2011. A copy of the Committee charter can be obtained by contacting the Committee's Executive Secretary. A copy of the Committee charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site address for the FACA database is *http://fido.gov/facadatabase*.

Dated: September 23, 2009.

Penelope Slade-Sawyer,

RADM, USPHS, Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion), Office of Disease Prevention and Health Promotion.

[FR Doc. E9–23539 Filed 9–29–09; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0434]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff: Humanitarian Device Exemption Regulation: Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 30, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and FDA Staff: Humanitarian Device Exemption Regulation: Questions and Answers; Availability. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and FDA Staff: Humanitarian Device Exemption Regulation: Questions and Answers—(OMB Control Number 0910–NEW)

Title III of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85) amended chapter V of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351 *et seq*.) by inserting section 515A, Pediatric Uses of Devices (21 U.S.C. 360e–1).

This new provision requires that new applications under section 520(m) of the act (21 U.S.C. 360j(m)) include both a description of any pediatric subpopulation that suffer from: (1) A disease or condition that the device is intended to treat, diagnose, or cure and (2) the number of affected pediatric patients.

Title III of FDAAA also amended section 520(m) of the act as follows:

Section 520(m)(6)(A)(ii) of the act provides that the Secretary of Health and Human Services will assign an annual distribution number (ADN) for devices indicated for use in a pediatric population or in a pediatric subpopulation. The ADN shall be based on the following information in a humanitarian device exemption (HDE) application: (1) The number of individuals affected by the disease or condition that such device is intended to treat, diagnose, or cure and of that number; (2) the number of individuals likely to use the device and (3) the number of devices reasonably necessary to to treat such individuals.

Section 520(m)(6)(A)(iii) of the act provides that an HDE holder immediately notify the agency if the number of devices distributed during any calendar year exceeds the ADN.

Section 520(m)(6)(C) of the act provides that an HDE holder may petition to modify the ADN if additional information on the number of individuals affected by the disease or condition arises.

In the **Federal Register** of August 5, 2008 (73 FR 45460), FDA published a 60-day notice requesting public comment on the information collection provisions. Seven comments were received in response to the 60-day notice. Of the seven comments received, six related to the guidance and the information collection requests. We received one comment that did not address the content of the guidance nor the information collection.

There were a number of comments received that clarified the reporting requirements for HDE holders and institutional review boards (IRBs). In response to these comments, FDA responded by referring to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 803.50 have been approved under OMB control number 0910–0437 and the collections of information in part 814 (21 CFR part 814) have been approved under OMB control number 0910–0332. FDA received comments that sought clarification regarding how an IRB distinguishes between the use of a humanitarian use device (HUD) and the study of an HUD in a clinical investigation. FDA responded by providing additional background information related to the collection of safety and effectiveness information related to clinical investigation for HDE approved indications and referring to previously approved collections of information found in FDA regulations. This collection of information is approved under OMB control number 0910–0078.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Federal Food, Drug, and Cosmetic Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515A(a)(2)	5	1	5	100	500

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Section of the Federal Food, Drug, and Cosmetic Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
520(m)(6)(A)(ii)	3	1	3	50	150
520(m)(6)(A)(iii)	1	1	1	100	100
520(m)(6)(C)	5	1	5	100	500
Total					1,250

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

FDA based these estimates on the number of original HDE applications that the Center for Devices and Radiological Health (CDRH) received in the period between October 1, 2004, and September 30, 2007. During that time, CDRH received 16 original HDE applications or about 5 per year.

FDA estimates that for each year, CDRH will receive five HDE applications and that three of these applications will be indicated for pediatric use. One HDE holder will notify the agency that the number of devices distributed in the year has exceeded the ADN and five HDE holders will petition to have the ADN modified due to additional information on the number of individuals affected by the disease of condition.

The draft guidance refers also to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in part 814, subparts A, B, and C have been approved under OMB control number 0910–0231; the collection of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in part 814, subpart H have been approved under OMB control number 0910–0332; and the collection of information requirements in 21 CFR 10.30 have been approved under OMB control number 0910–0183.

Dated: September 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23521 Filed 9–29–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ADDRESSES: 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.

Immortalized Transformed Lymphoblastoid Cell Lines From Patients with François-Neetens Mouchetée Fleck Corneal Dystrophy (CFD)

Description of Invention: Researchers at the National Eye Institute, NIH, have made available a set of immortalized transformed lymphoblastoid cell lines created from human T-lymphocytes obtained from patients with François-Neetens Mouchetée Fleck Corneal Dystrophy (CFD). The cells were transformed with defective Epstein-Barr virus using established methods.

CFD is a rare, autosomal dominant corneal dystrophy characterized by numerous small white flecks scattered in all layers of the stroma. CFD has been associated with mutations in the PIP5K3 protein, which is important for post-Golgi vesicle processing.

Applications:

• Useful in the study of proteins expressed by lymphocytes, including in some cases the protein encoded by the mutant gene KCNJ13.

• Useful as a renewable source of DNA for genetic studies related to CFD or the PIP5K3 protein.

Inventors: J. Fielding Hejtmancik and Xiaodong Jiao (NEI).

Relevant Publications:

1. S Li *et al.* Mutations in PIP5K3 are associated with François-Neetens mouchetée fleck corneal dystrophy. Am J Hum Genet. 2005 Jul;77(1):54–63.

2. X Jiao *et al.* Genetic linkage of Francois-Neetens fleck (mouchetée) corneal dystrophy to chromosome 2q35. Hum Genet. 2003 May; 112(5–6):593–599.

Patent Status: HHS Reference No. E–270–2009/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a biological material license.

Licensing Contact: Patrick P. McCue, PhD; 301–435–5560; *mccuepat@mail.nih.gov.*

Novel Chemoattractant-Based Toxins to Improve Vaccine Immune Responses for Cancer and Infectious Diseases

Description of Invention: Cancer is one of the leading causes of death in United States and it is estimated that there will be more than half a million deaths caused by cancer in 2009. A major drawback of the current chemotherapy-based therapeutics is the cytotoxic side-effects associated with them. Thus there is a dire need to develop new therapeutic strategies with fewer side-effects. Immunotherapy has taken a lead among the new therapeutic approaches. Enhancing the innate immune response of an individual has been a key approach for the treatment against different diseases such as cancer and infectious diseases.