

Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013-23265 Filed 9-24-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0530]

Mobile Medical Applications; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Mobile Medical Applications." The FDA is issuing this guidance to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms (mobile applications or "mobile apps"). At this time, the FDA intends to apply regulatory requirements to only a small subset of mobile apps referred to in this guidance as mobile medical applications (mobile medical apps).

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document

entitled "Mobile Medical Applications" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), 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 request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *For devices regulated by CDRH:* Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993-0002, 301-796-5528.

For devices regulated by CBER: 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.

I. Background

Given the rapid expansion and broad applicability of mobile apps, the FDA is issuing this guidance document to clarify the subset of mobile apps to which the FDA intends to apply its authority. Many mobile apps are not medical devices (meaning such mobile apps do not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and FDA does not regulate them. Some mobile apps may meet the definition of a medical device but because they pose a lower risk to the public, FDA intends to exercise enforcement discretion over these devices (meaning it will not enforce requirements under the FD&C Act). The majority of mobile apps on the market at this time fit into these two categories.

Consistent with the FDA's existing oversight approach that considers functionality rather than platform, the FDA intends to apply its regulatory oversight to only those mobile apps that

are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended. This subset of mobile apps the FDA refers to as mobile medical apps.

FDA is issuing this guidance to provide clarity and predictability for manufacturers of mobile medical apps. Should FDA determine at a later date that the policy in this guidance should be changed in light of new information, the agency would follow a public process, including the opportunity for public input, consistent with FDA's good guidance practices (GGP) regulation in 21 CFR 10.115.

In the **Federal Register** of July 21, 2011 (76 FR 43689), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by October 19, 2011. FDA reviewed the comments and revised the guidance, as appropriate.

II. Significance of Guidance

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 mobile medical applications. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. To receive "Mobile Medical Applications" from CDRH, you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1741 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved information collections found in FDA regulations. These collections of information 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 21 CFR part 801 are approved under OMB control number 0910–0485; the collection of information in 21 CFR part 803 are approved under OMB control number 0910–0437; the collections of information in 21 CFR part 806 are approved under OMB control number 0910–0359; the collections of information in 21 CFR part 807 Subpart B are approved under OMB control number 0910–0387; the collections of information in 21 CFR part 807 Subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 Subparts B and E are approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073.

V. 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>.

Dated: September 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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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. 209 and 37 CFR Part 404 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.

Small Interfering RNA Knock-Down of Cannabinoid-1 Receptor (CB1R) for the Treatment or Prevention of Type-2 Diabetes

Description of Technology: Endocannabinoids (EC) are lipid signaling molecules that act on the same cannabinoid receptors that recognize and mediate the effects of marijuana. Activation of the EC receptor CB1R has been shown to play a key role in the development of obesity and its metabolic consequences, including insulin resistance and type 2 diabetes. Researchers at NIH have now demonstrated in the Zucker diabetic fatty (ZDF) rat model of type-2 diabetes that beta-cell loss is caused by the CB1R-mediated activation of a macrophage-mediated inflammatory response. They have further demonstrated that treatment of ZDF rats with a peripheral CB1R antagonist restores normoglycemia and preserves beta-cell function and that similar results were seen following selective *in vivo* knockdown of macrophage CB1R by daily treatment of ZDF rats with D-glucan-encapsulated CB1R Small interfering RNA (siRNA). Therefore, knock-down of CB1R with siRNA may represent a new method of treating type-2 diabetes or preventing the progression of insulin resistance to overt diabetes.

Potential Commercial Applications: Treatment of obesity, insulin resistance, and diabetes.

Competitive Advantages: A new means of inhibiting the endocannabinoid receptor CB1R.

Development Stage: In vivo data available (animal).

Inventors: George Kunos (NIAAA), Tony Jourdan (NIAAA), Michael P. Czech (UMass Medical School), Myriam Aouadi (UMass Medical School).

Intellectual Property: HHS Reference No. E–103–2013/0—US Application No. 61/839,239 filed June 25, 2013.

Licensing Contact: Jaime M. Greene; 301–435–5559; greenajaime@mail.nih.gov.

Methods for the Treatment of AIDS and Other Retroviral Diseases Using Plant-Derived Compounds

Description of Technology: Human immunodeficiency virus-1 (HIV–1) affects 1.4 million patients in the U.S. and over 33 million worldwide. While highly active antiretroviral therapy (HAART), the current standard of care, is effective in suppressing retroviral activity, cure has not been achieved due to the persistence of latently infected T cells in treated patients. An agent capable of sensitizing this T cell subpopulation concordant with HAART may add significant benefit to individuals with retroviral diseases.

Researchers at the NIH have identified Englerin A and its derivatives as potent and specific activators of viral replication in infected T cells. Use of these compounds in conjunction with existing antiviral therapies has been described for the treatment of AIDS, adult T cell leukemia/lymphoma and other retroviral diseases.

Intellectual property assets available for license include novel compositions of Englerin A along with methods of their use in the treatment of retroviral diseases.

Potential Commercial Applications

- Novel adjuvant therapy for the treatment of retroviral diseases such as AIDS or HTLV-induced leukemia/lymphoma.
- Therapeutic for the management of T lymphocytopenia.

Competitive Advantages

- Englerin A and its derivatives are potent and selective activator of protein kinase C theta in immune cells.
- Compounds are anticipated to have fewer off-target toxicities relative to currently available PKC activators (e.g., interleukins-2 and 7).
- Compounds are optimized for use in combination with clinically available antiviral agents.

Development Stage

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

Inventors: Leonard Neckers, Marston Lineham, Carole Sourbier, Jane Trepel, Min-jung Lee, Bradley Scroggins, John Beutler (all of NCI).

Publications

1. Ratnayake R, *et al.* Englerin A, a selective inhibitor of renal cancer cell growth, from *Phyllanthus engleri*. *Org Lett.* 2009 Jan 1;11(1):57–60. [PMID 19061394].