assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 24, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DIFFERIN Solution represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA had determinated that the applicable regulatory review period for DIFFERIN Solution is 2,814 days. Of this time, 1,651 days occurred during the testing phase of the regulatory review period, while 1,163 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: September 18, 1988. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on September 18, 1988.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: March 26, 1993. The applicant claims March 19, 1993, as the date the new drug application (NDA) for DIFFERIN Solution (NDA 20–338) was initially submitted. However, FDA records indicate that NDA 20–338 was submitted on March 26, 1993.

3. *The date the application was approved:* May 31, 1996. FDA has verified the applicant's claim that NDA 20–338 was approved on May 31, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 257 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 31, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 28, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 17, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–2068 Filed 1–27–97; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Submission for OMB Review; Comment Request; NCI Cancer Information Service Community Services Database Survey and Verification

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on May 3, 1996, page 19943 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: Describe the proposed information collection activity as follows. Include:

Title: NCI Cancer Information Service Community Services Database Survey and Verification.

Type of Information Collection Request: New.

Form Number: Not applicable.

Need and Use of Information Collection: The CIS provides the general public, cancer patients, families, health professionals, and others with the latest information on cancer. Essential to fulfilling its role as a referral source for cancer patients and their families is the identification, acquisition, and dissemination of information about hospitals, breasts and cervical cancer screening clinics, and cancer pain management programs. This effort involves sending a survey tool or a verification instrument annually to approximately 17,135 respondents.

Frequency of Response: Annual.

Affected Public: Not-for-profit institutions; Business or other for-profit; Federal Government; State, Local or Tribal Government.

Type of Respondent: Administrators of hospitals, pain centers, screening facilities.

The annual reporting burden is as follows:

Estimated Number of Respondents: 17,135 respondents.

Estimated Number of Responses per Respondent: One (1) per year).

Average Burden Hours Per Response: .167 hours.

Estimated Total Annual Burden Hours Requested: 2,862 hours.

The annualized cost to respondents is estimated at: $34,338.54. There are no Capital Costs to report. There are no Operating of Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Year 1:				
Administrators of hospitals, pain centers, screening facilities	18,027	1	0.167	3,011
Year 2:				
New Organizations and verification	16,605	1	0.167	2,773
Year 3:				
New Organizations and verification	16,774	1	0.167	2,801

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Annualized Totals	17,315			2,862

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Chris Thomsen, Acting Chief, Cancer Information Service, RIB, OCC, OD, NCI, Building 31, Room 10A16, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 496–5583 ext. 239 or E-mail your request, including your address to: thomsenc@occ.nci.nih.gov

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before February 27, 1997.

Dated: December 12, 1996.

Nancie L. Bliss,

OMB Project Clearance Liaison.

[FR Doc. 97–1982 Filed 1–27–97; 8:45 am]

BILLING CODE 4140–01–M

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health.

ACTION: Notice.

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 U.S. 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). An signed Confidential Disclosure Agreement (CDA) will be required to receive copies of the patent applications.

Immunotoxin (MAB–RICIN), for the Treatment of Focal Movement Disorders

J Hott, R Youle, M Hallet, M Dalakas (NINDS)
Serial No. 60/027,458 filed 19 Sep 96
Licensing Contact: Stephen Finley, 301/496–7735 ext 215

This invention describes the use of an immunotoxin designed to treat focal dystonias that are currently being treated by injections of botulinum toxin (BTX) or by surgical myectomy. The immunotoxin (ITX) is prepared from a monoclonal antibody (MoAb35), specific to the nicotinic acetylcholine receptor in skeletal muscle, and is covalently linked to the toxin, ricin. ITX utilizes ricin's alpha chain and beta chain for its improved potency. ITX's potency was demonstrated by intramuscular injections into a rat model. The effects of intermuscular injections of ITX were compared to that of BTX. Even lower doses of ITX proved more effective and longer lasting than BTX in weakening muscle. The ITX selectively removed muscle fiber at the injection sites. It is believed that ITX may have clinical applications to those patients who have become refractory to BTX, or when used in combination or in place of BTX. In addition to the use of ITX in the treatment of all focal muscular spasms, ITX may prove useful in the treatment of other disorders of muscular spasms such as blepharospasms, cervical dystonia, hand dystonia, limb dystonia, hemifacial spasm, bruxism, strabismus, VI nerve palsy, for spasmodic, dysphonia, and oromandibular dystonia. (portfolios: Central Nervious System—Therapeutics, neurological, other; Central Nervous System—Therapeutics, neurological, muscle relaxants; Internal Medicine—Therapeutics, other)

Methods and Compositions for p300/CBP-Associated Transcriptional Co-Factor (P/CAF)

Y Nakatani, B Howard (NICHD)
Serial No. 60/022,273 filed 23 Jul 96
Licensing Contact: Ken Hemby, 301/496–7735 ext 265

The adenoviral oncoprotein E1A induces cell transformation by binding to various cellular components, such as the products of the retinoblastoma and p300/CBP gene families. This invention provides a transcriptional co-factor, p300/CBP-associated factor (P/CAF), which has intrinsic histone acetylase activity and also competes with E1A for binding to cellular targets. Also provided are methods of screening for compounds that affect P/CAF activity. Methods for directed gene therapy to provide functional wild-type or mutant P/CAF to cells producing varying levels of P/CAF protein are also provided. (portfolios: Cancer—Diagnostics; Cancer—Therapeutics, biological response modifiers; Devices—Research Tools and Materials, biologicals and chemicals)

Conformationally Locked Nucleoside Analogs

VE Marquez, JB Rodriquez, MC Nicklaus, JJ Barchi Jr, MA Siddiqui (NCI)
Serial Number 08/311,425 filed 23 Sep 94 (with priority to 24 Sep 93) and

Conformationally Locked Nucleoside Analogs as Antiherpetic Agents

VE Marquez, MC Nicklaus, JJ Barchi Jr, JB Rodriguez, MA Siddiqui (NCI)
Serial Number 60/023,565 filed 07 Aug 96
Licensing Contact: Robert Benson, 301/496–7056 ext 267