

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0544]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the Medical Device Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the application for participation in the Medical Device Fellowship Program (MDFP).

DATES: Submit either electronic or written comments on the collection of information by December 27, 2010.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether

the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Application for Participation in the Medical Device Fellowship Program—5 U.S.C. 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 (OMB Control Number 0910-0551)—Extension

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code, authorize Federal agencies to rate applicants for Federal jobs. Collecting applications for the MDFP will allow FDA's Center for Devices and Radiological Health (CDRH) to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

5 U.S.C. Section	FDA form No.	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
1104, 1302, 3301, 3304, 3320, 3361, 3393, 3394	3608	250	1	250	1	250

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

FDA based these estimates on the number of inquiries that have been received concerning the program and

the number of requests for application forms over the past 3 years.

Dated: October 21, 2010.
Leslie Kux,
Acting Assistant Commissioner for Policy.
 [FR Doc. 2010-27158 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-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.

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.

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