
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approach to the manufacturing, distribution, and marketing of drug products labeled as homeopathic, as described in the draft guidance, when finalized.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resources and recognizes that many such products likely will fall outside the risk-based categories described in the draft guidance.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on drug products labeled as homeopathic.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


Dated: December 6, 2017.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2017–27157 Filed 12–18–17; 11:15 am]
• 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:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Estimated Number of Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Expected Annual Number of activities</td>
<td>7</td>
</tr>
<tr>
<td>Average number of Respondents per Activity</td>
<td>350</td>
</tr>
<tr>
<td>Annual responses</td>
<td>4,158</td>
</tr>
<tr>
<td>Frequency of Response</td>
<td>Once per request</td>
</tr>
<tr>
<td>Average minutes per response</td>
<td>5</td>
</tr>
<tr>
<td>Burden hours</td>
<td>1,041</td>
</tr>
</tbody>
</table>

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.

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. Lamberton, 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.lamberton@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property


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...