

framework for such products (Docket No. FDA-2015-N-0540; available at <https://www.regulations.gov/docket?D=FDA-2015-N-0540>). FDA sought broad public input on its enforcement policies related to drug products labeled as homeopathic in an effort to better promote and protect the public health.

As a result of the Agency's evaluation, including consideration of the public input received on this issue, FDA has determined that it is in the best interest of public health to issue a new guidance that applies a risk-based enforcement approach to drug products labeled as homeopathic and marketed in the United States without the required FDA approval, consistent with FDA's risk-based regulatory approaches generally. The Agency generally intends to apply a risk-based enforcement approach to the manufacturing, distribution, and marketing of drug products labeled as homeopathic, as described in the draft guidance, when finalized. However, the Agency has limited enforcement resources and recognizes that many such products likely will fall outside the risk-based categories described in the draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on drug products labeled as homeopathic. 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: December 6, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: U.S. Department of Health and Human Services.

ACTION: 30-Day Day Notice template for Request for Generic Clearance for the Collection of Routine Customer Feedback on (HITRC).

AGENCY: U.S. Department of Health and Human Services (HHS).

ACTION: Notice and request for comments. Office of the National Coordinator for Health Information Technology is requesting OMB approval for an extension on the Generic Clearance for the Collection of Routine Customer Feedback by OMB.

SUMMARY: Department of Health and Human Services, The Office of the Secretary (OS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on the "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery" for approval under the Paperwork Reduction Act (PRA). This collection was developed as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery. This notice announces our intent to submit this collection to OMB for approval and solicits comments on specific aspects for the proposed information collection.

DATES: Consideration will be given to all comments received by January 19, 2018.

ADDRESSES: Submit comments by one of the following methods:

- **Website:** www.regulations.gov. Direct comments to Docket ID OMB-2010-0021.
- **Email:** Information.CollectionClearance@hhs.gov.
- **Phone:** (202) 795-7714.

Comments submitted in response to this notice may be made available to the public through relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to

this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT:

Sherrette Funn, Sherrrette.funn@HHS.GOV or (202) 795-7714.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;

- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Current Actions: Extension of approval for a collection of information.

Type of Review: Extension.

Affected Public: Individuals, households, professionals, public/private sector.

Estimated Number of Respondents:

Below we provide projected average estimates for the next three years:

Average Expected Annual Number of activities: 7.

Average number of Respondents per Activity: 350.

Annual responses: 4,158.

Frequency of Response: Once per request.

Average minutes per response: 5.

Burden hours: 1,041.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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.

All written comments will be available for public inspection *Regulations.gov*.

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 Office of Management and Budget control number.

Terry S. Clark,

Asst. Information Collection Clearance Officer.

[FR Doc. 2017-27399 Filed 12-19-17; 8:45 am]

BILLING CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of an Anti-CD30 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

AGENCY: National Institutes of Health

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 Kite Pharma, Inc. ("Kite") located in Santa Monica, CA.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before January 4, 2018 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: David A. Lambertson, Ph.D., 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)-276-5530; Facsimile: (240)-276-5504; Email: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. 62/241,896, filed 15 October 2015 and entitled "Anti-CD30 Chimeric Antigen Receptors" [HHS Reference No. E-016-2018/0-US-01]; PCT Patent Application PCT/US2016/056262, filed 10 October 2016 and entitled "Anti-CD30 Chimeric Antigen Receptors" [HHS Reference No. E-016-2018/0-PCT-02]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the following:

"The development of a CD30 chimeric antigen receptor (CAR)-based