of any non-clinical laboratory studies with good laboratory practices; (4) the name and address of each clinical investigator; (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped; and (6) information regarding the use of edible tissues from investigational animals. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to assure that its use is safe and that the distribution is controlled to prevent potential abuse. The agency uses these required records under its Bio-Research Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are used primarily by the pharmaceutical industry, academic institutions, and the government. Investigators may include individuals from these entities as well as research firms and members of the medical professional. Respondents for this collection of information are investigators who use new animal drugs for investigational purposes.

FDA estimates the burden for this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 511.1(b)(4) | 134 | 7.66 | 1,027 | 8 | 8,216 |
| 511.1(b)(5) | 134 | .19 | 25 | 140 | 3,500 |
| 511.1(b)(6) | 134 | .01 | 2 | 1 | 2 |
| 511.1(b)(8)(ii) | 134 | .11 | 15 | 20 | 300 |
| 511.1(b)(9) | 134 | 6.7 | 20 | 8 | 160 |
| Total | | | | | 12,178 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| 511.1(a)(3) | 134 | 2.96 | 400 | 9 | 3,600 |
| 511.1(b)(3) | 134 | 7.66 | 1,027 | 1 | 1,027 |
| 511.1(b)(7)(ii) | 134 | 7.46 | 1,000 | 3.5 | 3,500 |
| 511.1(b)(8)(i) | 134 | 7.46 | 1,000 | 3.5 | 3,500 |
| Total | | | | | 11,627 |

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

The burden estimates for reporting requirements, record preparation, and maintenance for this collection of information are based on agency communication with industry and agency records. Based on the number of sponsors subject to animal drug user fees, FDA estimates there are 134 respondents. This estimate is used consistently throughout the burden tables and for example, the ''annual frequency per respondent'' was calculated by dividing the total annual responses by the number of respondents. Additional information needed to make final calculations for the total burden estimates in tables 1 and 2 of this document, i.e., the hours per response, the hours per record, the number of NCIEs received, etc., was derived from agency records.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: March 31, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–7255 Filed 4–7–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–D–0199] (formerly Docket No. 2006D–0526)**

### International Conference on Harmonisation; Guidance on E15 Pharmacogenomics Definitions and Sample Coding; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''E15 Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories.'' The guidance was prepared

under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance contains definitions of key terms in the discipline of pharmacogenomics and pharmacogenetics, namely genomic biomarkers, pharmacogenomics, pharmacogenetics, and genomic data and sample coding categories. In the effort to develop harmonized approaches to drug regulation, it is important to ensure that consistent definitions of terminology are being applied across all constituents of the ICH. The guidance is intended to facilitate the integration of the discipline of pharmacogenomics and pharmacogenetics into global drug development and approval processes.

**DATES:** Submit written or electronic comments on agency guidance at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

*Regarding the guidance*: Felix Frueh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4512,Silver Spring, MD 20993–0002, 301–796–1530; or

Raj K. Puri, Center for Biologics Evaluation and Research (HFM–735), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0471.

*Regarding the ICH*: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a guidance entitled ''E15 Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories.'' In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of January 8, 2007 (72 FR 793), FDA published a notice announcing the availability of a draft guidance entitled ''E15 Terminology in Pharmacogenomics.'' The notice gave interested persons an opportunity to submit comments by April 9, 2007.

After consideration of the comments received and revisions to the guidance, a final version of the draft guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in October 25, 2006.

The guidance represents an international effort to harmonize pharmacogenomics definitions and sample coding. Inconsistent definitions make it difficult to achieve agreement on parameters for implementation of pharmacogenomics in global pharmaceutical development, and might lead to inconsistent assessments by regulators. The guidance provides definitions of key terms in the discipline of pharmacogenomics and pharmacogenetics, namely genomic biomarkers, pharmacogenomics, pharmacogenetics, and genomic data and sample coding categories. The guidance is intended to facilitate the integration of the discipline of pharmacogenomics and pharmacogenetics into global drug development and approval processes. Timely harmonization of terminology and definitions will create a common foundation for future guidance on pharmacogenomics.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic

comments or submissions will be accepted by FDA through FDMS only.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: March 28, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8–7237 Filed 4–7–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Prospective Grant of Exclusive License: Codon Optimized IL–15 and IL–15R–Alpha Genes for Expression in Mammalian Cells

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in U.S. Serial Numbers 60/758,819, filed January 13, 2006 and 60/812,566, filed June 9, 2006; PCT filed (PCT/US2007/000774) on January 12, 2007, entitled ''Codon Optimized IL–15 and IL–15R—Alpha Genes for Expression in Mammalian Cells'' (HHS Ref. E–254–2005/2) to Marine Polymer Technologies, Inc., having a place of business in Danvers, Massachusetts. The patent rights in these inventions have been assigned to the United States of America.

**DATES:** Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before April 28, 2008 will be considered.

**ADDRESSES:** Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Susan Ano, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; E-mail: *anos@od.nih.gov;* Telephone: (301) 435–5515; Facsimile: (301) 402–0220.

**SUPPLEMENTARY INFORMATION:** This technology provides for optimized nucleic acids for improved expression of interleukin–15 (IL–15) and IL–15 receptor alpha (IL–15R–alpha) in mammalian cells. IL–15 is a cytokine important for both the innate and adaptive immune systems. Based on its many functions and relative safety in animal models, IL–15 finds use in vaccines, cancer immunotherapeutics, and autoimmune disease and as a vaccine adjuvant. The present technology enhances the production and bioavailability of IL–15 through use of optimized nucleic acid sequences. Native IL–15 coding sequences do not express IL–15 optimally for several reasons, and the optimized sequences of the subject technology overcome these deficiencies. The nucleic acids can be part of expression vectors, which could be utilized either in vitro or in vivo. The expression vectors express IL–15 alone, IL–15R–alpha alone, or both molecules together from a single vector. Further enhanced expression of IL–15 and/or IL–15R–alpha can be achieved through the use of signal peptides or propeptides from heterologous proteins. These nucleic acids can be administered to enhance the immune response of an individual against one or more antigens. Primate studies have shown that co-administration of IL–15 and IL–15R–alpha increased antigen specific cells, cells expressing IL–2, and/or cells expressing IL–2 and IFN–gamma (i.e. multifunctional cells). The present compositions are useful for the increased bioavailability and therefore biological effects of IL–15 after its administration to humans or other mammals.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 20 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The field of use may be limited to the prevention, treatment and/or management of diseases involving IL–15 mediated signaling, comprising cancer, Hepatitis B and C infection, and immunotherapy (excluding Human Immunodeficiency Virus).

The licensed territory will be exclusive worldwide.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: March 31, 2008.

**Steven M. Ferguson,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. E8–7260 Filed 4–7–08; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Privacy Office

**[Docket No. DHS–2008–0031]**

### Committee Management; Notice of Committee Charter Renewal

**AGENCY:** Privacy Office; Department of Homeland Security.

**ACTION:** Committee Management; Notice of Committee Charter Renewal.

**SUMMARY:** The Secretary of Homeland Security has determined that the renewal of the charter of the Data Privacy and Integrity Advisory Committee is necessary and in the public interest in connection with the Department of Homeland Security's performance of its duties. This determination follows consultation with the Committee Management Secretariat, General Services Administration.

*Name of Committee:* Data Privacy and Integrity Advisory Committee.

**ADDRESSES:** If you desire to submit comments on this action, they must be submitted by June 2, 2008. Comments must be identified by DHS–2008–0031 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *E-mail: privacycommittee@dhs.gov*. Include the docket number in the subject line of the message.
- *Fax:* 703–235–0442.
- *Mail:* Ken Hunt, Executive Director, 245 Murray Lane, Mail Stop 0550, Washington, DC 20528.
- *Instructions:* All submissions received must include the words ''Department of Homeland Security'' and DHS–2008–0031, the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov* including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov*.