mechanisms into MDI drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

### II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: December 3, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01–30491 Filed 12–10–01; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 00D–1681]**

### Guidance on Use of Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies.'' This guidance updates a notice of availability entitled ''Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use'' published in the **Federal Register** on June 29, 1982, concerning the prophylactic use of potassium iodide (KI) in the event of release of radioactive isotopes of iodine. In this guidance, FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland and, thus, reduce the risk of thyroid cancer in the event of a radiation emergency. The guidance recommends lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than previously recommended.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Rose Cunningham, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779.

**SUPPLEMENTARY INFORMATION:**

### I. Background

The Federal Emergency Management Agency (FEMA) has established roles and responsibilities for Federal agencies in assisting State and local governments in their radiological emergency planning and preparedness activities. The Federal agencies, including the Department of Health and Human Services (DHHS), are intended to accomplish these roles and responsibilities as part of the Federal Radiological Preparedness Coordinating Committee. Among other responsibilities, DHHS is to provide guidance on the use of radioprotective substances to reduce radiation doses to specific organs from the release into the environment of large quantities of radioactivity. FDA is specifically charged with providing guidance on the prophylactic use of KI in the event of release of radioactive isotopes of iodine.

As part of its responsibilities as established by FEMA, on June 29, 1982, FDA published in the **Federal Register** a notice entitled ''Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use'' (47 FR 28158). In that notice, the agency made recommendations regarding the use of KI as a thyroid blocking agent. During 1999 to 2000, the agency reviewed additional data gathered primarily after the Chernobyl reactor accident. On January 4, 2001 (66 FR 801), the agency issued a draft guidance that revised some of the 1982 recommendations. The initial comment period on the draft guidance closed on February 5, 2001. On February 9, 2001 (66 FR 9711), the agency extended the comment period to April 30, 2001. After consideration of all comments, the agency is issuing this final version of the guidance. Other than clarifying edits, the agency has made no substantial changes to the recommendations incorporated in the draft guidance. In this guidance the agency maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland and thus to reduce the risk of thyroid cancer in the event of a radiation emergency. FDA proposes lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than previously recommended. FDA's revised recommendations are in general accordance with those of the World Health Organization, as expressed in its ''Guidelines for Iodine Phrophylaxis Following Nuclear Accidents'' (1999), except for minor modifications.

The recommendations in the guidance were prepared by FDA scientists from the Center for Drug Evaluation and Research and from the Center for Devices and Radiological Health, in consultation with other governmental experts.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the use of potassium iodide as a thyroid blocking agent in radiation emergencies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

### II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: December 3, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01–30492 Filed 12–10–01; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by agencies 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.

**Imaging of Extracellular Proteases in Cells Using Mutant Anthrax Toxin Protective Antigens**

Bugge et al. (NIDCR)

DHHS Reference No. E–295–01/0 filed 05 Sep 2001

*Licensing Contact:* Richard Rodriguez; 301/496–7056 ext. 287; e-mail: *rodrigur@od.nih.gov.*

The claimed invention provides highly specific and sensitive methods for in vivo, in vitro, or ex vivo imaging of specific extracellular protease activity using an anthrax binary toxin system. The system targets cells that express extracellular proteases of interest. Such a system would be highly useful since various studies have demonstrated a positive correlation between the activity of extracellular proteases and various diseases and undesirable physiological conditions. For example, breakdown of the extracellular matrix by extracellular proteases is a prerequisite for the invasive growth of malignant cells, metastatic spread of tumors, and other pathological remodeling of tissue. In this case, methods are provided for the imaging of a specific extracellular protease by contacting a cell with: (1) A mutant anthrax toxin protective antigen (mPrAg) that binds to a cell surface receptor of a cell expressing an extracellular protease and is cleaved by a specific extracellular protease expressed by the cell and (2) a ligand that specifically binds to the cleaved mPrAg and is linked to a moiety that is detected by an imaging procedure, thereby forming a ligand-mPrAg complex that is translocated into the cell. The detectable moiety linked to the ligand in the ligand-mPrAg complex can be imaged before, during, or after translocation. Specific disease examples might include, but are not necessarily limited to, cancer, inflammation, and tumor progression or regression.

**Neural Crest-Melanocyte cDNA Based Microarray Analysis for Human Skin Pigmentation Research**

William Pavan and Stacie K. Loftus (NHGRI)

DHHS Reference No. E–014–02/0

*Licensing Contact:* Pradeep Ghosh; 301/496–7736 ext. 211; e-mail: *ghoshp@od.nih.gov.*

Microarrays have wide applications in basic research and are used for the discovery of candidate genes as markers for disease and for therapeutic intervention. This invention pertains to the identification of a set of neural crest-melanocyte (NC–M) genes through microarray analysis and informatic analysis. Utilizing the extensive sequence information in the expressed sequence tag database (dbEST), the specific set of cDNA sequence was identified for microarray analysis of melanocyte function and diseases. This integrated technique of sequencing with bioinformatics led to the discovery of novel genes. The cDNA sequences selected in this invention are differently expressed in neural crest melanocyte derivates relative to non-neural derived samples. Given that many of the neural-crest melanocyte genes are expressed at embryonic stages of neural crest-melanocyte development, the gene set identified in this invention should provide a useful tool for the analysis of patterns of transcriptional regulation of NC–M development. Thus, this technology will be useful for the characterization of altered expression patterns in diseases such as melanoma. Further, this new microarray research tool has been developed using the set of genes that are likely to be involved in the control of human skin pigmentation. The microarray system utilizing these genes is of significant importance in identifying small molecules that may modulate their activity leading to alterations in human skin pigmentation. Therefore, this invention is significantly useful to the researchers to study alterations in human skin pigment amount and type.

Dated: November 29, 2001.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 01–30515 Filed 12–10–01; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of person privacy.

*Name of Committee:* National Cancer Institute Initial Review Group. Subcommittee A—Cancer Centers.

*Date:* December 7, 2001.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn, 5520 Wisconsin Ave., Palladin West, Chevy Chase, MD 20815.

*Contact Person:* David E. Maslow, Ph.D., Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive