## IV. Paperwork Reduction Act of 1995

This guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). The collections of information in 21 CFR part 801 are approved under OMB control number 0910–0485 and the collections of information in 21 CFR part 610, subpart G, are approved under OMB control number 0910–0338.

The labeling provisions recommended in this guidance are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA. Rather, the recommended labeling is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

## V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: November 25, 2014.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2014–28265 Filed 12–1–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–1936]**

### Establishment of a Public Docket; Electronic Cigarettes and the Public Health Workshop

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

**ACTION:** Notice; establishment of docket; request for data, information, and comments.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Tobacco Products, is establishing a public docket in conjunction with the first public workshop to gather scientific information about electronic cigarettes (e-cigarettes) as announced in Docket No. FDA–2014–N–0001–0079. Regardless of attendance at the public workshop, interested parties are invited to submit comments, supported by research and data, regarding electronic cigarettes and the public health.

**DATES:** Submit written or electronic comments by April 15, 2015.

**ADDRESSES:** Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *workshop.CTPOS@fda.hhs.gov.*

## I. Background

On September 17, 2014, FDA announced a public workshop to gather information about e-cigarettes and the public health (Electronic Cigarettes and the Public Health; Public Workshop; 79 FR 55815, September 17, 2014, Docket No. FDA–2014–N–0001). The focus of the workshop is product science (specifically device designs and characteristics, and e-liquid and aerosol constituents), product packaging, constituent labeling, and environmental impact. FDA intends to follow the first workshop with two additional e-cigarette workshops; one on individual health effects and one on population health effects. As stated in the **Federal Register** notice of the public workshop, the workshops are not intended to inform the Agency's deeming rulemaking. The workshops are intended to better inform FDA about these products. Should the Agency move forward as proposed to regulate e-cigarettes, additional information about the products would assist the Agency in carrying out its responsibilities under the law.

## II. Submission of Comments

Regardless of attendance at the public workshop, interested parties are invited to submit comments, supported by research and data, regarding e-cigarettes and the public health. Information related to workshop presentations and discussion topics, including specific questions to be addressed at the workshop, can be found at *http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm.*

Interested persons may submit either electronic comments to this docket at *http://www.regulations.gov or* written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: November 25, 2014.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2014–28261 Filed 12–1–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than January 2, 2015.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Data System for Organ Procurement and Transplantation Network OMB No. 0915–0157—Revision.

*Abstract:* Section 372 of the Public Health Service (PHS) Act requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). This is a request for revisions to current OPTN data collection forms associated with donor organ procurement and an individual's clinical characteristics at the time of registration, transplant, and follow-up after the transplant.

*Need and Proposed Use of the Information:* Data for the OPTN data system are collected from transplant hospitals, organ procurement organizations, and tissue-typing laboratories. The information is used to indicate the disease severity of transplant candidates, to monitor compliance of member organizations with OPTN rules and requirements, and to report periodically on the clinical and scientific status of organ donation and transplantation in this country. Data are used to develop transplant, donation and allocation policies, to determine whether institutional members are complying with policy, to determine member-specific performance, to ensure patient safety, and to fulfill the requirements of the OPTN Final Rule. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and members of the public for evaluation, research, patient information, and other important purposes.

*Likely Respondents:* Transplant programs, organ procurement organizations, histocompatibility laboratories, medical and scientific organizations, and public organizations.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

| Form name | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| Deceased Donor Registration | 58 | 158.2 | 9174 | 1.1 | 10091.4 |
| Living Donor Registration | 296 | 20.2 | 5984 | 1.8 | 10771.2 |
| Living Donor Follow-up | 296 | 59.5 | 17610 | 1.3 | 22893.0 |
| Donor Histocompatibility | 154 | 94.8 | 14598 | 0.2 | 2919.6 |
| Recipient Histocompatibility | 154 | 170.1 | 26199 | 0.4 | 10479.6 |
| Heart Candidate Registration | 131 | 30.5 | 3991 | 0.9 | 3591.9 |
| Heart Recipient Registration | 131 | 19.3 | 2525 | 1.4 | 3535.0 |
| Heart Follow Up (6 Month) | 131 | 17.0 | 2229 | 0.4 | 891.6 |
| Heart Follow Up (1–5 Year) | 131 | 73.9 | 9683 | 0.9 | 8714.7 |
| Heart Follow Up (Post 5 Year) | 131 | 115.2 | 15091 | 0.5 | 7545.5 |
| Heart Post-Transplant Malignancy Form | 131 | 11.0 | 1447 | 0.9 | 1302.3 |
| Lung Candidate Registration | 65 | 39.0 | 2534 | 0.9 | 2280.6 |
| Lung Recipient Registration | 65 | 29.6 | 1923 | 1.4 | 2692.2 |
| Lung Follow Up (6 Month) | 65 | 25.8 | 1677 | 0.5 | 838.5 |
| Lung Follow Up (1–5 Year) | 65 | 97.9 | 6364 | 1.1 | 7000.4 |
| Lung Follow Up (Post 5 Year) | 65 | 64.6 | 4201 | 0.6 | 2520.6 |
| Lung Post-Transplant Malignancy Form | 65 | 1.5 | 99 | 0.4 | 39.6 |
| Heart/Lung Candidate Registration | 63 | 0.7 | 46 | 1.1 | 50.6 |
| Heart/Lung Recipient Registration | 63 | 0.3 | 21 | 1.4 | 29.4 |
| Heart/Lung Follow Up (6 Month) | 63 | 0.3 | 20 | 0.8 | 16.0 |
| Heart/Lung Follow Up (1–5 Year) | 63 | 1.5 | 97 | 1.1 | 106.7 |
| Heart/Lung Follow Up (Post 5 Year) | 63 | 3.1 | 194 | 0.6 | 116.4 |
| Heart/Lung Post-Transplant Malignancy Form | 63 | 0.2 | 12 | 0.4 | 4.8 |
| Liver Candidate Registration | 136 | 88.6 | 12048 | 0.8 | 9638.4 |
| Liver Recipient Registration | 136 | 47.5 | 6457 | 1.3 | 8394.1 |
| Liver Follow-up (6 Month–5 Year) | 136 | 229.4 | 31194 | 1.0 | 31194.0 |
| Liver Follow-up (Post 5 Year) | 136 | 254.6 | 34622 | 0.5 | 17311.0 |
| Liver Recipient Explant Pathology Form | 136 | 12.2 | 1665 | 0.6 | 999.0 |
| Liver Post-Transplant Malignancy | 136 | 13.1 | 1786 | 0.8 | 1428.8 |
| Intestine Candidate Registration | 41 | 4.4 | 182 | 1.3 | 236.6 |
| Intestine Recipient Registration | 41 | 2.7 | 109 | 1.8 | 196.2 |
| Intestine Follow Up (6 Month–5 Year) | 41 | 13.3 | 547 | 1.5 | 820.5 |
| Intestine Follow Up (Post 5 Year) | 41 | 13.5 | 553 | 0.4 | 221.2 |
| Intestine Post-Transplant Malignancy Form | 41 | 0.6 | 25 | 1.0 | 25.0 |
| Kidney Candidate Registration | 235 | 161.2 | 37880 | 0.8 | 30304.0 |
| Kidney Recipient Registration | 235 | 71.9 | 16904 | 1.3 | 21975.2 |
| Kidney Follow-Up (6 Month–5 Year) | 235 | 376.3 | 88422 | 0.9 | 79579.8 |
| Kidney Follow-up (Post 5 Year) | 235 | 343.7 | 80770 | 0.5 | 40385.0 |
| Kidney Post-Transplant Malignancy Form | 235 | 17.9 | 4213 | 0.8 | 3370.4 |
| Pancreas Candidate Registration | 135 | 3.5 | 479 | 0.9 | 431.1 |
| Pancreas Recipient Registration | 135 | 1.9 | 259 | 1.1 | 284.9 |

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

| Form name | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| Pancreas Follow-up (6 Month–5 Year) | 135 | 10.4 | 1398 | 1.0 | 1398.0 |
| Pancreas Follow-up (Post 5 Year) | 135 | 13.4 | 1804 | 0.5 | 902.0 |
| Pancreas Post-Transplant Malignancy Form | 135 | 0.8 | 108 | 0.6 | 64.8 |
| Kidney/Pancreas Candidate Registration | 13 | 98.5 | 1280 | 0.9 | 1152 |
| Kidney/Pancreas Recipient Registration | 135 | 5.6 | 760 | 1.1 | 836.0 |
| Kidney/Pancreas Follow-up (6 Month–5 Year) | 135 | 33.4 | 4509 | 1.0 | 4509.0 |
| Kidney/Pancreas Follow-up (Post 5 Year) | 135 | 47.9 | 6465 | 0.6 | 3879.0 |
| Kidney/Pancreas Post-Transplant Malignancy Form | 135 | 1.6 | 211 | 0.4 | 84.4 |
| Vascular Composite Allograft Candidate Registration | 16 | 0.9 | 15 | 0.4 | 6.0 |
| Vascular Composite Allograft Recipient Registration | 16 | 0.9 | 15 | 1.3 | 19.5 |
| Vascular Composite Allograft Recipient Follow Up | 16 | 0.9 | 15 | 1.0 | 15.0 |
| Total | *456 | | 460414 | | 358092.5 |

*Total number of OPTN member institutions as of 09/9/2014. Number of respondents for transplant candidate or recipient forms based on number of organ specific programs associated with each form.

**Jackie Painter,**

*Acting Director, Division of Policy and Information Coordination.*

[FR Doc. 2014–28343 Filed 12–1–14; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than January 2, 2015.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* The Health Professions Student Loan (HPSL) and Nursing Student Loan (NSL) Programs: Deferment-HRSA Form 519 and AOR–HRSA Form 501, OMB No. 0915–0044-Extension

*Abstract:* The HPSL Program, as authorized by Public Health Service (PHS) Act sections 721–722, and 725–735, provides long-term, low-interest loans to students attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The NSL program as authorized by PHS Act sections 835–842, provides long-term, low-interest loans to students who attend eligible schools of nursing in programs leading to a diploma in nursing, including an associate degree, a baccalaureate degree, or graduate degree in nursing.

*Need and Proposed Use of the Information:* Participating HPSL and NSL schools are responsible for determining eligibility of applicants, making loans, and collecting monies owed by borrowers on their outstanding loans. The Deferment Form (Deferment-HRSA Form 519) provides the schools with documentation of a borrower's deferment status, as detailed for the HPSL program under 42 CFR 57.210 and for NSL under 42 CFR 57.310. The Annual Operating Report (AOR–HRSA Form 501) provides the U.S. Department of Health and Human Services with information from participating schools (including schools that are no longer disbursing loans but are required to report and maintain program records, student records, and repayment records until all student loans are repaid in full and all monies due to the federal government are returned) relating to HPSL and NSL program operations and financial activities.

*Likely Respondents:* Financial Aid Directors working at institutions participating in the HPSL and NSL Programs.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.