E. Periodic Reporting

FDA is soliciting comments on the advisability of requiring periodic reporting for modifications to 510(k)-cleared devices that do not require new 510(k) submissions. FDA does not typically review 510(k) modifications decisions that do not result in 510(k) submissions, unless that information is specifically looked at during an inspection or submitted in conjunction with future changes that do require a 510(k). If manufacturers were required to submit periodic reports identifying and describing their design changes that did not result in 510(k) submissions, FDA would then review these changes and ensure that decisions were made appropriately. This process would likely be similar to annual reporting of device changes for approved class III devices. Over time, periodic reporting would give FDA a more complete picture of the changes industry is making to 510(k)-cleared devices, and may allow FDA to tailor 510(k) modifications requirements to ensure that the Agency is reviewing only the changes it needs to in new 510(k) submissions. Review of periodic reports, however, would require additional FDA resources. Comments on periodic reporting should address the following questions.

1. How often should FDA require periodic reports, e.g., annually, biannually, etc.?

2. Should FDA require periodic reports for all 510(k) devices or only certain devices? If not all devices, then which ones?

3. What information should be included in a periodic report?

F. Other Policy Proposals

FDA acknowledges that any one of the above options may be insufficient on its own; if any changes are made to FDA's 510(k) modification policy, the Agency may adopt a combination of those options. FDA also acknowledges that other options may exist that have not been identified above. FDA is therefore soliciting any other proposals for revising the Agency's 510(k) modification policy. Any policy must ensure:

- Consistent decision-making by both industry and FDA;
- Adequate control of device modifications that could significantly affect safety or effectiveness; and
- Effective FDA oversight of modifications to 510(k)-cleared devices to adequately protect the public health and allow for medical device innovation.

Proposals should be as detailed and specific as possible, and should take into account the issues discussed above in the individual options.

G. Examples

In addition to the options discussed above, FDA is seeking specific examples of device changes that manufacturers have made that should not trigger the requirement for a new 510(k) submission, with explanations as to why 510(k) submissions should not be required. These examples will help FDA develop an appropriate 510(k) modifications policy. FDA typically sees only those device modifications that result in new 510(k) submissions; device changes that do not result in new 510(k) submissions generally are not reviewed by the Agency. Industry provision of these changes will help inform FDA's 510(k) modifications interpretation.

Examples of device changes may also be used for discussion during this public meeting. All examples discussed publicly will be de-identified. Examples may be submitted to the Agency in de-identified form through third parties such as trade associations.

Dated: May 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10888 Filed 5–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Summary of Responses To Request for Information (RFI): Opportunities To Apply a Department of Health and Human Services Message Library To Advance Understanding About Toddler and Preschool Nutrition and Physical Activity

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Summary of Responses to Request for Information (RFI).

SUMMARY: On January 29, 2013, the Health Resources and Services Administration (HRSA) issued a *Request for Information (RFI)* to solicit ideas and information related to ways in which the U.S. Department of Health and Human Services (HHS) can work with interested partners to disseminate and apply *TXT4Tots,* a library of short, evidence-based messages on nutrition and physical activity targeted to parents, caregivers, and health care providers of children ages 1–5 years. HRSA released the *TXT4Tots library* in English and Spanish on February 19, 2013; and followed with an Open Forum on February 20, 2013, to provide further opportunity for input on dissemination and application of the library of messages. HHS received over 25 written responses to the RFI, and approximately 100 individuals participated in the Open Forum.

Comments and Responses: The written responses to the RFI as well as the comments received through the Open Forum indicate that TXT4Tots aligns with the activities of many existing organizations and programs. Several of the respondents expressed an interest in collaborative opportunities to incorporate the messages into current outreach and educational efforts. Some examples of current programs that could leverage the TXT4Tots messages include initiatives at the federal, state, and local levels. The majority of the suggested organizations and programs focus on promoting healthy choices for children and their families. Recommendations included integrating the TXT4Tots messages into their programs and services or using the internet to disseminate the information through Web sites and social media.

Respondents also emphasized that mobile health, social media, and other innovative strategies are a valuable resource to reach a diverse population and can be effectively leveraged to support equitable access to health information. With regard to vehicles for dissemination of the TXT4Tots messages, respondents suggested that they needn't be complicated, but should be user friendly. In addition, respondents noted that the most effective tools for dissemination are those that can fully engage the end users. Specific suggestions for dissemination of the TXT4Tots messages included social media, existing tools and applications, existing Web sites and web services, and text messages, as well incorporating messages into baby product packaging, curricula, health fairs, emails, newsletters, and print materials. Emphasis was placed on leveraging existing platforms that promote healthy choices for young children and could readily integrate the TXT4Tots message content. Respondents also recommended that the TXT4Tots messages be linked to additional sources of information; for example, if utilized as a text message program, URLs could be included to link the message recipients to Web sites with additional information. In addition, social media posts could link to Web sites with ideas for healthy recipes and age-appropriate activities to compliment the messages.

Some respondents indicated that the use of certain technology-based platforms may restrict access to the underserved, who might have limited access to smartphones or the internet. One additional concern that was voiced by numerous respondents was confusion regarding the purpose of TXT4Tots and how it is intended to be used. Specifically, it was unclear that this is a library of messages that could be used in a variety of existing platforms and products and not exclusively a text messaging service. Guidance regarding specific details about the use of the TXT4Tots messages has been added to the TXT4Tots Web page (*http://www.hrsa.gov/healthit/txt4tots*).

HRSA appreciates all of the thoughtful comments received either via the RFI or Open Forum. Guidance regarding specific details about the use of the TXT4Tots messages has been added to the TXT4Tots Web page (*http://www.hrsa.gov/healthit/txt4tots*). It is our hope that the thoughtful recommendations and comments will spur others to explore innovative ways for disseminating the TXT4Tots content.

FOR FURTHER INFORMATION CONTACT: Bethany Applebaum, MPH, Health Resources and Services Administration, Office of Women's Health and Office of Health Information Technology and Quality, 5600 Fishers Lane, Room 7–100, Rockville, Maryland 20857, or email *bapplebaum@hrsa.gov.*

Dated: May 2, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–10968 Filed 5–7–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Induced Pluripotent Stem Cells Generated Using Lentivirus-Based Reprogramming

Description of Technology: Five human induced pluripotent stem cells (iPSC) lines are generated using lentivirus-based reprogramming technology. These lines are pluripotent, meaning they have the potential to differentiate into all cells in the body, and theoretically can proliferate/self-renew indefinitely. The iPSC lines are: NC1 (derived from female's fibroblasts), NC2 (derived from female's fibroblasts), NC3 (derived from male's HUVECS), NC4 (derived from male's fibroblasts) and NC5 (derived from female's fibroblasts). Further details of these cells are available upon request. NC1 uses a retrovirus delivery system incorporating the following vectors: pMIG–hKLF4, pMIG–hOCT4, pMIG–hSOX2, and MSCV h c–MYC IRES GFP. NC2–NC5 use the hSTEMCCA–loxP lentivirus delivery system (a gift from Dr. Gustavo Mostoslavsky). These cell lines will be useful for studies related to stem cell biology, understanding diseases, potential cell therapies, and small molecule screening.

Potential Commercial Applications: The iPSCs of this technology are useful:

(a) To study the biology of stem cell development,

(b) as controls in studies to screen for small molecules to change cell fate and/or to alleviate the phenotypes of various diseases, and

(c) to test different characterization and differentiation assays.

Competitive Advantages:

- These cells can serve as control cells and, thus, significantly reduce the cost of initiating many research projects.
- These cells can be a good source of control cells.

Development Stage:

- Prototype
- Pilot
- Early-stage
- In vitro data available

Inventors: Drs. Guibin Chen and Manfred Boehm (NHLBI)

Intellectual Property: HHS Reference No. E–274–2012/0—Research Tools. Patent protection is not being pursued for this technology.

Licensing Contact: Suryanarayana (Sury) Vepa, Ph.D., J.D.; 301–435–5020; *vepas@mail.nih.gov*.

Collaborative Research Opportunity: The National Heart, Lung, and Blood Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Induced Pluripotent Stem Cells. For collaboration opportunities, please contact Denise Crooks, OTTAD, at 301–435–0103.

Stapled Peptides for Treatment of Cardiovascular Diseases and Inflammation

Description of Technology: The invention is directed to small molecule mimetics of apolipoproteins that have an inter-helical hydrocarbon bond, which stabilizes helix formation.

Apolipoproteins facilitate the transport of lipids and cholesterol in the body. Mimetics of apolipoproteins have been used to treat cholesterol-related disorders. However, these mimetics are susceptible to degradation in biological fluids and as a result, their ability to bind cholesterol becomes diminished over time.

Scientists at NHLBI have devised methods to stabilize and improve the performance of apolipoprotein mimetic peptides, using a modified hydrocarbon chain (''stapled apolipoproteins''). These stapled apolipoproteins are superior to singular apolipoproteins in that they are more resistant to enzymatic degradation and efflux a greater amount of cellular cholesterol.

Stapled apolipoproteins can be used in the treatment of cardiovascular diseases, particularly for treatment of atherosclerosis.

Potential Commercial Applications:

- Treatment of inflammation and cardiovascular diseases, including hyperlipidemia, atherosclerosis, restenosis, and acute coronary syndrome.
- Inclusion in oral, intravenous or transdermal peptide formulations.

Competitive Advantages:

- Stapled apolipoproteins are more resistant to proteolysis and display enhanced bioavailability.
- Stapled apolipoproteins are amenable to oral delivery and have increased permeability to the blood brain barrier.

Development Stage:

- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Alan T. Remaley (CC), Marcelo A. Amar (NHLBI), Imoh Z.