sample Product | 145 | 11.03 | 1,600 | 0.09 | 144 |
| 1005.25(b) | | 1 | 1 | 1 | 1 | 1 |
| | 2877—Imports Declaration | 600 | 32 | 19,200 | 0.2 | 3,840 |
| 1010.2 and 1010.3 | | 1 | 1 | 1 | 5 | 5 |
| 1010.4(b) | 3633—General Variance Request<br>3147—Laser Show Variance Request<br>3635—Laser Show Notification | 1 | 1 | 1 | 120 | 120 |
| 1010.5(c) and (d) | | 2 | 1 | 2 | 22 | 44 |
| 1010.13 | | 1 | 1 | 1 | 10 | 10 |
| 1020.20(c)(4) | | 1 | 1 | 1 | 1 | 1 |
| 1020.30(d), (d)(1), and (d)(2) | 2579—Assembler Report | 2,345 | 8.96 | 21,000 | 0.30 | 6,300 |
| 1020.30(g) | | 200 | 1.33 | 265 | 35 | 9,275 |
| 1020.30(h)(1) through (h)(4) and 1020.32(a)(1) and (g) | | 200 | 1.33 | 265 | 35 | 9,275 |
| 1020.30(h)(5) and (h)(6) and 1020.32(j)(4) | | 20 | 5 | 100 | 180 | 18,000 |
| 1020.32(g) and 1020.33(c), (d), and (g)(4) | | 9 | 1.00 | 9 | 40 | 360 |
| 1020.40(c)(9)(i) and (c)(9)(ii) | | 8 | 1.00 | 8 | 40 | 320 |
| 1030.10(c)(4) | | 41 | 1.61 | 66 | 20 | 1,320 |
| 1030.10(c)(5)(i) through (c)(5)(iv) | | 41 | 1.61 | 66 | 20 | 1,320 |
| 1030.10(c)(6)(iii) and (c)(6)(iv) | | 1 | 1 | 1 | 1 | 1 |
| 1040.10(a)(3)(i) | 3637—OEM Report | 83 | 1 | 83 | 3 | 249 |
| 1040.10(h)(1)(i) through (h)(1)(vi) | | 805 | 1.00 | 805 | 8 | 6,440 |
| 1040.10(h)(2)(i) and (h)(2)(ii) | | 100 | 1.00 | 100 | 8 | 800 |

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

| 21 CFR Section | FDA Form Number | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|---|
| 1040.11(a)(2) | | 190 | 1.00 | 190 | 10 | 1,900 |
| 1040.20(d)(1)(ii) through (d)(1)(vi) and (e)(1) and (e)(2) | | 110 | 1.00 | 110 | 10 | 1,100 |
| 1040.30(c)(1)(ii) | | 1 | 1.00 | 1 | 1 | 1 |
| 1040.30(c)(2) | | 7 | 1.00 | 7 | 1 | 7 |
| 1050.10(d)(1) through (d)(4) and (f)(1) through (f)(2)(iii) | | 10 | 1.00 | 10 | 56 | 560 |
| Total | | | | | | 107,209 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| 1002.30 and 1002.31(a) | 1,150 | 1,655.5 | 1,903,825 | 198.7 | 228,505 |
| 1002.40 and 1002.41 | 2,950 | 49.2 | 145,140 | 2.4 | 7,080 |
| 1020.30(g) | 22 | 1 | 22 | 0.5 | 11 |
| 1040.10(a)(3)(ii) | 83 | 1 | 83 | 1.0 | 83 |
| Totals | | | | | 235,679 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection requirements under OMB control number 0910–0564 and Form FDA 3626, the data collection instrument for this collection, have been consolidated under the information collection activity of OMB control number 0910–0025, thus resulting in an adjustment (increase) in the current burden estimate.

The burden estimates were derived by consultation with FDA and industry personnel and actual data collected from industry. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry. When information is generally provided to users, assemblers, or dealers in the same manual, they have been grouped together in the ''Estimated Annual Reporting Burden'' table (table 1 of this document).

The following information collection requirements are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA: Sections 1002.31(c); 1003.10(a), (b), and (c); 1003.11(a)(3) and (b); 1003.20(a) through (h); 1003.21(a) through (d); 1003.22(a) and (b); 1003.30(a) and (b); 1003.31(a) and (b); 1004.2(a) through (i); 1004.3(a) through (i); 1004.4(a) through (h); 1005.21(a) through (c); and 1005.22(b). These requirements ''apply to the collection of information during the conduct of general investigations or audits'' (5 CFR 1320.4(b)). The following labeling requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (1410.10 of the FDA Staff Manual Guide and §§ 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1)).

Dated: February 20, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7–3258 Filed 2–26–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2007N–0051]**

### Safety of Fresh Produce; Public Hearings; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public hearings; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing two public hearings concerning the safety of fresh produce. The purpose of the hearings is for FDA to share information about recent outbreaks of foodborne illness associated with microbial contamination of fresh produce, and to solicit comments, data, and other scientific information about current agricultural and manufacturing practices used to produce, harvest, pack, cool, process, and transport fresh produce; risk factors for contamination of fresh produce associated with these practices; and possible measures by FDA to enhance the safety of fresh produce.

**DATES:** The first public hearing will be held on March 20, 2007, from 9 a.m. to