Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ann Marie Trentacosti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6485, Silver Spring, MD 20993–0002, 301–796–2901; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway.'' Labeling must conform to the content and format requirements delineated in §§ 201.56(d) and 201.57 (21 CFR 201.56(d) and 201.57). Special provisions exist for older drug labeling under §§ 201.56(e) and 201.80. Labeling for drugs approved under the accelerated approval process is fundamentally the same as for drugs approved under the traditional pathway; however, for drugs approved under accelerated approval there are additional labeling requirements as described in § 201.57(c)(2)(i)(B) and recommended elements for consideration.

This draft guidance discusses FDA's recommendations for developing the indication and usage statements in the prescribing information for drugs approved under accelerated approval as defined in 21 CFR part 314, subpart H (for new drug applications) and 21 CFR part 601, subpart E (for biologics license applications) when the approval is based on an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The guidance also discusses labeling considerations for indications approved under accelerated approval when clinical benefit has been verified and FDA terminates the conditions of accelerated approval under 21 CFR 314.560 or 21 CFR 601.46, or when FDA withdraws accelerated approval of an indication while other indications for the drug remain approved.

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 Agency's current thinking on labeling for human prescription drug and biologic products approved under accelerated approval. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation/guidances/default.htm,* or *http://www.regulations.gov*.

Dated: March 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–06471 Filed 3–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; The Hispanic Community Health Study/Study of Latinos (HCHS/SOL)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Larissa Aviles-Santa, 6701 Rockledge, Epidemiology Branch, Program in Prevention and Population Sciences, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Dr., MSC 7936, Bethesda, MD 20892–7936, or call non-toll-free number 301–435–0450, or Email your request, including your address to *avilessantal@nhlbi.nih.gov*. Formal requests for additional plans and

instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: The Hispanic Community Health Study/Study of Latinos (HCHS/SOL), Revised, National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose and use of the information collection for this project is to study the prevalence of cardiovascular and pulmonary disease and other chronic diseases, and their risk and protective factors, understand their relationship to all-cause, cardiovascular and pulmonary morbidity and mortality, and understand the role of sociocultural factors (including acculturation) on the prevalence or onset of disease among over 16,400 Hispanics/Latinos of diverse origins, aged 18–74 years at enrollment, living in four U.S. communities: San Diego, California; Chicago, Illinois; Miami, Florida, and the Bronx, New York. In order to achieve these objectives, the HCHS/SOL had two integrated components:

1. Examination of the cohort following a standardized protocol, which consisted of interviews and clinical measurements to assess physiological and biochemical measurements including DNA/RNA extraction for ancillary genetic research studies.

2. Follow-up of the cohort, which consists of an annual telephone interview to assess vital status, changes in health status and medication intake, and new cardiovascular and pulmonary events (including fatal and non-fatal myocardial infarction and heart failure; fatal and non-fatal stroke; and exacerbation of asthma and chronic obstructive pulmonary disease).

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 30,940.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total burden hours
Participants Visit 2 Examination (Appendix 15).	Pre-visit scheduling & safety screening	13,878	1	2/60	463
	Reception, informed consent, medical releases.	13,878	1	20/60	4,626
	Ppt. safety update and routing	13,878	1	2/60	463
	Change clothes, urine specimen	13,878	1	10/60	2,313
	Updated personal information	13,878	1	5/60	1,157
	Anthropometry	13,878	1	7/60	1,619
	Determination of fasting & blood draw	13,878	1	11/60	2,544
	Determination of blood glucose, OGTT	13,878	1	6/60	1,388
	Seated BP	13,878		9/60	2,082
	Echocardiography	8,000		30/60	4,000
	2-hour blood draw, snack	13,878		12/60	2,776
	Personal Medical History	13,878	1	10/60	2,313
	Reproductive Medical History	9,000	1	9/60	1,350
	Pregnancy Complications History	9,000	1	4/60	600
	Socio-economic Status—Occupation	13,878	1	3/60	694
	Health Care Access and Utilization	13,878	1	15/60	3,470
	Chronic Stress	13,878	1	4/60	925
	Family Cohesion	13,878	1	5/60	1,157
	Social Support	13,878	1	3/60	694
	Acculturation	13,878	1	3/60	694
	Well Being	13,878	1	4/60	463
	Abbreviated Medication Use	13,878	1	4/60	925
	Tobacco Use	13,878	1	4/60	925
	Alcohol Use	13,878	1	3/60	694
	Participant Feedback	13,878	1	12/60	2,776
Total				197/60	41,111
Participants Annual Follow-Up Interview. (Appendix 16)	AFU Year 3	3,146	1	15/60	787
	AFU Year 4	9,033	1	15/60	2,258
	AFU Year 5	14,259	1	15/60	3,565
	AFU Year 6	16,222	1	15/60	4,055
	AFU Year 7	16,222	1	15/60	4,055
	AFU Year 8	16,222	1	15/60	4,055
	AFU Year 9	16,222	1	15/60	4,055
	AFU Year 10	16,222	1	15/60	4,055
	AFU Year 11	16,222	1	15/60	4,055
Total				120/60	30,940

Dated: March 11, 2014.

Michael Lauer,

Director, DCVS, NHLBI, NIH.

Dated: March 11, 2014.

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–06401 Filed 3–24–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive License: Device and System for Expression Microdissection (xMD)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a co-exclusive commercial license agreement to practice the inventions embodied in International PCT Application S/N PCT/US03/23317 (HHS Ref. No. E–113–2003/0–PCT–02) filed July 23, 2003, which published as WO 2004/068104 on August 12, 2004, now expired; U.S. Patent No. 7,709,047 (HHS Ref. No. E–113–2003/0–US–03) issued May 4, 2010; U.S. Patent Application S/N 12/753,566 (HHS Ref. No. E–113–2003/0–US–07) filed April 2, 2010; U.S. Patent No. 7,695,752 (HHS Ref. No. E–113–2003/1–US–01) issued April 13, 2010; U.S. Patent No. 8,460,744 (HHS Ref. No. E–113–2003/1–US–02) issued June 11, 2013; Australian Patent No. 2003256803 (HHS Ref. No. E–113–2003/0–AU–04) issued January 21, 2010; Australian Patent No. 2009250964 (HHS Ref. No. E–113–2003/0–AU–06) issued March 25, 2013; and Canadian Patent No. 2513646 (HHS Ref. No. E–113–2003/0–CA–05) issued September 17, 2013, all entitled; ''Target Activated Microtransfer''; and all continuing applications and foreign counterparts to Ventana Medical Systems, Inc. a company having a place of business in Arizona. The patent rights in these inventions have been assigned to the Government of the United States of America.

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

Devices, systems, kits and related consumables, and methods using device, systems, kits and related consumables, for micro-dissection of biological specimens, as covered by the Licensed Patent Right. Excluded from the exclusive field of use are (1) methods, kits, and related consumables that are used independent of the devices or systems by individual researchers employed at non-profit and academic institutions, if such kits were built by the researchers themselves from component parts and used for their own individual research purposes, and (2) diagnostic services performed using devices, systems, kits and related consumables purchased from Ventana or Ventana's authorized distributor(s) by those persons employed at non-profit and academic institutions that purchased the devices, systems, kits and related consumables used in the diagnostic services, shall not infringe Ventana's rights.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 9, 2014 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated co-exclusive license should be directed to: Kevin W. Chang, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5018; Facsimile: (301) 402–0220; Email: *changke@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The subject technologies are methods, devices, and kits for target activated transfer of a target from a biological sample such as a tissue section, comprising: Contacting the biological sample with a reagent that selectively acts on the target within the biological sample; placing a transfer surface adjacent the biological sample, wherein the reagent produces a change in the transfer surface by heating the target; heating the target to produce a change in the transfer surface and selectively adhere the target to the transfer surface, or to selectively increase permeability of the transfer surface to the target; and selectively removing the target from the biological sample by removing the transfer surface and the adhered target from the biological sample, or by moving the target through the transfer surface.

The prospective co-exclusive commercial license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective co-exclusive commercial license may be granted unless within fifteen (15) days from the date of this published notice, the 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 Part 404.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated co-exclusive license. Comments and objections submitted 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 19, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014–06413 Filed 3–24–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans to Treat Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Kite Pharma, Inc., which is located in Los Angeles, California to practice the inventions embodied in the following patent applications:

1. U.S. Provisional Patent Application No. 61/650,020 filed May 22, 2012 entitled ''Murine anti-NY–ESO–1 T cell receptors'' (HHS Ref No. E–105–2012/0–US–01) and
2. PCT Application No. PCT/US13/042162 filed May 22, 2013 entitled ''Murine anti-NY–ESO–1 T cell receptors'' (HHS Ref No. E–105–2012/0–PCT–02)

The patent rights in these inventions have been assigned to the United States of America. The prospective exclusive license territory may be worldwide and the field of use may be limited to the development, manufacture, distribution, sale, and use of the compositions and methods set forth in the Licensed Patent Rights using genetically engineered autologous T lymphocytes derived from the peripheral blood of humans for the treatment of NY–ESO–1-expressing cancers.