TABLE 4—SUMMARY OF ON-SCHEDULE POSTMARKETING COMMITMENTS

[Numbers as of September 30, 2011]

On-Schedule open PMCs	NDA/ANDA (percent of total PMC)	BLA (percent of total PMC) [1]
Pending	141 (38%)	81 (29%)
Ongoing	77 (21%)	72 (26%)
Submitted	77 (21%)	56 (20%)
Combined total	295 (80%)	209 (75%)

[1] See note 1 for table 1 of this document.

TABLE 5—SUMMARY OF OFF-SCHEDULE POSTMARKETING COMMITMENTS

[Numbers as of September 30, 2011]

Off-Schedule open PMCs	NDA/ANDA (percent of total PMC)	BLA (percent of total PMC) [1]
Delayed	69 (19%)	69 (25%)
Terminated	5 (1%)	2 (0.7%)
Combined total	74 (20%)	71 (25%)

[1] See note 1 for table 1 of this document.

TABLE 6—SUMMARY OF CONCLUDED POSTMARKETING REQUIREMENTS AND COMMITMENTS

[October 1, 2010 to October 1, 2011]

	NDA/ANDA (percent of total)	BLA (percent of total) [1]
Concluded PMRs:		
Requirement met (fulfilled)	55 (70%)	16 (84%)
Requirement not met (released and new revised requirement issued)	21 (27%)	0 (0%)
Requirement no longer feasible or product withdrawn (released)	3 (4%)	3 (16%)
Total	79	19
Concluded PMCs:		
Commitment met (fulfilled)	109 (85%)	44 (80%)
Commitment not met (released and new revised requirement/commitment issued)	12 (9%)	2 (4%)
Commitment no longer feasible or product withdrawn (released)	7 (5%)	9 (16%)
Total	128	55

[1] See note 1 for table 1 of this document.

Dated: February 28, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–5302 Filed 3–5–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0788]

Pilot Program for Early Feasibility Study Investigational Device Exemption Applications; Termination of Acceptance of Nominations and Extending the Duration of the Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the acceptance of nominations for the Early Feasibility Study Investigational Device Exemption (IDE) Applications pilot program. This program allowed the submission of nominations from sponsors of innovative device technologies to participate in a pilot program for early feasibility study IDE applications. FDA is also announcing that the duration of the pilot program is extended to May 8, 2013, for sponsors that have already been accepted for the program.

DATES: This notice is effective March 6, 2012.

FOR FURTHER INFORMATION CONTACT: Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–5640.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 10, 2011 (76 FR 70150), FDA announced the availability of a draft guidance entitled ''Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies.'' This guidance document is intended to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the IDE requirements. Simultaneous with the publication of the draft guidance, FDA also announced an Early Feasibility Study IDE Pilot Program (76 FR 70152, November 10, 2011) intended to collect

information and experience on the application of the draft guidance in order to inform the final guidance document.

FDA began accepting nominations for the pilot program on December 12, 2011. In the **Federal Register** notice announcing the pilot program, FDA stated its intention to limit the pilot program to nine candidates. After review of the nominations received in response to the pilot program notice, FDA accepted nine appropriate candidates for the pilot program.

In the pilot program notice, FDA stated its intention to accept nominations to participate in the pilot program until May 8, 2012. Because FDA has already accepted nine sponsors to participate in the program, FDA will no longer accept nominations to participate in the program and will conduct the pilot program for the nine sponsors that have already been accepted.

In the pilot program notice, FDA also stated that the pilot program will terminate on May 8, 2012. Instead, the pilot program will be extended for the nine accepted sponsors until May 8, 2013.

Dated: February 28, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–5311 Filed 3–5–12; 8:45 am]

BILLING CODE 4160–01–P

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.

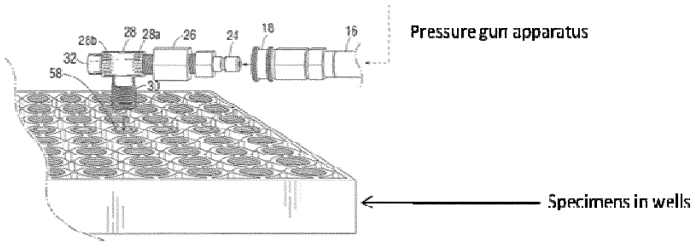
ACTION: Notice.

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.

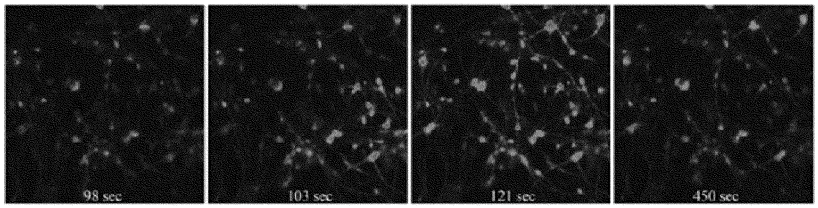
ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057;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

Device for Simulating Explosive Blast Trauma

Description of Technology: NIH scientists have developed a novel device to simulate the effects of pressure waves resulting from explosions or blasts on biological tissue. This methodology allows real-time monitoring of tissue damage while it is occurring and can track the secondary effects of pressure damage after tissue insult. This tool is well-adapted for investigating traumatic brain injury and organ damage resulting from explosion pressure waves, such as in military combat.



Images of cells under microscope taken over time during pressure blast
White label indicates dying cells



Blast given here

Potential Commercial Applications:

- Real-time monitoring of tissue damage from primary blast pressure
- Real-time monitoring of tissue damage from secondary effects of blast pressure, such as tissue shearing against surfaces
- Can monitor tissue through both live imaging and assaying cell viability
- Can measure pressure effects on various tissues

Competitive Advantages:

- Allows differentiation of primary and secondary blast pressure effects on tissue damage
- Employs multiple methods to assess cell viability
- Possesses high temporal resolution

Development Stage: Prototype.

Inventors: Rea Ravin, Paul Blank, Alex Steinkamp, Joshua Zimmerberg, Sergey Bezrukov, and Kim Lee Mcafee (all of NICHD).

Intellectual Property: HHS Reference No E–068–2012/0—U.S. Provisional Application No. 61/590,209 filed 24 Jan 2012.

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

Small-Molecule Inhibitors of Human Galactokinase for the Treatment of Galactosemia and Cancers

Description of Technology: Lactose, found in dairy products and other foods, is comprised of two simple sugars, glucose and galactose. In galactosemia,