Respondents to this proposed collection of information would be manufacturers of biosimilar biological product candidates. Based on FDA’s database system, there are an estimated 18 manufacturers that fall into this category. However, not all manufacturers will have submissions in a given year and some may have multiple submissions. FDA estimates 9 annual responses that include the following: 6 INDs or BPD meetings, 2 applications, and 1 supplement. The estimated hours per response are based on FDA’s past experience with other submissions, which average 30 minutes.

Dated: June 12, 2012.

Leslie Kux,
Assistant Commissioner for Policy.

Background: In 1998, OIG published the Provider Self-Disclosure Protocol (the Protocol) to establish a process for health care providers to disclose potential fraud involving the Federal health care programs. The Protocol provides guidance on how to investigate this conduct, quantify damages, and report the conduct to OIG to resolve the provider’s liability exposure under OIG’s civil money penalty (CMP) authorities. Over the past 14 years, we have resolved over 800 disclosures, resulting in recovering over $280 million to the Federal health care programs. Through our experience in resolving Protocol matters, we identified areas where additional guidance would be beneficial to the provider community and would improve the efficient resolution of Protocol matters.

Specifically, we issued three Open Letters to Health Care Providers to address some of these issues. First, in 2006 we announced an initiative to encourage disclosure of conduct creating liability under OIG’s anti-kickback and physician self-referral law CMP authorities. In 2008, we issued additional guidance and requirements for Protocol submissions to increase the efficiency of the Protocol, including new requirements for the initial submission and specific time commitments from the provider. This Open Letter also announced the presumption of not requiring a compliance agreement as part of settling a cooperative and complete disclosure.

Finally, in 2009, we stated we would no longer accept disclosure of a matter into the Protocol that involved only liability under the physician self-referral law in the absence of a colorable anti-kickback violation. We also announced a minimum $50,000 settlement amount for kickback-related submissions.

After over a decade of experience in resolving Protocol disclosures, we are considering revising the Protocol to provide additional guidance. We are soliciting comments, recommendations, and other suggestions from concerned parties and organizations on how best to revise the Protocol to address relevant issues and to provide useful guidance to the health care industry.

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

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: 301–435–5019; mish@codon.nih.gov.

Collaborative Research Opportunity: The NCI, CCR, Laboratory of Molecular Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize endothelial cells to study prevention of atherosclerosis. For collaboration opportunities, please contact John Hewes, Ph.D. at hewesj@mail.nih.gov.

Mouse Model of STAT5 for the Drug Screen and the Research of Cancer and Autoimmunity

Description of Technology: The invention is a STAT5 mutant mouse that can be used in research related to cancer, autoimmunity and infectious diseases as well as drug screening. The model has multiple immunological defects resulting in formation of STAT5 dimers but not tetramers.

Dated: June 8, 2012.

Daniel R. Levinson, Inspector General.

[FR Doc. 2012–14585 Filed 6–15–12; 8:45 am]

BILLING CODE 4152–01–P

[PMID 2562466]

http://www.accelereyes.com/examples/drug_delivery_model


[PMID 21569804]


Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich; 301–435–5019; mish@codon.nih.gov.

Collaborative Research Opportunity: The NCI, CCR, Laboratory of Molecular Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize targeted delivery of anticancer agents in solid tumors. For collaboration opportunities, please contact John Hewes, Ph.D. at hewesj@mail.nih.gov.

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