Developers whose approved companion diagnostics may be appropriate for broader labeling are encouraged to contact CDRH or CBER, as appropriate to discuss. Developers of the companion diagnostics discussed in the guidance as an example should see the ''Other Issues for Consideration'' section of this notice for information regarding broader labeling for those companion diagnostics.

This guidance finalizes the draft guidance entitled ''Developing and Labeling In Vitro Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products'' dated December 2018 (83 FR 63166). Comments received on the draft guidance were taken into consideration when finalizing the guidance. Based on the comments received, clarifications were made and information regarding the content of broader labeling was added.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Developing and Labeling In Vitro Companion Diagnostic Devices for a Specific Group of Oncology Therapeutic Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Other Issues for Consideration

Based on publicly available information, which includes valid scientific evidence (*i.e.,* clinical and scientific experience) with specific companion diagnostics and the associated therapeutic products, FDA has concluded that certain statements set forth in the FDA-approved labels of these companion diagnostics, related to intended use with therapeutic products, can be modified. The specific companion diagnostics are those discussed as an example in the guidance announced in this notice (*i.e.,* companion diagnostics that identify patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor approved by FDA for that indication). FDA believes it is appropriate for sponsors to consider modifying the intended use of these companion diagnostics to describe the specific group of oncology therapeutic products, rather than listing individual therapeutic product(s). The guidance states that, rather than listing individual therapeutic product(s), the intended use for the indication for the specific companion diagnostics would be, ''identifying patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor approved by FDA for that indication.'' It is possible for the companion diagnostics to also have other indications, not captured by the broader indication. FDA encourages the submission of PMA supplements, identifying the change and referring to this notice as the reason for the change, to request modification of the intended use of these companion diagnostics. This broader labeling may enable greater flexibility for clinicians in choosing the most appropriate therapeutic product based on a patient's biomarker status.

In the **Federal Register** document that announced the availability of the draft guidance, FDA requested feedback on specific issues, including challenges with developing the evidence needed to support broader companion diagnostic labeling, challenges with submitting a PMA supplement to broaden the labeling of an approved companion diagnostic and actions FDA can take to facilitate or encourage broader companion diagnostic labeling in oncology. Comments that stakeholders submitted to the docket for the draft guidance are generally supportive of the concept of broader labeling for companion diagnostics in oncology to facilitate the treatment of patients with cancer. To encourage implementation of broader labeling of companion diagnostics in oncology, FDA is finalizing the guidance and encouraging submission of PMA supplements containing the needed information for FDA review of the modified labeling of the companion diagnostics discussed in the guidance as an example.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance. 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. 3501–3521). The collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332; the collections of information in the guidance document ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' have been approved under OMB control number 0910–0756; and the collections of information in the guidance ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844.

IV. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: April 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–07816 Filed 4–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Early Career Reviewer Program Online Application and Vetting System (Center for Scientific Review)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular

information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Hope Cummings, Project Clearance Liaison, Center for Scientific Review, NIH, Room 4134, 6701 Rockledge Drive, Bethesda, Maryland, 20892 or call non-toll-free number (301) 402–4706 or Email your request, including your address to: *hope.cummings@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on January 31, 2020, pages 5677–5678 (85 FR 21) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Center for Scientific Review (CSR), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Early Career Reviewer Program Online Application and Vetting System—0925–0695, REVISION—expiration date 05/31/2020, Center for Scientific Review (CSR), National Institutes of Health (NIH).

Need and Use of Information Collection: The Center for Scientific Review (CSR) is the portal for NIH grant applications and their review for scientific merit. Our mission is to see that all NIH grant applications receive fair, independent, expert, and timely reviews—free from inappropriate influences—so NIH can fund the most promising research. To accomplish this goal, Scientific Review Officers (SRO) form study sections consisting of scientists who have the technical and scientific expertise to evaluate the merit of grant applications. Study section members are generally scientists who have established independent programs of research as demonstrated by their publications and their grant award experiences.

The CSR Early Career Reviewer program was developed to identify and train qualified scientists who are early in their scientific careers and who have not had prior CSR review experience. The goals of the program are to expose these early career scientists to the peer review experience so that they become more competitive as applicants as well as to enrich the existing pool of NIH reviewers. Currently, the online application software, the Early Career Reviewer Application and Vetting System, is accessed online by applicants to the Early Career Reviewer Program who provide information such as their name, contact information, a description of their areas of expertise, their study section preferences, and their professional Curriculum Vitae. This Information Collection Request (ICR) is to revise the Early Career Reviewer Application and Vetting System to include additional questions and be more user friendly. Additional questions are in line with NIH's renewed Interest in Diversity (NOT–OD–20–031) and include questions such as applicants' race, ethnicity, gender, disability, and disadvantage backgrounds. Applicants can choose if they would like to answer these additional questions (*i.e.* optional). Applicants are also now able to check their eligibility before applying to the program.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 505.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Research scientists	1212	1	25/60	505
Total		1212		505

Dated: March 30, 2020.

Hope M. Cummings,

Project Clearance Liaison, Center for Scientific Review (CSR), National Institutes of Health.

[FR Doc. 2020–07708 Filed 4–13–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4485–DR; Docket ID FEMA–2020–0001]

Texas; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Texas (FEMA–4485–DR), dated March 25, 2020, and related determinations.

DATES: The declaration was issued March 25, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated March 25, 2020, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the emergency conditions in the State of Texas resulting from the Coronavirus Disease 2019 (COVID–19) pandemic beginning on January 20, 2020,