

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2009-N-0163]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Draft Guidance, Emergency Use Authorization of Medical Products****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Draft Guidance, Emergency Use Authorization of Medical Products" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, e-mail: [Jonnalynn.capezzuto@fda.hhs.gov](mailto:Jonnalynn.capezzuto@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 6, 2009 (74 FR 51285), 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 0910-0595. The approval expires on January 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: October 21, 2010.

**Leslie Kux,***Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-27160 Filed 10-26-10; 8:45 am]

**BILLING CODE 4160-01-P****DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2010-N-0121]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; The Mammography Quality Standards Act Requirements****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "The Mammography Quality Standards Act Requirements" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, e-mail: [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 15, 2010 (75 FR 33811), 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 0910-0309. The approval expires on October 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: October 21, 2010.

**Leslie Kux,***Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-27159 Filed 10-26-10; 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.

**Immunotoxin for the Treatment of Neuroblastoma Relapse***Description of Technology:*

Immunotoxins are proteins which have two distinct domains: (1) An antibody or antibody binding fragment which is capable of recognizing a single specific cell surface protein and (2) a toxin domain which is capable of inducing cell death. Immunotoxins are currently being pursued as therapeutics because they specifically kill diseased cells while leaving essential, healthy cells alone. This increases the effectiveness of the therapy while reducing the appearance of side-effects. A particular immunotoxin that is being studied in clinical trials consists of an anti-CD22 antibody binding fragment and a mutated *Pseudomonas* exotoxin A. Although this immunotoxin is being explored primarily as a treatment for hematological malignancies, it can be used to treat any condition where CD22 is overexpressed on the cell membrane of diseased cells.

Neuroblastomas are malignant cancers that start in nerve tissue and primarily affect infants and children. Although frontline treatments for neuroblastoma are often effective, relapse frequently occurs in high risk cases. The most common form of relapse in neuroblastoma patients is caused by Neuroblastoma tumor initiating cells (NB-TIC). Therefore, if NB-TIC could be eliminated, high risk neuroblastoma patients could have a therapeutic option for preventing a relapse.

This invention concerns the discovery that NB-TIC expresses CD22. As a result, NB-TIC are susceptible to treatment with an anti-CD22 immunotoxin. By combining frontline