food product benefits consumers who purchase that food product. Because even small exposure to a food allergen can potentially cause an adverse reaction, consumers use food labeling information to help determine their product choices.

Based on a review of the information collection since our last request for OMB approval, we are decreasing our burden estimate for the redesign of labels. FALCPA was enacted in 2004, and we issued associated Agency guidance in 2015. Firms have had substantial time to redesign their labels for compliance with section 403(w) of the FD&C Act. We do not anticipate any firms needing to redesign their label to come into compliance with section 403(w)(1) of the FD&C Act. Thus, we are decreasing the number of respondents redesigning their label from 3,875 to 1 and the number of hours from 62,000 to 16. We estimate one respondent for the purpose of maintaining this information collection provision.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Section; Activity	Number of respondents	Number of responses perrespondent	Total annual responses	Average burden per response	Total hours
403(w)(6); petition for exemption	5	1	5	100	500
403(w)(7); notification	5	1	5	68	340
Total					840

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

B. Reporting

Under sections 403(w)(6) and (7) of the FD&C Act, respondents may request from us a determination that an ingredient is exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. An ingredient may obtain an exemption through submission and approval of a petition containing scientific evidence that demonstrates that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(6) of the FD&C Act). This section also states that ''the burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.'' Alternately, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient ''does not contain allergenic protein'' or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(7) of the FD&C Act).

We issued a guidance document entitled ''Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications,'' which is available on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-allergen-labeling-exemption-petitions-and-notifications.* The guidance sets forth our recommendations with regard to the information that respondents should submit in such a petition or notification. The guidance states that to evaluate these petitions and notifications, we will consider scientific evidence that describes: (1) The identity or composition of the ingredient; (2) the methods used to produce the ingredient; (3) the methods used to characterize the ingredient; (4) the intended use of the ingredient in food; and (5) either (a) for a petition, data and information, including the expected level of consumer exposure to the ingredient, that demonstrate that the ingredient, when manufactured and used as described, does not cause an allergic response that poses a risk to human health; or (b) for a notification, data, and information that demonstrate that the ingredient, when manufactured as described, does not contain allergenic protein, or documentation of a previous determination under a process under section 409 of the FD&C Act that the ingredient does not cause an allergic response that poses a risk to human health. We use the information submitted in the petition or notification to determine whether the ingredient satisfies the criteria of section 403(w)(6) and (7) of the FD&C Act for granting the exemption.

Dated: March 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07002 Filed 4–5–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS 4040–0018]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before June 7, 2021.

ADDRESSES: Submit your comments to *Ed.Calimag@hhs.gov* or (202) 690–7569.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 4040–0018–60D and project title for reference to *Ed.Calimag@hhs.gov,* or call (202) 690–7569, the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Title of the Collection: SF–428 Tangible Personal Property Report.

Type of Collection: Reinstatement of an expired information collection.

OMB No.: 4040–0018.

Abstract: Reporting on the status of Federally-owned property, including disposition, is necessitated in 2 CFR part 215, the ''Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations'', and the ''Uniform Administrative Requirements for Grants and Agreements with State and Local Governments'', Additionally, Public Law 106–107, the Federal Financial Assistance Management Improvement Act requires that agencies ''simplify Federal financial assistance application and reporting requirements.'' 31 U.S.C. 6101, Section 3.

Agencies are currently using a variety of forms to account for both Federally-owned and grantee owned equipment and property. During the public consultation process mandated by Public Law 106–107, grant recipients requested a standard form to help them submit appropriate property information when required. The Public Law 106–107 Post Awards Subgroup developed a new standard form, the Tangible Personal Property Report, for submission of the required data. The form consists of the cover sheet (SF–428), three attachments to be used as required: Annual Report, SF–428–A; Final Report, SF–428–B; Disposition Request/Report, SF–428–C and a Supplemental Sheet, SF–428S to provide detailed individual item information when required.

Changes shall be made to the form and instructions of the SF–428–B and the SF–428–C.

ANNUALIZED BURDEN HOUR TABLE

Forms	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
SF–428 Tangible Personal Property Report.	Grant applicants	2,000	1	1	2,000
Total		2,000	1	1	2,000

Sherrette A. Funn,

Paperwork Reduction Act Report Clearance Officer, Office of the Secretary.

[FR Doc. 2021–07039 Filed 4–5–21; 8:45 am]

BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Amy F. Petrik, Ph.D., 240–627–3721; *amy.petrik@nih.gov*. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows:

Newcastle Disease Virus-Like Particle Displaying Prefusion Stabilized SARS–CoV–2 Spike and Its Use

Description of Technology:

SARS–CoV–2 has resulted in a global pandemic, sparking urgent vaccine development efforts. The trimeric SARS–CoV–2 spike stabilized in its prefusion conformation by the addition of 2 proline mutations (''SARS–CoV–2 S2P'') is the antigenic basis of SARS–CoV–2 vaccines that are currently authorized for use in the United States.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) sought to optimize the presentation of SARS–CoV–2 S2P to the immune system with the goal of eliciting a strong and durable immune response. The researchers designed fusion proteins made of SARS–CoV–2 S2P and Newcastle Disease fusion transmembrane domain and cytosolic tail which form virus like particles (VLPs) displaying the SARS–CoV–2 S2P on the particle surface.

SARS–CoV–2 S2P displaying Newcastle Disease virus-like particles (''S2P–NDVLP'') elicited a robust immune response two weeks after a single immunization. The S2P–NDVLP also elicited an improved immunogenicity despite delivering a lower number of SARS–CoV–2 S2P antigens than the soluble SARS–CoV–2 S2P to which they were compared. This improved immunogenicity is likely due to several characteristics of S2P–NDVLPs such as the mass and large size of the VLP particle that can result in a strong immune response and increase uptake of the S2P by dendritic cells Displaying multiple SARS–CoV–2 S2P on a single particle could allow multiple B-cell receptors on individual B cells to bind that single particle, thereby cross-linking the B-cell receptors and activating those B cells. Lastly, the lipid membrane of the S2P–NDVLP could allow the immunogen to more closely mimic the real virus and boost immune response.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

- A single dose SARS–CoV–2 vaccine

Competitive Advantages:

- S2P–NDVLP with potential to elicit higher levels of neutralizing antibodies than current vaccines with a single dose

Development Stage: Preclinical Research.

Inventors: Peter D. Kwong (NIAID); Yongping Yang (NIAID); Wei Shi (NIAID); John R. Mascola (NIAID); Olubukola Abiona (NIAID); Kizzmekia Corbett (NIAID); Barney Graham (NIAID).

Publications: Yang, Y *et al.,* (2021). Newcastle Disease Virus-Like Particles Displaying Prefusion-Stabilized SARS–