Dated: May 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–11745 Filed 5–12–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0005; FDA 225–09–0014]

Memorandum of Understanding Between the Food and Drug Administration and the International Anesthesia Research Society for the Strategies for Mitigating Anesthesia Related Neuro-Toxicity in Tots Public-Private Partnership

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of an amendment to memorandum of understanding (MOU) 222–09–0014 between the International Anesthesia Research Society (IARS) and FDA. The purpose of this MOU is to establish the framework for collaboration between the parties and to support their shared interest of promoting the safe use of anesthetics and sedatives in children. This is an amendment to this MOU to rename the SAFEKIDS (Safety of Key Inhaled and Intravenous Drugs in Pediatrics) Public-Private Partnership (PPP) to SmartTots (Strategies for Mitigating Anesthesia Related Neuro-Toxicity in Tots) PPP.

DATES: The agreement became effective March 17, 2011.

FOR FURTHER INFORMATION CONTACT: Wendy R. Sanhai, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4128, Rockville, MD 20857, 301–796–8518, Fax: 301–827–5891, *Wendy.sanhai@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In March 2009, FDA launched the SAFEKIDS Initiative to address major gaps in scientific information about the effects of anesthetics and sedatives on neurocognitive development of infants and young children. Under the framework of the SAFEKIDS Initiative, FDA and IARS entered into MOU 222–09–0014 to develop the SAFEKIDS PPP—a collaboration among multiple stakeholders to support shared interest of promoting the safe use of anesthetics and sedatives in children.

Per this announcement, the SAFEKIDS Initiative has been renamed the FDA Pediatric Anesthesia Safety Initiative (PASI). As such, all activities supported under the former SAFEKIDS Initiative, including existing projects funded by FDA, will now be supported under PASI.

The amended MOU is intended to revise MOU 222–09–0014 to reflect the official renaming of the FDA–IARS PPP to SmartTots PPP.

In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the Agency is publishing notice of this MOU.

Dated: May 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

225-09-0014

MEMORANDUM OF UNDERSTANDING BY AND BETWEEN THE

UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA)

AND THE

INTERNATIONAL ANESTHESIA RESEARCH SOCIETY (IARS)

FOR

THE STRATEGIES FOR MITIGATING ANESTHESIA RELATED NEURO-TOXICITY IN TOTS

PUBLIC-PRIVATE PARTNERSHIP (SMARTTOTS PPP)

This Memorandum of Understanding (MOU) is executed by and between the United States Food and Drug Administration (FDA) and the International Anesthesia Research Society (IARS), hereafter referred to collectively as the "Parties." This MOU is deemed effective as of the date it is fully signed by both Parties (Effective Date).

WHEREAS, non-clinical studies in juvenile animal models show that exposure to some anesthetics and sedatives is associated with memory and learning deficits and other neurodegenerative changes in the central nervous system;

WHEREAS, insufficient human data exist to support or refute the possibility that similar effects could occur in children; thus, there is a critical need to address the public health issues associated with the safe use of anesthesia and sedatives in children;

WHEREAS, the FDA, under its public health mission, is interested in partnering with multiple stakeholders (e.g. professional societies, academic research institutions, patient advocacy groups, industry and other government and nonprofit organizations) to investigate the effect of anesthetics and sedatives on the developing human brain, including long-term studies in neonates and young children, and to ensure that information and outcomes generated from this research can be used to benefit public health;

WHEREAS, the IARS is a nonpolitical nonprofit voluntary membership society, organized and operated exclusively for exempt purposes as set forth in section 501(c)(3) of the Internal Revenue Code, whose mission is to encourage, stimulate, and fund ongoing anesthesia related research projects and to disseminate current, state-of-the-art, basic and clinical research data in all areas of clinical anesthesia;

WHEREAS, the FDA and the IARS seek to develop a Public-Private Partnership (PPP) to leverage the resources and expertise of the Parties and develop an overarching framework to bring together multiple stakeholders to address the major scientific and clinical gaps regarding the safe use of anesthetics and sedatives in children;

WHEREAS, the Parties have agreed to enter into this MOU to develop the SmartTots (Strategies for Mitigating Anesthesia Related Neuro-Toxicity in Tots)) PPP, a multi-year, multi-phased collaborative effort to make anesthesia safer for children, which will include multiple public and private partners working together in the interest of public health.

NOW, THEREFORE, in consideration of the mutual agreement of the Parties, and of the covenants and conditions hereinafter expressed, the Parties hereby agree as follows:

I. PURPOSE

The purpose of this MOU is to establish the framework for collaboration between the Parties and to support their shared interest of promoting the safe use of anesthetics and sedatives in children. The strategic goals and expected results of this collaboration are to:

1. Establish the SmartTots PPP for the purpose of supporting, implementing, and managing a series of scientific projects to bridge the knowledge gaps that exist in elucidating whether certain anesthetic and sedative agents cause neurotoxicity in rodents, non-human primates, and humans.

2. Share information and data to the extent permitted by State and Federal law, and ensure that information, know-how, and best practices resulting from the scientific projects conducted under the SmartTots PPP are placed in the public domain for the benefit of all stakeholders.

3. Inform clinicians, patients, and other stakeholders about any potential safety risks associated with certain anesthetic and sedative agents, through joint publications, workshops, and other educational efforts.

4. Inform future activities, including clinical trials, and the research and development of anesthetic and sedative agents for intended use in the pediatric population, to the extent permitted by available scientific data.

II. AUTHORITY

FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the Act) as amended (21 U.S.C. 301). In fulfilling its responsibilities under the Act, FDA among other things, directs its activities toward promoting and protecting the public health by assuring the safety, efficacy, and security of drugs. To accomplish its mission, FDA must stay abreast of the latest developments in research and also communicate with stakeholders about complex scientific and public health issues. Increased development of research, education and outreach partnerships with IARS will greatly contribute to FDA's mission.

III. RESPONSIBILITIES OF THE PARTIES

In pursuit of the goals described above, the Parties agree to work through the following process.

1. Under the framework of the SmartTots PPP, the FDA and the IARS will develop an overarching infrastructure to implement and sustain additional pre-clinical and clinical research, leveraging a combination of public and private resources and expertise to bridge the scientific and public health gaps in the pediatric population.

2. The Parties will establish a public-private governance structure including a Steering Committee, an Executive Board, a Scientific Advisory Board, and technical subcommittees. These governance committees will develop strategic and operational plans, set priorities, and review, implement, oversee, and evaluate individual projects conducted under the SmartTots PPP. The membership of the governance committees will be inclusive and will be comprised of representatives of the Parties and other stakeholders. The Parties will develop specific policies and procedures to carry out the work of the governance committees within the framework of the PPP. No

committee, board, or subcommittee established pursuant to this MOU will provide advice or recommendations to FDA or to any government agency.

3. To ensure integrity, scientific rigor, and consistency with the goals and objectives of the SmartTots PPP, all projects proposed for implementation will undergo peer review, with final project selection to be accomplished through a consensus among qualified experts operating in a consistent and unbiased manner within the overall governance structure of the PPP.

4. Data, outcomes and best practices generated under the SmartTots PPP will be placed in the public domain for the benefit of all stakeholders and patients.

IV. RESOURCES

Sources of support for projects under this MOU will be governed by State and Federal law and applicable policies and procedures. The terms for such support will be set forth in the specific and separate written agreements for each project. The MOU does not create binding, enforceable obligations against any Party. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Parties. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which the FDA and IARS operate.

V. GENERAL PROVISIONS

1. Nothing in this MOU alters the statutory authorities or obligations of FDA. This MOU is intended to facilitate cooperative efforts between the Parties in the area of pediatric anesthesiology.

2. U.S. Federal law governs this MOU for all purposes, including, but not limited to, determining the validity of the MOU, the meaning of its provisions, and the rights, obligations, and remedies of the Parties.

3. Access to non-public information shall be governed by separate Confidentiality Disclosure Agreements in which the Parties will agree and certify in writing that they shall not further release, publish or disclose such information and that they shall protect such information. No proprietary data, trade secrets or patient confidential information shall be disclosed among the Parties unless permitted by the provisions of 21 U.S.C. 331(j), 21 U.S.C. 360j(c), 18 U.S.C. 1905, and other pertinent laws and regulations governing the confidentiality of such information.

4. Release of information to the media or to the general public about the SmartTots PPP or the activities conducted by the Parties pursuant to the PPP and this MOU shall be subject to prior review by and agreement between the Parties.

5. It is understood that, although the Parties have mutual interests, there may be opportunities for independent collaborations and activities outside the scope of this MOU, but which are within the scope of the Parties' respective missions. As such, the Parties may, as appropriate, enter into independent negotiations and agreements with prospective partner/s without any effect on this MOU.

6. Rights to inventions or intellectual property developed will be addressed in separate written development and implementation agreements among the Parties. To the extent there is FDA participation in any projects related to development of any product, invention, or property developed, such activities will be governed by applicable Federal law.

7. Any notice or other communication required or permitted under this MOU shall be in writing and will be deemed effective on the date it is received by the receiving Party.

8. FDA participation in this MOU is governed by Federal statutes and regulations.

VI. TERM, TERMINATION AND MODIFICATIONS

1. This MOU constitutes the entire agreement between the Parties as to the matters herein. There are no representations, warranties, agreements, or understandings, expressed or implied, written or oral, between the Parties relating to the subject matter of this MOU that are not fully expressed herein.

2. This MOU may be modified only upon the mutual written consent of the Parties. Modifications must be signed by the original signatories to this MOU, or by their designees or successors. No oral statement by any person shall be interpreted as modifying or otherwise affecting the terms of this MOU.

3. This MOU, when accepted by the Parties, will remain in effect for three (3) calendar years from the Effective Date, unless modified or terminated.

4. Either Party to this MOU may terminate its participation by written notice at any time, with or without cause, and without incurring any liability or obligation. Such written notice shall be given by the terminating Party to the other Party at least 60 days prior to the date of actual termination.

VII. CONTACTS

Notices or formal communications pursuant to this MOU shall be sent in writing by personal delivery, overnight delivery, facsimile telecommunication with confirmatory receipt, or certified or registered mail, return receipt requested, to the following contact for each Party:

For FDA: Wendy R. Sanhai, Ph.D., M.B.A.
Senior Scientific Advisor
Office of the Commissioner, FDA
5600 Fishers Lane, Suite 6A-08
Rockville, MD. 20857
Fax: (301) 827-5891

With a copy to: Chekesha S. Clingman, Ph.D.
Senior Scientific Program Manager
Office of the Commissioner, FDA
5600 Fishers Lane, Suite 6A-08
Rockville, MD 20857
Fax: (301) 827-5891

For IARS: Robert N. Sladen, MD
Chair, IARS Board of Trustees
International Anesthesia Research Society
100 Pine Street, Suite 230
San Francisco, CA 94111
Fax: (415) 296-6901

With a copy to: Thomas A. Cooper
Executive Director
International Anesthesia Research Society
100 Pine Street, Suite 230
San Francisco, CA 94111
Fax: (415) 296-6901

The Parties shall notify each other of any change of address or change of named contact by written notice as specified in this paragraph VI. All notices shall be effective upon date of receipt.

Signatures begin on next page

SIGNATURES OF RESPONSIBLE PARTIES:

We, the undersigned, agree to abide by the terms and conditions of this MOU.

APPROVED AND ACCEPTED FOR THE
UNITED STATES FOOD AND DRUG ADMINISTRATION

_____ Date _____
Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration

APPROVED AND ACCEPTED FOR THE
INTERNATIONAL ANESTHESIA RESEARCH SOCIETY

_____ Date _____
Robert N. Sladen, M.D.
Chair, IARS Board of Trustees
International Anesthesia Research Society

[FR Doc. 2011–11746 Filed 5–12–11; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Interactive Diet and Activity Tracking in AARP (iDATA): Biomarker Based Validation Study (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 14, 2011 (76 FR 13647) and allowed 60-days for public comment. There were no public comments in response to the notice. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has