technology provides the methods of delivering nucleic acids to cells of specific regions, tissues and cell types of the central nervous system (CNS); as well as to cells of the lung, by using AAV5 vectors and particles. The specific brain cells that are targeted by AAV5 belong to both non-neuronal/glial cells and neuronal cells, such as cerebellar cells and ependymal cells. The specific lung cells targeted by AAV5 are the apical surfaces of the airway such as alveolar cells.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 7, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–22833 Filed 9–13–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Immunotoxins/Targeted Toxins for the Treatment of Human Cancers

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in U.S. Patent Application 61/241,620 entitled "Development of an Immunotoxin in Which All B–Cell Epitopes Have Been Removed and Which Has High Cytotoxic Activity" [HHS Ref. E–269–2009/0–US–01], U.S. Patent Application 60/969,929 entitled "Deletions in Domain II of Pseudomonas Exotoxin A That Reduce Non-Specific Toxicity" [HHS Ref. E–292–2007/0–US–01], U.S. Patent Application 60/703,798 entitled "Mutated Pseudomonas Exotoxins with Reduced Antigenicity" [HHS Ref. E–262–2005/0–US–01], U.S. Patent Application 60/160,071 entitled "Immunoconjugates Having High Binding Affinity" [HHS Ref. E–139–1999/0–US–01], U.S. Patent Application 60/067,175 entitled "Antibodies, Including Fv Molecules, and Immunoconjugates Having High Binding Affinity for Mesothelin and Methods for Their Use" [HHS Ref. E–021–1998/0–US–01], U.S. Patent Application 60/010,166 entitled "Molecular Cloning of Mesothelin, a Differentiation Antigen Present on Mesothelium, Mesotheliomas and Ovarian Cancers" [HHS Ref. E–002–1996/0–US–01], PCT Application PCT/US97/00224 entitled "Mesothelin Antigen and Methods and Kits for Targeting It" [HHS Ref. E–002–1996/1–PCT–01], U.S. Patent 5,747,654 entitled "Recombinant Disulfide-Stabilized Polypeptide Fragments Having Binding Specificity" [HHS Ref. E–163–1993/0–US–01], PCT application PCT/US96/16327 entitled "Immunotoxin Containing A Disulfide-Stabilized Antibody Fragment" [HHS Ref. E–163–1993/2–PCT–01], U.S. Patent Application 07/596,291 entitled "A Monoclonal Antibody" [HHS reference E–195–1990/0–US–01], and all continuing applications and foreign counterparts, to Morphotek, Inc. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to:

The use of the MORAb-009–PE–LR/8X immunotoxin for the treatment of mesothelin-expressing cancers, the use of the anti-CD300LF–PE/LR/8X immunotoxin for the treatment of CD300LF-expressing cancers such as acute myelogenous leukemia (AML), and the use of annexin A2-targeted PE–LR/8X toxin for the treatment of annexin A2-expressing cancers such as glioma, ovarian cancer and pancreatic cancer.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before October 14, 2010 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, PhD., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4632; Facsimile: (301) 402–0220; E-mail: *lambertsond@od.nih.gov.*

SUPPLEMENTARY INFORMATION: These inventions concern immunotoxins and targeted toxins, and methods of using the immunotoxins/targeted toxins for the treatment of (a) mesothelin-expressing cancers (such as mesothelioma, ovarian cancer and pancreatic cancer), (b) CD300LF-expressing cancers (such as acute myelogenous leukemia (AML)) or (c) Annexin A2-expressing cancers (such as glioma, ovarian cancer and pancreatic cancer). Several specific immunotoxins/targeted toxins are covered by this technology, including MORAb-009–PE–LR/8X, anti-CD300LF–PE–LR/8X and Annexin A2-targeted PE–LR/8X.

Each of these immunotoxins/targeted toxins comprises (1) a toxin moiety (PE–LR/8X) that is a modified version of the *Pseudomonas* exotoxin A ("PE") and (2) either (a) an antibody fragment domain that is capable of binding to mesothelin, (b) an antibody fragment domain that is capable of binding to CD300LF, or (c) a peptide that is capable of binding to Annexin A2. The toxin moiety been modified in various manners in order reduce immunogenicity, thereby improving the therapeutic value of PE while maintaining its ability to trigger cell death. Since mesothelin, CD300LF and Annexin A2 are each preferentially expressed on certain types of cancer cells, the targeting domains of the immunotoxins/targeted toxins (MORAb-009, anti-CD300LF and Annexin A2 binding peptide) allows the immunotoxins/targeted toxins to selectively bind to certain cancer cells so that only the cancer cells are killed. This results in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7 within thirty (30) days from the date of this published notice.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 7, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–22844 Filed 9–13–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0425]

Withdrawal of Approval of New Animal Drug Applications; Chloramphenicol, Lincomycin, Pyrantel Tartrate, and Tylosin Phosphate and Sulfamethazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of four new animal drug applications (NADAs). In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the regulations to remove portions reflecting approval of these NADAs.

DATES: Withdrawal of approval is effective September 24, 2010.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9079, email: *john.bartkowiak@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611; International Nutrition, Inc., 7706 "I" Plaza, Omaha, NE 68127; and Feed Service Co., Inc., 303 Lundin Blvd., P.O. Box 698, Mankato, MN 56001 have requested that FDA withdraw approval of the four NADAs listed in table 1 because they are no longer manufactured or marketed:

TABLE 1.

Sponsor	NADA Number Product (Established Name of Drug)	21 CFR Cite (Sponsor's Drug Labeler Code)
John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611	NADA 65–137 AMPHICOL–V Capsules (chloramphenicol)	§ 520.390b (058034)
International Nutrition, Inc., 7706 "I" Plaza, Omaha, NE 68127	NADA 121–337 INI Swine Ban-Wormer B–9.6 BA. (pyrantel tartrate)	§ 558.485 (043733)
International Nutrition, Inc., 7706 "I" Plaza, Omaha, NE 68127	NADA 132–923 LINCO 8/LINCO 20 (lincomycin)	§ 558.325 (043733)
Feed Service Co., Inc., 303 Lundin Blvd., P.O. Box 698, Mankato, MN 56001	NADA 138–342 TYLAN 5 Sulfa-G Premix (tylosin and sulfamethazine)	§ 558.630 (030841)

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 65–137, 121–337, 132–923, and 138–342, and all supplements and amendments thereto, is hereby withdrawn, effective September 24, 2010.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these NADAs.

Dated: September 1, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010–22809 Filed 9–13–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3315–EM; Docket ID FEMA–2010–0002]

Massachusetts; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the Commonwealth of Massachusetts (FEMA–3315–EM), dated September 2, 2010, and related determinations.

DATES: Effective Date: September 2, 2010.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 2, 2010, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the Commonwealth of Massachusetts resulting from Hurricane Earl beginning on September 1, 2010, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* ("the Stafford Act"). Therefore, I declare that such an emergency exists in the Commonwealth of Massachusetts.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program. This assistance excludes regular time costs for subgrantees' regular employees.

Consistent with the requirement that Federal assistance is supplemental, any