each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Irradiation in the Production, Processing, and Handling of Food	0910–0186	7/31/2021
State Enforcement Notifications	0910–0275	7/31/2021
Veterinary Feed Directive	0910–0363	7/31/2021
Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications	0910–0796	7/31/2021
Quality Facility Attestation	0910–0854	7/31/2021
Administrative Practices and Procedures; Formal Evidentiary Public Hearing	0910–0191	8/31/2021
Regulations Under the Federal Import Milk Act	0910–0212	8/31/2021
Medical Device Reporting	0910–0437	8/31/2021
Animal Food Labeling; Declaration of Certifiable Color Additives	0910–0721	8/31/2021
Evaluation of the Food and Drug Administration's Fresh Empire Multicultural Youth Tobacco Prevention Campaign	0910–0788	8/31/2021
National Agriculture and Food Defense Strategy Survey	0910–0855	8/31/2021

Dated: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21209 Filed 9–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0438]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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.

DATES: Fax written comments on the collection of information by October 29, 2018.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0583. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

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.

Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

OMB Control Number 0910–0583—Extension

Since May 29, 1992, when FDA issued a policy statement on foods derived from new plant varieties, including those varieties that are developed through biotechnology, we have encouraged developers of new plant varieties to consult with us early in the development process to discuss possible scientific and regulatory issues that might arise (57 FR 22984).

The guidance, entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use,'' (available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm096156.htm*) continues to foster early communication by encouraging developers to submit to us their evaluation of the food safety of their new protein. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of the new protein.

We believe that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. The guidance describes the recommended procedures for early food safety evaluation of new proteins produced by new plant varieties, including bioengineered food plants, and the procedures for communicating with us about the safety evaluation.

Interested persons may use Form FDA 3666 to transmit their submission to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition. Form FDA 3666 is entitled, ''Early Food Safety Evaluation of a New Non-Pesticidal Protein Produced by a New Plant Variety (New Protein Consultation),'' (*https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM350010.pdf*) and may be used in lieu of a cover letter for a New Protein Consultation (NPC). Form FDA 3666 prompts a submitter to include certain elements of an NPC in a standard format and helps the respondent organize their submission to focus on the information needed for our safety review. The form, and elements that would be prepared as attachments to the form, may be submitted in electronic format via the Electronic Submission Gateway, or may be submitted in paper format, or as electronic files on physical media with paper signature page. The information is used by us to evaluate the food safety of

a specific new protein produced by a new plant variety.

Description of Respondents: The respondents to this collection of information are developers of new plant varieties intended for food use.

In the **Federal Register** of May 25, 2018 (83 FR 24315), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but did not respond to any of the four information collection topics solicited and is therefore not addressed.

We therefore estimate the burden for the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Category	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
First four data components	3666	6	1	6	4	24
Two other data components	3666	6	1	6	16	96
Total						120

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. The estimated number of annual responses and average burden per response are based on our experience with early food safety evaluations. Completing an early food safety evaluation for a new protein from a new plant variety is a one-time burden (one evaluation per new protein). Many developers of novel plants may choose not to submit an evaluation because the field testing of a plant containing a new protein is conducted in such a way (*e.g.,* on such a small scale, or in such isolated conditions, etc.) that cross-pollination with traditional crops or commingling of plant material is not likely to be an issue. Also, other developers may have previously communicated with us about the food safety of a new plant protein, for example, when the same protein was expressed in a different crop.

We estimate the annual number of NPCs submitted by developers will be six or fewer. The early food safety evaluation for new proteins includes six main data components. Four of these data components are easily and quickly obtainable, having to do with the identity and source of the protein. We estimate that completing these data components will take about 4 hours per NPC. We estimate the reporting burden for the first four data components to be 24 hours (4 hours × 6 responses).

Two data components ask for original data to be generated. One data component consists of a bioinformatics analysis which can be performed using publicly available databases. The other data component involves ''wet'' lab work to assess the new protein's stability and the resistance of the protein to enzymatic degradation using appropriate in vitro assays (protein digestibility study). The paperwork burden of these two data components consists of the time it takes the company to assemble the information on these two data components and include it in an NPC. We estimate that completing these data components will take about 16 hours per NPC. We estimate the reporting burden for the two other data components to be 96 hours (16 hours × 6 responses). Thus, we estimate the total annual hour burden for this collection of information to be 120 hours.

Dated: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21148 Filed 9–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this Notice to Tailored Therapeutics, LLC. (''Tailored''), located in Potomac, MD.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before October 15, 2018 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, Rm. 1E530, MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702; Telephone: (240) 276–5484; Facsimile: (240) 276–5504; Email: *andy.burke@nih.gov*.

SUPPLEMENTARY INFORMATION:

Intellectual Property

Group A

E–028–2015: Anti-Mutated KRAS T Cell Receptors

1. U.S. Provisional Patent Application 62/084,654, filed November 26, 2014 (E–028–2015–0–US–01);
2. International Patent Application PCT/US2015/062269, filed November 24, 2015 (E–028–2015–1–PCT–01);
3. Australian Patent Application 2015353720, filed May 18, 2017 (E–028–2015–1–AU–02);
4. Canadian Patent Application 2968399, filed May 18, 2017 (E–028–2015–1–CA–03);
5. Chinese Patent Application 201580070673.7, filed June 23, 2017 (E–028–2015–1–CN–04);
6. European Patent Application 15807756.0 filed June 23, 2017 (E–028–2015–1–EP–05);
7. Israeli Patent Application 252258, filed May 14, 2017 (E–028–2015–1–IL–06);
8. Japanese Patent Application 527874/2017, filed May 24, 2017 (E–028–2015–1–JP–07);
9. Korean Patent Application 2017–7017289, filed June 23, 2017 (E–028–2015–1–KR–08);
10. Mexican Patent Application MX/a/2017/006865, filed May 25, 2017 (E–028–2015–1–MX–09);