Dated: September 26, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–25144 Filed 9–29–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 65 FR 41079, dated July 3, 2000) is amended to reflect the retitling of the Division of Public Health Systems and the Division of Media and Training Services, Public Health Practice Program Office, to the Division of Public Health Systems Development and Research and the Division of Professional Development and Evaluation respectively.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete the title *Division of Public Health Systems (CH5)* and insert the title *Division of Public Health Systems Development and Research (CH5).*

Delete the title *Division of Media and Training Services (CH7)* and insert the title *Division of Professional Development and Evaluation (CH7).*

Dated: September 20, 2000.

Martha Katz,

Acting Director.

[FR Doc. 00–25261 Filed 9–29–00; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1516]

Apothecon, Inc., et al.; Withdrawal of Approval of 76 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 76 abbreviated new drug applications (ANDA's). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: October 10, 2000.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

ANDA No.	Drug	Applicant
60–100	Crysticillin (Penicillin G Procaine Suspension USP).	Apothecon, Inc., P.O. Box 4500, Princeton, NJ 08543.
60–618	Grifulvin V (Griseofluvin Microsize) Tablets, 125 milligrams (mg), 250 mg, and 500 mg.	Johnson & Johnson Consumer Co, Inc., 199 Grandview Rd., Skillman, NJ 08858.
61–220	Opthochlor (Chloramphenicol Ophthalmic Solution USP) 5 mg/milliliter (mL).	Parkedale Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620.
61–334	Bactocill (Oxacillin Sodium for Injection).	SmithKline Beecham Pharmaceuticals, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101.
61–449	Staphcillin (Methicillin Sodium).	Apothecon, Inc.
61–452	Cloxacillin Sodium Capsules USP, 250 mg and 500 mg.	Do.
61–739	Garamycin Pediatric Injection (Gentamicin Sulfate Injection USP).	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
62–328	Erythromycin Topical Solution USP, 1.5%.	Alpharma, 333 Cassell Dr., suite 3500, Baltimore, MD 21224.
62–727	Totacillin-N (Ampicillin Sodium) for Injection.	Smithkline Beecham Pharmaceuticals.
62–755	Nallpen (Nafcillin Sodium Powder for Injection USP).	Do.
70–356	Diazepam Tablets USP, 2 mg.	Roxane Laboratories, Inc., P.O. Box 16532, Columbus, OH 43216.
70–357	Diazepam Tablets USP, 5 mg.	Do.
70–358	Diazepam Tablets USP, 10 mg.	Do.
71–010	Acetominophen Suppositories, 120 mg.	Do.
71–011	Acetominophen Suppositories, 650 mg.	Do.
71–018	Metaproterenol Sulfate Inhalation Solution USP, 0.6%.	AstraZeneca, L.P.
71–275	Metaproterenol Sulfate Inhalation Solution USP, 0.4%.	Do.
72–018	Droperidol Injection USP, 2.5 mg/mL.	Do.
72–019	Droperidol Injection USP, 2.5 mg/mL.	Do.
72–021	Droperidol Injection USP, 2.5 mg/mL.	Do.
72–648	Timolol Maleate Tablets USP, 5 mg.	Novopharm Limited, c/o Novopharm NC, Inc., 4700 Novopharm Blvd., Wilson, NC 27893.
72–649	Timolol Maleate Tablets USP, 10 mg.	Do.
72–650	Timolol Maleate Tablets USP, 20 mg.	Do.

ANDA No.	Drug	Applicant
73–187	Loperamide Hydrochloride Oral Solution, 1 mg/5 mL.	Alpharma.
73–340	Prometa Inhalation Solution (Metaproternol Sulfate Inhalation Solution USP), 5%.	Muro Pharmaceutical, Inc., 890 East St., Tewksbury, MA 01876.
74–361	Cimetidine Tablets USP, 300 mg, 400 mg, and 800 mg.	Roxane Laboratories, Inc.
74–371	Cimetidine Tablets USP, 800 mg.	Do.
74–790	Ketorolac Tromethamine Tablets USP.	Do.
74–832	Captopril and Hydrochlorothiazide Tablets USP, 50 mg/25 mg.	Danbury Pharmacal, Inc., 131 West St., Danbury, CT 06810.
80–001	Calcium Gluceptate Injection USP.	Abbott Laboratories.
80–327	Prednisolone Tablets USP, 5 mg.	Roxane Laboratories, Inc.
80–474	Hytone (Hydrocortisone) Ointment 0.25%, 0.5%, 1%, and 2.5%.	Dermik Laboratories, Inc., 500 Arcola Rd., P.O. Box 1200, Collegeville, PA 19426–0107.
83–682	Phendimetrazine Tartrate Tablets USP, 35 mg.	Zenith Goldline Pharmaceuticals, Inc., 140 Legerand Ave., Northvale, NJ 07647.
84–655	Prednicen-M (Prednisone Tablets USP), 5 mg.	Schwarz Pharma, Inc., P.O. Box 2038, Milwaukee, WI 53201.
84–659	Acetominophen and Codeine Phosphate Tablets USP, 300 mg/15 mg.	Roxane Laboratories, Inc.
84–667	Acetominophen and Codeine Phosphate Tablets USP, 300 mg/60 mg.	Do.
84–811	Apresazide (Hydralazine Hydrochloride and Hydrochlorothiazide USP) Capsules, 100/50 mg.	Novartis Pharmaceuticals Corp.
84–990	Dexone (Dexamethasone Tablets, USP), 1.5 mg.	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
85–539	Flutex (Triamcinolone Acetonide Cream USP), 0.1%, 0.5%, and 0.025%.	Zenith Goldline Pharmaceuticals, Inc.
85–686	Curretab (Medroxyprogesterone Acetate Tablets, USP) 10 mg.	Solvay Pharmaceuticals, Inc.
85–733	Hydrocortisone Cream USP, 1%.	Zenith Goldline Pharmaceuticals, Inc.
85–777	Selenium Sulfide Lotion USP, 2.5%.	Do.
85–873	Butabarbital Sodium Elixir, 30 mg/5 mL.	Alpharma.
85–944	Amitriptyline Hydrochloride Tablets USP, 25 mg.	Roxane Laboratories, Inc.
85–945	Amitriptyline Hydrochloride Tablets USP, 50 mg.	Do.
86–002	Amitriptyline Hydrochloride Tablets USP, 10 mg.	Do.
86–003	Amitriptyline Hydrochloride Tablets USP, 100 mg.	Do.
86–004	Amitriptyline Hydrochloride Tablets USP, 75 mg.	Do.
86–065	Procan SR (Procainamide Hydrochloride Extended-Release Tablets, USP), 500 mg.	Parkedale Pharmaceuticals, Inc.
86–090	Amitriptyline Hydrochloride Tablets USP, 150 mg.	Roxane Laboratories, Inc.
87–025	Isoetharine Inhalation Solution USP, 0.125%.	Roxane Laboratories, Inc.
87–203	Flurandrenolide Lotion USP.	Alpharma.
87–328	Trifluoperazine Hydrocholride Tablets USP, 5 mg.	Zenith Goldline Pharmaceuticals, Inc.
87–375	Flutex (Triamcinolone Acetonide Ointment USP).	Do.
87–376	Flutex (Triamcinolone Acetonide Ointment USP).	Do.
87–377	Flutex (Triamcinolone Acetonide Ointment USP).	Do.
87–396	Isoetharine Inhalation Solution USP, 0.1%.	Roxane Laboratories, Inc.
87–427	Nogenic HC (Hydrocortisone Cream USP), 1%.	Zenith Goldline Pharmaceuticals, Inc.
87–428	Triatex (Triamcinolone Acetonide Cream USP), 0.5%.	Do.
87–429	Triatex (Triamcinolone Acetonide Cream USP), 0.1%.	Do.
87–430	Triatex (Triamcinolone Acetonide Cream USP), 0.025%.	Do.
87–510	Procan SR (Procainamide Hydrochloride Extended-Release Tablets, USP), 750 mg.	Parkedale Pharmaceuticals, Inc.
87–611	Liquid Pred (Prednisone Syrup USP), 5 mg/5 mL.	Muro Pharmaceutical, Inc.
87–612	Trifluoperazine Hydrochloride Tablets USP, 1 mg.	Zenith Goldline Pharmaceuticals, Inc.
87–613	Trifluoperazine Hydrochloride Tablets USP, 2 mg.	Do.
87–614	Trifluoperazine Hydrochloride Tablets USP, 10 mg.	Do.
87–742	Oxycodone Hydrochloride 2.25 mg, Oxycodone Terephthalate 0.19 mg, and Aspirin 325 mg Tablets.	Roxane Laboratories, Inc.
88–275	Isoetharine Inhalation Solution USP, 0.25%.	Do.
88–489	Procan SR (Procainamide Hydrochloride Extended-Release Tablets, USP), 1 gram.	Parkedale Pharmaceuticals, Inc.
89–193	Methocarbamol and Aspirin Coated Tablets, 400 mg/325 mg.	McNeil Consumer Healthcare, 7050 Camp Hill Rd., Fort Washington, PA 19034–2299.
89–427	Dipyridamole Tablets USP, 75 mg.	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
89–614	Isoetharine Inhalation Solution USP, 0.062%.	AstraZeneca, L.P.
89–615	Isoetharine Inhalation Solution USP, 0.125%.	Do.

ANDA No.	Drug	Applicant
89–616	Isoetharine Inhalation Solution USP, 0.167%.	Do.
89–617	Isoetharine Inhalation Solution USP, 0.2%.	Do.
89–618	Isoetharine Inhalation Solution USP, 0.25%.	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective October 10, 2000.

Dated: September 12, 2000.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 00–24844 Filed 9–29–00; 8:45 am]

BILLING CODE 4160–01–F

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.

Method and Device for Analysis of Biological Specimens

M. Emmert-Buck (NCI), C. Englert (NCI), R. Bonner (NICHD), and L. Liotta (NCI)

DHHS Reference No. E–197–00/0 filed 26 Jul 2000

Licensing Contact: Uri Reichman; 301/496–7736 ext. 240; e-mail: reichmau@od.nih.gov

The invention discloses methods for selective analysis of cellular samples, and more particularly it provides methods for selective analysis of tissue samples, such as tumors. The methods include placing the tissue on a surface such as membrane for example, and activating the surface at selected sites adjacent to the cells of interest. The activated sites become permeable and thus transferable to fluids. The cells adjacent to the permeable sites can than be selectively extracted and their content analyzed by standard biochemical procedures or by applying the extract to microarray devices, such as cDNA arrays, for analysis of gene expression etc. The technique presents a convenient alternative to existing methods of tissue microdissection. For further convenience, the technique can be readily combined with a variety of analytical devices such as microarrays biochips or other devices which include multiple regions carrying multiple capture molecules.

Hepatitis A Virus Clones Adapted for Growth in African Green Monkey Kidney (AGMK) Cells and Vaccines Comprising said Clones

Robert H. Purcell *et al.* (NIAID)

DHHS Reference No. E–008–95/0 filed 06 Aug 1999

Licensing Specialist: Carol Salata; 301/496–7735 ext. 232; e-mail: salatac@od.nih.gov

The present invention relates to hepatitis A virus clones adapted to growth in African Green Monkey Kidney Cells intended to be used as a live attenuated vaccine. Several cell culture-adapted strains of hepatitis A virus (HAV) are currently being used as inactivated vaccines. However, the inactivated vaccines have the limitation that multiple doses are required for effective immunization. Thus, a live vaccine could have the advantage of inducing life-long immunity following administration of only a single dose.

Preclinical studies have been done using virus isolates of this invention. Preliminary observations suggest that some of the HM–175 P39 virus isolates analyzed may be promising candidates for use as a live attenuated vaccine. HM–175 P39 clone 15 appears to have the growth and attenuation properties that are desirable in a live vaccine for HAV as it is partially attenuated for tamarins and fully attenuated for chimpanzees. HM–175 P39 clone 13 may also be a potential vaccine candidate as it replicates efficiently in tamarins, resulting in moderate increases in serum liver enzyme and early seroconversion to anti-HAV positivity but is still fully attenuated for chimpanzees.

Method of Predicting Susceptibility to HIV Infection or Progression of HIV Disease

Michael W. Smith, Hyoung Doo Shin, Stephen J. O'Brien (NCI)

DHHS Reference No. E–066–99/0 filed 09 Apr 1999 and DHHS Reference No. E–066–99/1 filed 06 Apr 2000

Licensing Contact: J. P. Kim; 301/496–7056 ext. 264; e-mail: kimj@od.nih.gov

This invention identifies the importance of a variant in the IL 10 gene (–592–5′A) that is commonly found in the population with HIV–1/AIDS. Individuals that inherit one or two copies of this form of IL 10 are at a greater risk for progression from HIV–1 infection to the development of clinical AIDS or death. The effects of IL 10–592 are particularly evident 5 years after infection. The gene variant and its product may be of diagnostic value in testing to determine treatment regimens for patients and mimicking the effect of the IL 10–5′A gene variant may be useful in developing therapies for HIV infection. The polymorphism of the present invention can be used in association with other alleles, such as CCR5–D32, CCR2–64I, CCR5– +.P1.+, HLA–B35 and HLA homozygosity, to determine an individual's susceptibility to HIV infection, and provide a prognosis for disease progression in those who have been infected. The potential therapies derived from the IL 10–592 genetic variant may be particularly applicable to patients on triple drug therapy since these patients have generally been infected for a number of years prior to treatment.