Dated: May 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–11744 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–2010–N–0355]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 27, 2010 (75 FR 59266), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0606. The approval expires on February 28, 2014. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–11743 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–P–0128]

Determination That XIBROM (Bromfenac Ophthalmic Solution) 0.09% Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that XIBROM (bromfenac ophthalmic solution) 0.09% was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for bromfenac ophthalmic solution 0.09% if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6368, Silver Spring, MD 20993–0002, 301–796–3522.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

XIBROM (bromfenac ophthalmic solution) 0.09% is the subject of NDA 021664 held by ISTA Pharmaceuticals, Inc. (Ista), approved March 24, 2005. XIBROM is a topical nonsteroidal anti-inflammatory drug for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction.

In a citizen petition dated March 1, 2011, and in a letter dated March 3, 2011, Ista informed FDA that it had discontinued shipping XIBROM (bromfenac ophthalmic solution) 0.09% as of February 28, 2011. Ista took the position that XIBROM (bromfenac ophthalmic solution) 0.09% had been discontinued for safety reasons.

After considering the citizen petition and reviewing Agency records, FDA determined under § 314.161 that XIBROM (bromfenac ophthalmic solution) 0.09% was not withdrawn for reasons of safety or effectiveness. We described the basis for this determination in our letter response to Ista's citizen petition (available on *http://www.regulations.gov* under Docket No. FDA–2011–P–0128).

Accordingly, the Agency will continue to list XIBROM (bromfenac ophthalmic solution) 0.09% in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to XIBROM (bromfenac ophthalmic solution) 0.09% may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

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)