of opportunity for a hearing on February 23, 2026. Mr. Bobo failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(3)(D) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. Oscar Bobo has engaged in a pattern of importing or offering for import (*i.e.,* in an amount, frequency, or dosage that is inconsistent with his personal or household use) misbranded drugs that are not designated in an authorized electronic data interchange system as products regulated by the FDA. FDA finds that this pattern of conduct should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Bobo is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Bobo during his period of debarment is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–09767 Filed 5–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0906–0110—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than July 14, 2026.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0906–0110—Revision

Abstract: Section 372 of the Public Health Service Act requires that the Secretary of HHS, by awards, provide for the establishment and operation of the Organ Procurement and Transplantation Network (OPTN), which, under HRSA's oversight, operates the U.S. organ procurement and transplantation system. HRSA, in alignment with the Paperwork Reduction Act of 1995, submits OPTN Board of Directors (BOD)-approved data elements for collection to OMB for official federal approval.

Need and Proposed Use of the Information: HRSA and the OPTN BOD use data to develop transplant, procurement, and allocation policies; to determine whether institutional members are complying with OPTN policies and HHS regulations; to determine member-specific performance; to ensure patient safety; and to fulfill the requirements of the HHS OPTN regulations at 42 CFR 121. In addition, the regulatory authority in 42 CFR 121.11 (*https://www.ecfr.gov/current/title-42/section-121.11*) requires the OPTN to maintain certain records and to make OPTN data available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of HHS, and members of the public for evaluation, research, patient information, and other important purposes.

This is a request to revise the current OPTN data collection which includes time-sensitive, life-critical data on transplant candidates and potential organ donors, the organ matching process, histocompatibility results, organ labeling and packaging, and pre- and post-transplantation data on recipients and donors. This revision also includes OPTN BOD-approved changes to the existing OMB data collection forms. The OPTN collects these specific data elements from transplant hospitals, organ procurement organizations, and histocompatibility laboratories.

HRSA and the OPTN use this information to (1) facilitate organ placement and match donor organs with recipients; (2) monitor compliance of member organizations with federal laws and regulations and with OPTN requirements; (3) review and report periodically to the public on the status of organ donation, procurement, and transplantation in the United States; (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation; and (5) perform transplantation-related public health surveillance, including the possible transmission of donor disease.

HRSA requests making the following changes to improve the OPTN organ matching and allocation process and improve OPTN member compliance with OPTN requirements:

1. Add two data collection forms from the OPTN Computer System (UNet platform) to the existing OMB-approved information collection.

a. The Patient Safety Contact Management form is used by OPTN members to identify the OPTN member organization's primary and secondary patient safety contact who fulfills the duties as outlined in OPTN policy 15.1.

b. The Patient Transfer form is used by transplant centers to facilitate the transfer of patients to another transplant center after transplant and throughout the annual follow-up periods.

2. Remove vascularized composite allografts (VCA) Transplant Candidate Registration. With the implementation of new VCA waitlist registration forms in the OPTN Waiting List system (in UNet), OPTN members will no longer need to validate the data on the form. The form is now read only. All changes and validations will be performed directly on the new waitlist registration forms.

3. The OPTN BOD-approved additional revisions to existing data collection forms to improve organ matching, allocation, and OPTN policy compliance.

Likely Respondents: Transplant Centers, Organ Procurement Organizations (OPOs), and Histocompatibility Laboratories.

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.

The total burden hours in the OMB inventory increased by 58,975.02 hours from the previously OMB-approved data collection package. This increase included 3,310.46 hours from the addition of two new data collection forms, an increase of 1,031.03 hours due to OPTN BOD-approved data collection changes, and an increase of 54,633.53 hours from updating the number of respondents and total responses using actual OPTN data from 2025.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form No.	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours *
1	Deceased Donor Registration	55	452.40	24,882	0.48	11,943.36
2	Living Donor Registration	209	31.45	6,573	2.2	14,460.71
3	Living Donor Follow-up	209	100.325	20,968	1.52	31,871.25
4	Donor Histocompatibility	137	178.555	24,462	0.15	3,669.31
5	Recipient Histocompatibility	137	323.81	44,362	0.32	14,195.83
6	Heart Transplant Candidate Registration	149	40.87	6,090	0.9	5,481.67
7	Heart Transplant Recipient Registration	149	30.78	4,586	1.96	8,988.99
8	Heart Transplant Recipient Follow Up (6 Month)	149	28.51	4,248	0.4	1,699.20
9	Heart Transplant Recipient Follow Up (1–5 Year)	149	122.62	18,270	0.9	16,443.34
10	Heart Transplant Recipient Follow Up (Post 5 Year)	149	202.66	30,196	0.5	15,098.17
11	Heart Post-Transplant Malignancy Form	149	14.584	2,173	0.9	1,955.71
12	Lung Transplant Candidate Registration	77	51.26	3,947	0.95	3,749.67
13	Lung Transplant Recipient Registration	77	45.34	3,491	1.14	3,979.95
14	Lung Transplant Recipient Follow Up (6 Month)	77	41.34	3,183	0.5	1,591.59
15	Lung Transplant Recipient Follow Up (1–5 Year)	77	147.70	11,373	1.1	12,510.19
16	Lung Transplant Recipient Follow Up (Post 5 Year)	77	162.26	12,494	0.6	7,496.41
17	Lung Post-Transplant Malignancy Form	77	22.73	1,750	0.4	700.08
18	Heart/Lung Transplant Candidate Registration	75	1.03	77	1.16	89.61
19	Heart/Lung Transplant Recipient Registration	75	0.80	60	2.09	125.40
20	Heart/Lung Transplant Recipient Follow Up (6 Month)	75	0.75	56	0.8	45.00
21	Heart/Lung Transplant Recipient Follow Up (1–5 Year)	75	2.69	202	1.1	221.93
22	Heart/Lung Transplant Recipient Follow Up (Post 5 Year).	75	3.64	273	0.6	163.80
23	Heart/Lung Post-Transplant Malignancy Form	75	0.20	15	0.4	6.00
24	Liver Transplant Candidate Registration	144	112.48	16,197	0.8	12,957.70
25	Liver Transplant Recipient Registration	144	85.715	12,343	1.2	14,811.55
26	Liver Transplant Recipient Follow Up (6 Month–5 Year).	144	384.50	55,368	1	55,368.00
27	Liver Transplant Recipient Follow Up (Post 5 Year)	144	466.79	67,218	0.5	33,608.88
28	Liver Recipient Explant Pathology Form	144	7.806	1,124	0.6	674.44
29	Liver Post-Transplant Malignancy Form	144	27.19	3,915	0.8	3,132.29
30	Intestine Transplant Candidate Registration	17	6.76	115	1.3	149.40
31	Intestine Transplant Recipient Registration	17	5.18	88	1.8	158.51
32	Intestine Transplant Recipient Follow Up (6 Month–5 Year).	17	23.29	396	1.5	593.90
33	Intestine Transplant Recipient Follow Up (Post 5 Year)	17	52.35	890	0.4	355.98
34	Intestine Post-Transplant Malignancy Form	17	0.35	6	1	5.95
35	Kidney Transplant Candidate Registration	232	225.83	52,393	0.8	41,914.05
36	Kidney Transplant Recipient Registration	232	118.935	27,593	1.2	33,111.50
37	Kidney Transplant Recipient Follow Up (6 Month–5 Year).	232	610.616	141,663	0.9	127,496.62
38	Kidney Transplant Recipient Follow Up (Post 5 Year)	232	617.823	143,335	0.5	71,667.47
39	Kidney Post-Transplant Malignancy Form	232	31.573	7,325	0.8	5,859.95
40	Pancreas Transplant Candidate Registration	127	2.20	279	0.6	167.64
41	Pancreas Transplant Recipient Registration	127	0.84	107	1.2	128.02
42	Pancreas Transplant Recipient Follow Up (6 Month–5 Year).	127	4.20	533	0.5	266.70
43	Pancreas Transplant Recipient Follow Up (Post 5 Year).	127	15.71	1,995	0.5	997.59
44	Pancreas Post-Transplant Malignancy Form	127	0.724	92	0.6	55.17
45	Kidney/Pancreas Transplant Candidate Registration	127	13.35	1,695	0.6	1,017.27
46	Kidney/Pancreas Transplant Recipient Registration	127	6.34	805	1.2	966.22
47	Kidney/Pancreas Transplant Recipient Follow Up (6 Month–5 Year).	127	35.55	4,515	0.5	2,257.43

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form No.	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours *
48	Kidney/Pancreas Transplant Recipient Follow Up (Post 5 Year).	127	68.19	8,660	0.6	5,196.08
49	Kidney/Pancreas Post-Transplant Malignancy Form	127	2.315	294	0.4	117.60
50	VCA Transplant Recipient Registration	23	0.39	9	1.36	12.20
51	VCA Transplant Recipient Follow Up	23	2.91	67	1.31	87.68
52	Organ Labeling and Packaging	55	308.47	16,966	0.18	3,053.85
53	Organ Tracking and Validating	306	18.68	5,716	0.08	457.29
54	Kidney Paired Donation Candidate Registration	155	0.40	62	0.26	16.12
55	Kidney Paired Donation Donor Registration	155	0.74	115	1.08	123.88
56	Kidney Paired Donation Match Offer Management	155	0.86	133	0.67	89.31
57	Disease Transmission Event	306	2.958	905	0.6	543.09
58	Living Donor Event	209	0.24	50	0.56	28.09
59	Safety Situation	443	1.325	587	0.24	140.87
60	Potential Disease Transmission Report	55	14.78	813	1.27	1,032.38
61	Request to Unlock Form	443	156.156	69,177	0.02	1,383.54
62	Initial Donor Registration	55	453.870	24,963	4.75	118,573.54
63	OPO Notification Limit Administration	55	0.16	9	0.17	1.50
64	Potential Transplant Recipient	306	5332.24	1,631,665	0.05	81,583.27
65	Death Notification Registration	55	227.35	12,504	0.42	5,251.79
66	Deceased Donor Death Referral	55	61.80	3,399	0.5	1,699.50
67	Donor Hospital Registration	55	0.07	4	0.08	0.31
68	Donor Organ Disposition	55	453.87	24,963	0.17	4,243.68
69	Transplant Center Contact Management	251	863.462	216,729	0.06	13,003.74
70	Adult Kidney Candidate Listing Registration	232	227.927	52,879	0.52	27,497.11
71	Pediatric Kidney Candidate Listing Registration	103	11.66	1,201	0.47	564.46
72	Adult Kidney Pancreas Candidate Listing Registration	127	13.32	1,692	0.37	625.91
73	Pediatric Kidney Pancreas Candidate Listing Registration.	29	0.10	3	0.3	0.87
74	Adult Pancreas Candidate Listing Registration	127	15.27	1,939	0.38	736.93
75	Pediatric Pancreas Candidate Listing Registration	30	1.17	35	0.38	13.34
76	Adult Pancreas Islet Listing Registration	18	4.44	80	0.38	30.37
77	Pediatric Pancreas Islet Listing Registration ***	18	0.00	0	0.33	0.00
78	Adult Liver Candidate Listing Registration	144	107.35	15,458	0.32	4,946.69
79	Pediatric Liver Candidate Listing Registration	59	12.51	738	0.4	295.24
80	Adult Intestine Candidate Listing Registration	17	4.53	77	0.38	29.26
81	Pediatric Intestine Candidate Listing Registration	17	2.24	38	0.43	16.37
82	Adult Heart Candidate Listing Registration	149	36.52	5,441	0.83	4,516.43
83	Pediatric Heart Candidate Listing Registration	63	10.30	649	0.58	376.36
84	Adult HeartLung Candidate Listing Registration	75	0.96	72	0.85	61.20
85	Pediatric HeartLung Candidate Listing Registration	25	0.20	5	0.93	4.65
86	Adult Lung Candidate Listing Registration	77	50.77	3,909	1.01	3,948.38
87	Pediatric Lung Candidate Listing Registration	45	0.84	38	0.84	31.75
88	Candidate Registration Listing Removal	251	305.653	76,719	0.18	13,809.40
89	VCA Abdominal Wall Candidate Listing Registration ***	8	0.00	0	0.33	0.00
90	VCA External Male Genitalia Candidate Listing Registration ***.	2	0.00	0	0.33	0.00
91	VCA Head and Neck Candidate Listing Registration	9	0.11	1	0.33	0.33
92	VCA Lower Limb Candidate Listing Registration ***	4	0.00	0	0.33	0.00
93	VCA Musculoskeletal Composite Graft Segment Candidate Listing Registration ***.	2	0.00	0	0.33	0.00
94	VCA Other Genitourinary Organ Candidate Listing Registration.	5	0.20	1	0.33	0.33
95	VCA Spleen Candidate Listing Registration ***	0	0.00	0	0.33	0.00
96	VCA Upper Limb Candidate Listing Registration ***	11	0.00	0	0.33	0.00
97	VCA Uterus Candidate Listing Registration	6	1.83	11	0.33	3.62
98	VCA Vascularized Gland Candidate Listing Registration ***.	1	0.00	0	0.33	0.00
99	Organ Export Verification Form	55	0.29	16	0.03	0.48
100	OPTN Waiting Time Transfer Form	251	5.323	1,336	0.23	307.30
101	OPTN Waiting Time Modification Form	251	23.73	5,956	0.22	1,310.37
102	OPTN Renal Waiting Time Reinstatement Form	232	1.33	309	0.27	83.31
103	OPTN Pancreas Waiting Time Reinstatement Form	127	0.04	5	0.2	1.02
104	Intestinal Waiting Time Reinstatement Form	17	0.06	1	0.25	0.26
105	Prior Living Donor Priority	232	0.414	96	0.27	25.93
106	Kidney Minimum Acceptance Criteria	232	0.957	222	0.3	66.61
107	Adult Liver Status 1A Initial Justification and Extension Form.	144	2.125	306	0.57	174.42
108	Pediatric Liver Status 1A Initial Justification and Extension Form.	59	3.00	177	0.57	100.89

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form No.	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours *
109	Pediatric Liver Status 1B Initial Justification and Extension Form.	59	7.10	419	0.47	196.88
110	Liver Cholangiocarcinoma Initial MELD/PELD Score Exception Form.	144	0.83	120	0.43	51.39
111	Liver Cholangiocarcinoma MELD/PELD Score Exception Extension Form.	144	0.674	97	0.32	31.06
112	Liver Cystic Fibrosis Initial MELD/PELD Score Exception and Extension Form.	144	0.08	12	0.33	3.80
113	Liver Familial Amyloid Polyneuropathy Initial MELD/PELD Score Exception Form ***.	144	0.00	0	0.4	0.00
114	Liver Familial Amyloid Polyneuropathy MELD/PELD Score Exception Extension Form.	144	0.01	1	0.3	0.43
115	Liver Hepatic Artery Thrombosis Initial MELD/PELD Score Exception and Extension Form.	144	0.55	79	0.35	27.72
116	Liver Hepatocellular Carcinoma Initial MELD/PELD Score Exception Form.	144	22.18	3,194	0.47	1,501.14
117	Liver Hepatocellular Carcinoma MELD/PELD Score Exception Extension Form.	144	28.84	4,153	0.35	1,453.54
118	Liver Hepatopulmonary Syndrome Initial MELD/PELD Score Exception Form.	144	1.424	205	0.32	65.62
119	Liver Hepatopulmonary Syndrome MELD/PELD Score Exception Extension Form.	144	0.806	116	0.25	29.02
120	Liver Metabolic Disease Initial MELD/PELD Score Exception and Extension Form.	144	0.84	121	0.28	33.87
121	Liver Portopulmonary Hypertension Initial MELD/PELD Score Exception Form.	144	0.52	75	0.42	31.45
122	Liver Portopulmonary Hypertension MELD/PELD Score Exception Extension Form.	144	0.375	54	0.33	17.82
123	Liver Primary Hyperoxaluria Initial MELD/PELD Score Exception and Extension Form.	144	0.104	15	0.35	5.24
124	Liver Other Diagnosis Initial MELD/PELD Score Exception and Extension Form.	144	14.326	2,063	0.35	722.03
125	Pediatric Heart and HeartLung Status 1A Initial Justification Form.	63	15.56	980	0.52	509.75
126	Pediatric Heart and HeartLung Status 1A Extension and Appeal Justification Forms.	63	73.57	4,635	0.47	2,178.41
127	Pediatric Heart and HeartLung Status 1B Initial Justification Form.	63	7.05	444	0.42	186.54
128	Adult Heart and HeartLung Status 1–6 Justification Form Demographic Data.	149	161.57	24,074	0.32	7,703.66
129	Adult Heart and HeartLung Status 1–6 Justification Form Risk Stratification Data.	149	161.57	24,074	0.72	17,333.23
130	Adult Heart and HeartLung Status 1 Initial Justification Form Medical Urgency Data.	149	8.315	1,239	0.58	718.58
131	Adult Heart and HeartLung Status 1 Exception Extension Justification Form Medical Urgency Data.	149	1.10	164	0.33	54.09
132	Adult Heart and HeartLung Status 1 Criteria 1 Extension Justification Form Medical Urgency Data.	149	0.87	130	0.53	68.70
133	Adult Heart and HeartLung Status 2 Initial Justification Form Medical Urgency Data.	149	28.644	4,268	0.8	3,414.36
134	Adult Heart and HeartLung Status 2 Exception Extension Justification Form Medical Urgency Data.	149	19.987	2,978	0.33	982.76
135	Adult Heart and HeartLung Status 2 Criteria 1 Extension Justification Form Medical Urgency Data.	149	0.013	2	0.42	0.81
136	Adult Heart and HeartLung Status 2 Criteria 4 Extension Justification Form Medical Urgency Data.	149	5.54	825	0.63	520.04
137	Adult Heart and HeartLung Status 2 Criteria 5 Extension Justification Form Medical Urgency Data.	149	1.87	279	0.6	167.18
138	Adult Heart and HeartLung Status 3 Initial Justification Form Medical Urgency Data.	149	11.25	1,676	0.63	1,056.04
139	Adult Heart and HeartLung Status 3 Exception Extension Justification Form Medical Urgency Data.	149	7.497	1,117	0.33	368.63
140	Adult Heart and HeartLung Status 3 Criteria 2 Extension Justification Form Medical Urgency Data.	149	0.544	81	0.32	25.94
141	Adult Heart and HeartLung Status 3 Criteria 5 Extension Justification Form Medical Urgency Data.	149	0.04	6	0.48	2.86
142	Adult Heart and HeartLung Status 4 Initial Justification Form Medical Urgency Data.	149	23.41	3,488	0.5	1,744.05

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form No.	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours *
143	Adult Heart and HeartLung Status 4 Exception Extension Justification Form Medical Urgency Data.	149	2.17	323	0.25	80.83
144	Adult Heart and HeartLung Status 4 Criteria 2 Extension Justification Form Medical Urgency Data.	149	0.78	116	0.4	46.49
145	Adult and Pediatric Lung and HeartLung Goal Exception Form.	149	2.785	415	0.75	311.22
146	Pediatric Lung Priority 1 Status Justification Form	45	0.53	24	0.33	7.87
147	Review Board Voter Form	251	24.745	6,211	0.23	1,428.53
148	Living Donor Feedback Form	209	38.856	8,121	0.13	1,055.72
149	Extra Vessels Reporting Form	251	59.28	14,879	0.03	446.38
150	Non-US Transplants Reporting Form ***	232	0.00	0	0.03	0.00
151	Discrepant HLA Typings Reporting Form	137	1.27	174	5.17	899.53
152	Interim Event Reporting Form	251	88.454	22,202	0.06	1,332.12
153	Patient Safety Contact Management Form **	306	42.20	12,913	0.14	1,807.85
154	Patient Transfer Form **	251	15.35	3,853	0.39	1,502.61
	Total	19,424	.....	3,101,339	.....	910,553.02

* **Note:** Totals for responses and burden hours may reflect minor discrepancies due to rounding; however, these rounding adjustments do not affect the overall burden estimates presented.
** New forms.
*** If a form has 0.00 under the average number of responses, this is an indicator that there were no submissions in calendar year 2025.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2026–09804 Filed 5–14–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for License: Synergistic Interactions for Improved Cancer Treatment

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks research co-development partners and/or licensees to develop hetIL-15 in combination with other agents, such as PPARa agonists (Fenofibrate), FLT3 inhibitors (quizartinib), IL–12, or chemotherapy into a therapeutic for cancer.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Rose Freel, Ph.D., Unit Supervisor, NCI, Technology Transfer Center, Email: *rose.freel@nih.gov* or Phone: 301–624–1257.

SUPPLEMENTARY INFORMATION: Immunotherapy has emerged as a promising treatment strategy for many types of cancer. However, a major challenge is ''exhausted'' tumor-infiltrating immune cells, which lose their ability to effectively eliminate cancer cells. To address this issue, researchers are exploring ways to reverse immune exhaustion and improve treatment outcomes. One potential approach involves interleukin-15 (IL–15), a cytokine that promotes the growth and killing ability of tumor-specific CD8+ T cells and NK cells. IL–15, either alone or in combination with other agents, has shown some promise in clinical trials. However, its use is hindered by toxicity at effective doses. Therefore, there is a critical need for safer and more effective combinations to improve patient outcomes.

Inventors at the NCI previously developed heterodimeric IL–15 (hetIL-15), composed of IL–15 and IL–15 receptor alpha (NIH Reference #E–254–2005, E–257–2009, E–141–2008, E–054–2013, and E–070–2015). The inventors now demonstrate novel combinations of hetIL-15 with other active agents to enhance the metabolic fitness of intratumoral lymphocytes to provide therapeutic improvement. Specifically, the combination of hetIL-15 and Fenofibrate, a cholesterol-lowering drug, increased cytotoxic T cell activity and provided an almost complete eradication of triple negative breast cancer tumors, including metastatic lesions. Similar results occurred in a mouse pancreatic cancer model. Using a mouse orthotopic breast cancer model, hetIL-15 combined with quizartinib—a potent Fms-like tyrosine kinase 3 (Flt3) inhibitor—resulted in a significant tumor growth delay and complete eradication of tumors in 50% of mice after 16 days of treatment. Additionally, the inventors constructed a fusion protein of IL–15 and IL–12 that controls metastatic disease in a mouse melanoma model. These novel combinations would be particularly useful for the treatment of triple negative breast or pancreatic cancer.

This Notice is in accordance with 37 CFR 404.4—Authority to grant licenses.

NIH Reference Number: E–174–2022.

Product Type: Therapeutic.

Therapeutic Area(s): Oncology | Immunology.

Potential Commercial Applications:

- Treatment for triple negative breast cancer.
- Treatment for pancreatic cancer.
- Treatment of solid tumors for which cellular immunotherapy outcomes are diminished due to T or NK cell exhaustion.
- Treatment of solid tumors for which IL–15-based therapy is diminished due to toxicity at clinically relevant doses.

Competitive Advantages:

- Novel combination showing improved therapeutic potential in